

AMARIN CORP PLC\UK  
Form 10-Q  
November 07, 2013  
[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, 2013

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. 000-21392

**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

172,195,467 shares held as American Depositary Shares (ADS), each representing one Ordinary Share, 50 pence par value per share, and 468,546 ordinary shares, were outstanding as of November 1, 2013.

**Table of Contents**

**INDEX TO FORM 10-Q**

	<b>Page</b>
<b><u>PART I Financial Information</u></b>	
Item 1. Financial Statements (Unaudited):	
<u>Condensed Consolidated Balance Sheets at September 30, 2013 and December 31, 2012</u>	1
<u>Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2013 and 2012</u>	2
<u>Condensed Consolidated Statement of Changes in Deficit at September 30, 2013 and September 30, 2012</u>	3
<u>Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2013 and 2012</u>	4
<u>Notes to Condensed Consolidated Financial Statements</u>	5
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	17
Item 3. <u>Quantitative and Qualitative Disclosures about Market Risk</u>	34
Item 4. <u>Controls and Procedures</u>	34
<b><u>PART II Other Information</u></b>	
Item 1. <u>Legal Proceedings</u>	35
Item 1A. <u>Risk Factors</u>	35
Item 5. <u>Other Information</u>	61
Item 6. <u>Exhibits</u>	61
<u>SIGNATURES</u>	62

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

	<b>September 30, 2013</b>	<b>December 31, 2012</b>
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 225,885	\$ 260,242
Restricted cash	1,400	
Accounts receivable	3,721	
Inventory, net	27,083	21,262
Deferred tax asset	936	937
Other current assets	3,537	3,253
<b>Total current assets</b>	<b>262,562</b>	<b>285,694</b>
Property, plant and equipment, net	646	811
Deferred tax asset	14,433	8,044
Other non-current assets	5,335	4,951
Intangible asset, net	10,870	11,355
<b>TOTAL ASSETS</b>	<b>\$ 293,846</b>	<b>\$ 310,855</b>
<b>LIABILITIES AND STOCKHOLDERS DEFICIT</b>		
Current Liabilities:		
Accounts payable	\$ 6,233	\$ 17,458
Accrued interest payable	10,901	2,520
Deferred revenue	1,617	
Accrued expenses and other liabilities	12,548	5,224
<b>Total current liabilities</b>	<b>31,299</b>	<b>25,202</b>
Long-Term Liabilities:		
Warrant derivative liability	39,598	54,854
Exchangeable senior notes	145,316	134,250
Long-term debt	87,319	85,153
Long-term debt redemption feature	7,200	14,577
Other long-term liabilities	811	816
<b>Total liabilities</b>	<b>311,543</b>	<b>314,852</b>
Commitments and contingencies (Note 7)		
Stockholders' Deficit:		
	141,455	124,597

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

Common stock, £0.50 par value, unlimited authorized; 172,664,013 issued, 172,643,934 outstanding at September 30, 2013; 150,360,933 issued, 150,340,854 outstanding at December 31, 2012		
Additional paid-in capital	739,524	619,266
Treasury stock; 20,079 shares at September 30, 2013 and December 31, 2012	(217)	(217)
Accumulated deficit	(898,459)	(747,643)
<b>Total stockholders' deficit</b>	<b>(17,697)</b>	<b>(3,997)</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT</b>	<b>\$ 293,846</b>	<b>\$ 310,855</b>

See notes to unaudited condensed consolidated financial statements.

**Table of Contents**

## AMARIN CORPORATION PLC

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

(Unaudited, in thousands, except per share amounts)

	Three months ended September 30,		Nine months ended September 30,	
	2013	2012	2013	2012
Product revenues	\$ 8,403	\$	\$ 16,245	\$
Operating Expenses:				
Cost of goods sold	3,682		7,813	
Research and development	16,821	20,913	56,148	39,735
Selling, general and administrative	28,274	13,397	101,502	41,059
Total operating expenses	48,777	34,310	165,463	80,794
Operating loss	(40,374)	(34,310)	(149,218)	(80,794)
(Loss) gain on change in fair value of derivative liabilities	(1,402)	16,454	21,059	(68,686)
Interest expense, net	(8,441)	(4,570)	(26,646)	(12,838)
Other (expense) income, net	(302)	(427)	(838)	(411)
Loss from operations before income taxes	(50,519)	(22,853)	(155,643)	(162,729)
Benefit from (provision for) income taxes	1,635	(3,573)	4,827	(5,888)
Net loss	\$ (48,884)	\$ (26,426)	\$ (150,816)	\$ (168,617)
Loss per share:				
Basic and diluted	\$ (0.29)	\$ (0.18)	\$ (0.96)	\$ (1.19)
Weighted average shares:				
Basic and diluted	170,187	149,200	157,105	141,947

See notes to unaudited condensed consolidated financial statements.

Table of Contents

## AMARIN CORPORATION PLC

## CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN DEFICIT

(Unaudited, in thousands, except share amounts)

	Common Shares	Common Stock	Additional Paid-in Capital	Treasury Stock	Accumulated Deficit	Total
<b>At January 1, 2013</b>	<b>150,360,933</b>	<b>\$ 124,597</b>	<b>\$ 619,266</b>	<b>\$ (217)</b>	<b>\$ (747,643)</b>	<b>\$ (3,997)</b>
Stock issued in equity financing	21,700,000	16,401	104,805			121,206
Exercise of warrants	120,000	91	29			120
Vesting of restricted stock units	93,048	71	(71)			
Exercise of stock options	386,000	292	335			627
Tax benefits realized from stock-based compensation			966			966
Shares issued for services	4,032	3	24			27
Stock-based compensation			14,170			14,170
Loss for the period					(150,816)	(150,816)
<b>At September 30, 2013</b>	<b>172,664,013</b>	<b>\$ 141,455</b>	<b>\$ 739,524</b>	<b>\$ (217)</b>	<b>\$ (898,459)</b>	<b>\$ (17,697)</b>
	Common Shares	Common Stock	Additional Paid-in Capital	Treasury Stock	Accumulated Deficit	Total
<b>At January 1, 2012</b>	<b>135,832,542</b>	<b>\$ 113,321</b>	<b>\$ 449,393</b>	<b>\$ (217)</b>	<b>\$ (568,459)</b>	<b>\$ (5,962)</b>
Exercise of warrants	10,881,276	8,407	8,119			16,526
Transfer of fair value of warrants exercised from liabilities to equity			103,885			103,885
Conversion option contained in exchangeable notes			22,898			22,898
Exercise of stock options	3,107,913	2,439	5,395			7,834
Tax benefits realized from stock-based compensation			10,106			10,106
Vesting of restricted stock units	97,398	76	(76)			
Shares issued for services	2,293	1	23			24
Stock-based compensation			13,344			13,344
Loss for the period					(168,617)	(168,617)
<b>At September 30, 2012</b>	<b>149,921,422</b>	<b>\$ 124,244</b>	<b>\$ 613,087</b>	<b>\$ (217)</b>	<b>\$ (737,076)</b>	<b>\$ 38</b>

See notes to unaudited condensed consolidated financial statements.

**Table of Contents**

## AMARIN CORPORATION PLC

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

(Unaudited, in thousands)

	Nine Months Ended September 30,	
	2013	2012
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (150,816)	\$ (168,617)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	179	123
Stock-based compensation	14,170	13,344
Stock-based compensation warrants	(1,179)	3,037
Shares issued for services	27	24
Excess tax benefit from stock-based awards	(966)	(10,106)
Accrued interest payable	8,381	1,094
Amortization of intangible asset	485	108
Amortization of debt discount and debt issuance costs	13,232	9,365
Deferred income taxes	(6,389)	
Change in lease liability	3	(55)
(Gain) loss on change in fair value of derivative liabilities	(21,059)	68,686
Changes in assets and liabilities:		
Restricted cash	(1,400)	
Accounts receivable	(3,721)	
Inventory	(5,821)	(8,989)
Other current assets	(283)	(2,273)
Other non-current assets	(384)	(17,355)
Accounts payable, accrued expenses and other liabilities	(1,714)	33,075
Net cash used in operating activities	(157,255)	(78,539)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchase of long-term investment		(1,238)
Purchases of equipment	(14)	(477)
Net cash used in investing activities	(14)	(1,715)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from issuance of common stock, net of transaction costs	121,206	
Proceeds from exercise of stock options, net of transaction costs	627	7,834
Proceeds from exercise of warrants, net of transaction costs	120	16,526
Excess tax benefit from stock-based awards	966	10,106
Proceeds from issuance of exchangeable debt, net of transaction costs		144,316
Payments under capital leases	(7)	(20)
Net cash provided by financing activities	122,912	178,762
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(34,357)	98,508
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	260,242	116,602
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 225,885	\$ 215,110



Supplemental disclosure of cash flow information:

Cash paid during the year for:

Interest	\$	5,250	\$	2,713
----------	----	-------	----	-------

Income taxes	\$	1,395	\$	697
--------------	----	-------	----	-----

Non-cash transactions:

Transfer from derivative liability to equity, fair value of warrants exercised	\$		\$	103,885
--	----	--	----	---------

See notes to unaudited condensed consolidated financial statements.

**Table of Contents**

## AMARIN CORPORATION PLC

**Notes to Unaudited 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 approval from the U.S. Food and Drug Administration, or FDA, to market and sell its lead product Vascepa<sup>®</sup> (icosapent ethyl) capsules (formerly known as AMR 101) as an adjunct to diet to reduce triglyceride levels in adult patients with severe (TG  $\geq$ 500mg/dL) hypertriglyceridemia, which the Company sometimes refers to as the MARINE indication. Triglycerides are fats in the blood. Vascepa became commercially available in the United States by prescription in January 2013, when the Company commenced sales and shipments to its network of U.S.-based wholesalers and specialty pharmacy providers. On January 28, 2013, the Company commenced its full commercial launch of Vascepa in the United States for use in the MARINE indication.

Amarin is also developing Vascepa for the treatment of patients with high triglyceride levels (TG  $\geq$ 200 mg/dL and  $<$ 500 mg/dL) who are also on statin therapy for elevated LDL-C levels. This indication is referred to as mixed dyslipidemia or the ANCHOR indication. In February 2013, the Company submitted a supplemental New Drug Application, or sNDA, to the FDA seeking approval of Vascepa for the ANCHOR indication. On October 16, 2013, the FDA convened an advisory committee to review the Company's sNDA for the ANCHOR indication and the advisory committee voted 9 to 2 against recommending approval of the ANCHOR indication based on information presented at the meeting. The FDA will consider the recommendation of the advisory committee, but the final decision regarding the approval of the sNDA will be made by the FDA. The application is subject to a standard review and has been assigned a Prescription Drug User Fee Act, or PDUFA, date of December 20, 2013. The PDUFA date is the target date for the FDA to complete its review of the sNDA. The FDA could complete its review of the sNDA prior to this date and there can be no assurance that the FDA will complete its review of the sNDA by this date. If the FDA does not approve the ANCHOR indication, it would have a material impact on the Company's future results of operations and financial condition (see Note 9 Subsequent Events).

**Basis of Presentation**

The condensed consolidated financial statements included herein have been prepared by the Company, without audit, in accordance with accounting principles generally accepted in the United States of America (the U.S. or the United States) and pursuant to the rules and regulations of the Securities and Exchange Commission (the SEC). Certain information in the notes to the financial statements (the Notes) has been condensed or omitted where it substantially duplicates information provided in the Company's latest audited consolidated financial statements, in accordance with the rules and regulations of the SEC. These condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and notes included in its Annual Report on Form 10-K for the fiscal year ended December 31, 2012, filed with the SEC (the 2012 Form 10-K). The balance sheet amounts at December 31, 2012 in this report were derived from the Company's audited 2012 consolidated financial statements included in the 2012 Form 10-K. The condensed consolidated financial statements reflect all adjustments that, in the opinion of management, are necessary to present fairly the Company's financial position, results of operations and cash flows for the periods indicated. The preparation of financial statements in conformity with U.S. Generally Accepted Accounting Principles (GAAP) requires management to make estimates and assumptions that affect the reported amounts and classifications of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. The results of operations for the three and nine months ended September 30, 2013 and 2012, respectively, are not necessarily indicative of the results for the entire fiscal year or any future period. The Company has evaluated subsequent events from September 30, 2013 through the date of the issuance of these condensed consolidated financial statements and has disclosed subsequent events in Note 9.

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

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

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 in 2012 and for which the Company commenced marketing and sales in 2013.

---

**Table of Contents**

At September 30, 2013, the Company had cash and cash equivalents of \$225.9 million. See also Note 8 Equity for a description of a public offering completed in July 2013 resulting in net proceeds to the Company of approximately \$121.2 million.

The Company's consolidated balance sheet also includes derivative liabilities (see Note 5 Warrants and Warrant Derivative Liability) as well as long term debt and exchangeable senior notes (see Note 6 Debt). The warrant derivative liability reflects 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. The long term debt is not callable except upon a change in control. The Exchangeable Senior Notes (the Notes) may be redeemed on or after January 19, 2017 at the option of the holders. The Notes are exchangeable under certain circumstances into cash, American Depositary Shares, or ADSs, or a combination of cash and ADSs, at the Company's election. Accordingly, the warrant derivative liability, long term debt and Exchangeable Senior Notes do not present a short term claim on the liquid assets of the Company.

The Company believes its cash and cash equivalents will be sufficient to fund its projected operations for at least the next twelve months.

**(2) Significant Accounting Policies****Use of Estimates**

The preparation of the Company's consolidated financial statements in conformity with accounting principles generally accepted in the United States of America, or GAAP, requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Accounting estimates are based on historical experience and other factors that are considered reasonable under the circumstances. Actual results could differ from those estimates. The preparation of the Company's condensed consolidated financial statements in accordance with GAAP requires management to make estimates, judgments and assumptions that may affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, the Company evaluates its estimates and judgments and methodologies, including those related to revenue recognition and related allowances, clinical trial expenses, the valuation of inventory, impairment and amortization of intangibles, share-based compensation, income taxes including the valuation allowance for deferred tax assets, valuation of investments and derivative instruments. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates.

**Revenue Recognition**

The Company sells Vascepa principally to a limited number of major wholesalers, as well as selected regional wholesalers and specialty pharmacy providers, or collectively, its Distributors, that in turn resell Vascepa to retail pharmacies for subsequent resale to patients and health care providers. Patients are required to have a prescription in order to purchase Vascepa. In accordance with GAAP, the Company's revenue recognition policy requires that: (i) there is persuasive evidence that an arrangement exists between the Company and the Distributor, (ii) delivery has occurred, (iii) collectability is reasonably assured and (iv) the price is fixed or determinable.

The Company commenced its commercial launch in the United States on January 28, 2013. Prior to 2013, the Company recognized no revenue from Vascepa sales. In accordance with GAAP, until the Company has the ability to reliably estimate returns of Vascepa from its Distributors, revenue will be recognized based on the resale of Vascepa for the purposes of filling patient prescriptions, and not based on sales from the Company to such Distributors. Consistent with industry practice, once the Company achieves sufficient history such that it can reliably estimate returns, the Company will recognize revenue based on sales to its Distributors. The Company currently defers Vascepa revenue recognition until the earlier of the product being resold for purposes of filling patient prescriptions; or the expiration of the right of return (twelve months after the expiration date of the product). The Company also defers the related cost of product sales and records such amounts as finished goods inventory held by others until revenue related to such product sales is recognized.

The Company has contracts with its primary Distributors and delivery occurs when a Distributor receives Vascepa. The Company evaluates the creditworthiness of each of its Distributors to determine whether revenues can be recognized upon delivery, subject to satisfaction of the other requirements, or whether recognition is required to be delayed until receipt of payment or when the product is utilized. In order to conclude that the price is fixed or determinable, the Company must be able to (i) calculate its gross product revenues from the sales to Distributors and (ii) reasonably estimate its net product revenues. The Company calculates gross product revenues based on the wholesale acquisition cost that the Company charges its Distributors for Vascepa. The Company estimates its net product revenues by deducting from its gross product revenues (a) trade allowances, such as invoice discounts for prompt payment and distributor fees, (b) estimated government and private payor rebates, chargebacks and discounts, such as Medicaid reimbursements, (c) reserves for expected product returns and (d) estimated costs of

incentives offered to certain indirect customers, including patients.

**Table of Contents**

*Trade Allowances:* The Company generally provides invoice discounts on Vascepa sales to its Distributors for prompt payment and pays fees for distribution services, such as fees for certain data that Distributors provide to the Company. The payment terms for sales to Distributors generally include a 2% discount for payment within 30 days. Based on the Company's judgment and experience, the Company expects its Distributors to earn these discounts and fees, and deducts the full amount of these discounts and fees from its gross product revenues and accounts receivable at the time such revenues are recognized.

*Rebates, Chargebacks and Discounts:* The Company contracts with Medicaid, other government agencies and various private organizations, or collectively, Third-party Payors, so that Vascepa will be eligible for purchase by, or partial or full reimbursement from, such Third-party Payors. The Company estimates the rebates, chargebacks and discounts it will provide to Third-party Payors and deducts these estimated amounts from its gross product revenues at the time the revenues are recognized. The Company estimates the rebates, chargebacks and discounts that it will provide to Third-party Payors based upon (i) the Company's contracts with these Third-party Payors, (ii) the government-mandated discounts applicable to government-funded programs, (iii) information obtained from the Company's Distributors and (iv) information obtained from other third parties regarding the payor mix for Vascepa.

*Product Returns:* The Company's Distributors have the right to return unopened unexpired Vascepa during the 18-month period beginning six months prior to the labeled expiration date and ending twelve months after the labeled expiration date. The expiration date for Vascepa is three years after it has been converted into capsule form, which is the last step in the manufacturing process for Vascepa and generally occurs within a few months before Vascepa is delivered to Distributors. As of September 30, 2013, the Company had experienced a de minimus quantity of product returns. During the nine months ended September 30, 2013, the period in which the Company began selling Vascepa, the Company was not able to reasonably estimate product returns for all product sold to Distributors but the Company was able to reasonably estimate product returns for certain sales of Vascepa based on product used to fill patient prescriptions as determined by inventory estimated to be in the distribution channel and third party reports of prescriptions filled. In making this assessment, the Company used (i) data provided to the Company by its Distributors (including weekly reporting of Distributors' sales and inventory held by Distributors that provided the Company with visibility into the distribution channel in order to determine what quantities were sold to retail pharmacies and other providers), (ii) information provided to the Company from retail pharmacies, (iii) data provided to the Company by a third party data provider which collects and publishes prescription data, and other third parties, (iv) historical industry information regarding return rates for similar pharmaceutical products, (v) the estimated remaining shelf life of Vascepa previously shipped and currently being shipped to Distributors and (vi) contractual agreements intended to limit the amount of inventory maintained by the Company's Distributors.

*Other Incentives:* Other incentives that the Company offers to indirect customers include co-pay mitigation rebates provided by the Company to commercially insured patients who have coverage for Vascepa and who reside in states that permit co-pay mitigation programs. The Company's co-pay mitigation program is intended to reduce each participating patient's portion of the financial responsibility for Vascepa's purchase price to a specified dollar amount. Based upon the terms of the program and information regarding programs provided for similar specialty pharmaceutical products, the Company estimates the average co-pay mitigation amounts and the percentage of patients that it expects to participate in the program in order to establish its accruals for co-pay mitigation rebates and deducts these estimated amounts from its gross product revenues at the time the revenues are recognized. The Company's co-pay mitigation rebates offered to date will expire on December 31, 2013. The Company adjusts its accruals for co-pay mitigation rebates based on its estimates regarding the portion of issued rebates that it estimates will not be redeemed. In addition, as is customary prior to the launch of new drugs, the Company provided certain of its Distributors with financial incentives to begin stocking Vascepa prior to the Company's commercial launch of Vascepa in order to ensure that Vascepa was readily available to fill patient prescriptions upon launch. Such incentives were only offered on purchases of initial launch quantities of Vascepa stocked by Distributors in January 2013. The amount of these financial incentives were recorded by the Company as a reduction to revenues on a pro-rata basis for each of the bottles subject to such financial incentives. The Company estimates that all of these initial launch quantities stocked by its primary Distributors in January 2013 were resold by such Distributors prior to September 30, 2013.

The following table summarizes activity in each of the product revenue allowance and reserve categories described above for the nine months ended September 30, 2013 (in thousands):

	Trade Allowances	Rebates, Chargebacks and Discounts	Product Returns	Other Incentives	Total
<b>Balance at January 1, 2013</b>	\$	\$	\$	\$	\$
Provision related to current period and deferred sales	2,839	2,418	72	2,018	7,347
Credits/payments made for current period and deferred sales	(1,951)	(1,484)		(1,835)	(5,270)

<b>Balance at September 30, 2013</b>	<b>\$ 888</b>	<b>\$ 934</b>	<b>\$ 72</b>	<b>\$ 183</b>	<b>\$ 2,077</b>
--------------------------------------	---------------	---------------	--------------	---------------	-----------------

**Table of Contents**

The following table summarizes product revenue recognized and deferred during the nine months ended September 30, 2013 (in thousands):

	September 30, 2013	December 31, 2012
Product revenue recognized	\$ 16,245	\$
Deferred product revenue	1,617	
	<b>\$ 17,862</b>	<b>\$</b>

In conjunction with the Company's recognition and deferral of product revenues, the Company expensed and capitalized the associated cost of goods, as follows, during the nine months ended September 30, 2013 (in thousands):

	September 30, 2013	December 31, 2012
Cost of goods sold expensed	\$ 7,813	\$
Finished goods inventory held by others	641	
	<b>\$ 8,454</b>	<b>\$</b>

**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. Restricted cash represents cash and cash equivalents pledged to guarantee repayment of certain expenses which may be incurred for business travel under corporate credit cards held by employees.

**Inventory**

The Company states inventories at the lower of cost or market value. Cost is determined based on actual cost using the average cost method. An allowance is established when management determines that certain inventories may not be saleable. If inventory cost exceeds expected market value due to obsolescence, damage 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 for Vascepa on July 26, 2012 and after that date began capitalizing inventory purchases of saleable product from approved suppliers. Until an API supplier is approved, all Vascepa API purchased from such supplier is included as a component of research and development expense. Upon sNDA approval of each additional supplier, the Company capitalizes subsequent Vascepa API purchases from such supplier as inventory. Purchases of Vascepa API received and expensed before such regulatory approvals is not subsequently capitalized, and all such purchases are quarantined and not used for commercial supply until such time as the sNDA for the supplier that produced the API is approved.

**Intangible Asset, net**

Intangible assets consist of a milestone payment paid to the former shareholders of Laxdale Limited related to the 2004 acquisition of our rights to Vascepa, which is the result of Vascepa receiving marketing approval for the first indication and is amortized over its estimated useful life on a straight-line basis. The Company concluded that use of the straight-line method was appropriate as the majority of cash flows are expected to be generated ratably over the estimated useful life and no degradation of the cash flows over time is currently anticipated. See Note 7 Commitments and Contingencies for further information regarding other obligations related to the acquisition of Laxdale Limited.

**Deferred Revenue**

Deferred revenue represents product shipments to Distributors for which the Company has invoiced the Distributors but not recognized revenue because the product was not reported to the Company as having been resold for the purpose of filling prescriptions on or before September 30, 2013.

**Research and Development Costs**



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

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. In addition, research and development costs include the costs of product supply received from suppliers when such receipt by the Company is prior to regulatory approval of the supplier.

## **Table of Contents**

### **Selling, General and Administrative Costs**

The Company charges sales, general and administrative costs to operations as incurred. Selling, general and administrative costs include costs of salaries, programs and infrastructure necessary for the general conduct of the Company's business, including the 2013 commercial launch of Vascepa in the United States for the MARINE indication. Included as part of selling, general and administrative costs is 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 which is recorded as compensation income (expense).

### **Income Taxes**

Deferred tax assets and liabilities are recognized for the future tax consequences of differences between the carrying amounts and tax bases of assets and liabilities and operating loss carry-forwards 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.

### **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 due to the nature of the instrument. The long term debt redemption feature is valued using a probability-weighted model incorporating management estimates for potential change in control, and by determining the fair value of the debt with and without the change in control provision included.

If the terms of warrants that initially require the warrant to be classified as a derivative financial liability lapse, the derivative financial liability is reclassified out of financial liabilities into equity at its fair value on that date. At the applicable 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.

### **Loss per Share**

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

### **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.

The Company's 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 to interest expense over the term of the debt.

The Company's December 2012 debt financing agreement contains a redemption feature triggered upon a change of control, which has been classified as an embedded derivative. The fair value of the derivative was recorded as a reduction to the fair value of the note payable. 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 discount recorded to the note payable is being amortized to interest expense over the term of the note payable.

**Table of Contents****Fair Value of Financial Instruments**

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

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

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

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

The following table presents information about the Company's assets and liabilities as of September 30, 2013 and December 31, 2012 that are 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, 2013</b>		
		<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>
<b>Asset:</b>				
Cash equivalents money markets	\$ 113.5	\$ 113.5	\$	\$
<b>Liabilities:</b>				
Warrant derivative liability	\$ 39.6	\$	\$	\$ 39.6
Long-term debt redemption feature	\$ 7.2	\$	\$	\$ 7.2
Foreign currency contracts	\$ 0.4	\$	\$	\$ 0.4

<i>In millions</i>	<b>Total</b>	<b>December 31, 2012</b>		
		<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>
<b>Asset:</b>				
Cash equivalents money markets	\$ 64.1	\$ 64.1	\$	\$
<b>Liability:</b>				
Warrant derivative liability	\$ 54.9	\$	\$	\$ 54.9
Long-term debt redemption feature	\$ 14.6	\$	\$	\$ 14.6

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

**Warrant Derivative Liability**

At December 31, 2012, the fair value of the warrant derivative liability was determined to be \$54.9 million using the Black-Scholes option valuation model applying the following assumptions: (i) risk-free rate of 0.25%, (ii) remaining term of 1.8 years, (iii) no dividend yield, (iv) volatility of 95% and (v) the stock price on the date of measurement.

At September 30, 2013, the fair value of the warrant derivative liability was determined to be \$39.6 million using the Black-Scholes option valuation model applying the following assumptions: (i) risk-free rate of 0.1%, (ii) remaining term of 1.0 year, (iii) no dividend yield, (iv) volatility of 91%, and (v) the stock price on the date of measurement. The \$3.6 million increase in the fair value of the warrant liability during the three months ended September 30, 2013 was recognized as: (i) a \$3.3 million loss on change in fair value of the remaining derivative liability and (ii) \$0.3 million in compensation expense for change in fair value of warrants issued to former employees. The \$15.3 million decrease in the fair value of the warrant liability during the nine months ended September 30, 2013 was recognized as: (i) a \$14.1 million gain on change in fair value of the remaining derivative liability and (ii) \$1.2 million in compensation income for change in fair value of warrants issued to former employees. Both amounts are included in the consolidated statement of operations for the nine months ended September 30, 2013. 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 the Company's common stock among other factors. In the event of a hypothetical 10% increase in the market price of the Company's common shares (\$6.95 based on the \$6.32 market price of the Company's stock at September 30, 2013) on which the September 30, 2013 valuation was based, the value of the derivative liability would have increased by \$5.0 million. Such increase would have been reflected as a loss on change in fair value of the warrant derivative liability in the Company's statement of operations. Significant increases (decreases) in this input in isolation would result in a significantly higher (lower) fair value asset measurement.

**Table of Contents****Long Term Debt Redemption Feature**

The Company's December 2012 financing agreement with BioPharma Secured Debt Fund II Holdings Cayman, L.P. or BioPharma, contains a redemption feature whereby, upon a change of control, the Company would be required to pay \$140 million, less any previously repaid amount, if the change of control occurs on or before December 31, 2013, or required to repay \$150 million, less any previously repaid amount, if the change of control event occurs after December 31, 2013. The Company determined this redemption feature to be an embedded derivative, which is carried at fair value and is classified as Level 3 in the fair value hierarchy due to the use of significant unobservable inputs. The fair value of the embedded derivative was calculated using a probability-weighted model incorporating management estimates for potential change in control, and by determining the fair value of the debt with and without the change in control provision included. The difference between the two fair values of the debt was determined to be the fair value of the embedded derivative. At December 31, 2012, the fair value of the derivative was determined to be \$14.6 million, and the debt was valued by comparing debt issues of similar companies with (i) terms of between 4.8 and 8.0 years, (ii) coupon rates of between 3.0% and 11.5% and (iii) market yields of between 10.7% and 27.7%. At September 30, 2013, the fair value of the derivative was determined to be \$7.2 million, and the debt was valued by comparing debt issues of similar companies with (i) remaining terms of between 3.5 and 4.4 years, (ii) coupon rates of between 9.9% and 12.5% and (iii) market yields of between 10.4% and 25.8%. The Company recognized a gain of \$1.4 million and \$7.4 million on the change in fair value of this derivative liability for the three and nine months ended September 30, 2013, respectively.

**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 period-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 (expense) income, net in the consolidated statements of operations. For transactions settled during the applicable period, gains and losses are included in other (expense) income, net in the consolidated statements of operations. The Company periodically uses foreign exchange forward contracts to hedge against changes in exchange rates for inventory purchases denominated in foreign currency. As of September 30, 2013, the Company held one foreign exchange forward contract with a notional amount of \$4.5 million. As of September 30, 2013, the outstanding foreign exchange forward contract derivative liability had a net fair value of \$0.4 million. The Company included this \$0.4 million as a component of change in fair value of derivative liabilities and in other current liabilities at September 30, 2013.

The change in the fair value of financial instruments is as follows (in thousands):

	October 2009 Warrants	Debt Redemption Feature	Foreign Exchange Contracts	Totals
<b>Balance at January 1, 2012</b>	<b>\$ 123,125</b>	<b>\$</b>	<b>\$</b>	<b>\$ 123,125</b>
Loss on change in fair value of derivative liability	68,686			68,686
Compensation expense for change in fair value of warrants issued to former employees	3,037			3,037
Transfers to equity	(103,885)			(103,885)
<b>Balance at September 30, 2012</b>	<b>\$ 90,963</b>	<b>\$</b>	<b>\$</b>	<b>\$ 90,963</b>

	October 2009 Warrants	Debt Redemption Feature	Foreign Exchange Contracts	Totals
--	-----------------------------	-------------------------------	----------------------------------	--------

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

<b>Balance at January 1, 2013</b>	<b>\$ 54,854</b>	<b>\$ 14,577</b>	<b>\$</b>	<b>\$ 69,431</b>
(Gain) loss on change in fair value of derivative liabilities	(14,077)	(7,377)	395	(21,059)
Compensation income for change in fair value of warrants issued to former employees	(1,179)			(1,179)
Transfers to equity				
<b>Balance at September 30, 2013</b>	<b>\$ 39,598</b>	<b>\$ 7,200</b>	<b>\$ 395</b>	<b>\$ 47,193</b>

**Table of Contents****Segment and Geographical Information**

For the three and nine months ended September 30, 2013 and 2012, 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 the Financial Accounting Standards Board, or FASB, and are adopted by the Company as of the specified effective date. The Company believes that the impact of 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) Intangible Asset**

Intangible asset consists of technology rights for Vascepa and have an estimated remaining useful life of 16.8 years. The carrying value as of September 30, 2013 and December 31, 2012 is as follows (in thousands):

	September 30, 2013	December 31, 2012
Technology rights	\$ 11,624	\$ 11,624
Accumulated amortization	(754)	(269)
	\$ 10,870	\$ 11,355

**(4) Inventory**

After approval of Vascepa on July 26, 2012 by the FDA, the Company began capitalizing its purchases of saleable inventory of Vascepa from suppliers that have been qualified by the FDA. Inventories consist of the following at September 30, 2013 and December 31, 2012 (in thousands):

	September 30, 2013	December 31, 2012
Raw materials	\$ 4,993	\$ 5,465
Work in process	12,166	15,471
Finished goods	9,283	326
Finished goods inventory held by others	641	
	\$ 27,083	\$ 21,262

Inventory is valued at lower of cost or market value. During the three months ended September 30, 2013, the Company recorded an inventory reserve of \$1.8 million related to certain inventories that are not recoverable in their current form. The materials are currently under investigation by the supplier and the Company. The reserve was recorded within research and development expense in the statement of operations as this supplier has yet to produce material qualified for commercial sale.

**(5) Warrants and Warrant Derivative Liability**

The Company had 9,816,826 warrants to purchase common shares outstanding at September 30, 2013 at a weighted-average exercise price of \$1.44, 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	1/17/14
7/31/09	1,684,888	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>9,816,826</b>	<b>\$ 1.44</b>	

**Table of Contents****October 2009 Warrant derivative liability**

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 of which 7.5 million are outstanding at September 30, 2013.

In conjunction with the October 2009 financing, the Company issued an additional 0.9 million warrants to three former officers of which 0.6 million are outstanding as of September 30, 2013. The warrants issued in connection with the October 2009 financing contained a pricing variability feature which provided for an increase to the exercise price if the exchange rate between the U.S. dollar and British pound adjusts such that the warrants could be exercised at a price less than the £0.5 par value of the common stock that is, if the exchange rate exceeded U.S. \$3.00 per £1.0 sterling. Due to the potential variable nature of the exercise price, the warrants are not considered to be indexed to the Company's common stock. Accordingly, the warrants do not qualify for the exception to classify the warrants within equity and are classified as a derivative liability.

The fair value of this warrant derivative liability is remeasured at each reporting period, with changes in fair value recognized in the statement of operations. Upon exercise, the fair value of the warrants exercised is remeasured and reclassified from warrant liability to additional paid-in capital. Although the warrants contain a pricing variability feature, the number of warrants issuable remains fixed. Therefore, the maximum number of common shares issuable as a result of the October 2009 private placement is 36.1 million. The change in fair value of the warrant derivative liability is discussed in Note 2.

**July 2009 and April 2007 Warrants**

The Company issued certain warrants in July 2009 and April 2007. As of September 30, 2013 and December 31, 2012 these warrants have been classified as equity instruments and have been included in the Company's consolidated balance sheet within additional paid-in-capital. During the nine months ended September 30, 2013, 120,000 of the July 2009 warrants were exercised resulting in proceeds to the Company of \$0.1 million.

**(6) Debt****Long term debt December 2012 Financing**

On December 6, 2012, the Company entered into an agreement with BioPharma. Under this agreement, the Company granted to BioPharma a security interest in future receivables associated with the Vascepa patent rights in exchange for \$100.0 million received at the closing of the agreement, which closing occurred in December 2012. The Company has agreed to repay BioPharma up to \$150 million of future revenue and receivables. The first scheduled repayment under the agreement is a repayment of \$2.5 million of interest due to be paid to BioPharma in November 2013 for the fiscal quarter ended September 30, 2013, subject to the limitation described below. Additional quarterly repayments are scheduled to be paid thereafter in accordance with the following schedule: \$2.5 million of interest in the first quarter of 2014; \$8.0 million per quarter in each of the next four quarters, \$10.0 million per quarter in each of the next four quarters, \$15.0 million per quarter in each of the next four quarters and a final payment of \$13.0 million scheduled for payment in May 2017. The quarterly repayments through the third quarter of September 2014 represent interest only. Quarterly payments do not begin to reduce the principal balance until the fourth quarter of 2014. These quarterly payments are subject to a quarterly threshold amount whereby, if a calculated threshold, based on quarterly Vascepa revenues, is not achieved, the quarterly payment payable in that quarter can at the Company's election be reduced, with the reduction carried forward without interest for payment in a future period. The payment of any carried forward amount is subject to similarly calculated threshold repayment amounts based on Vascepa revenue levels. Except upon a change of control in Amarin, the agreement does not expire until \$150 million has been repaid. Under the agreement, upon a change of control, the Company would be required to pay \$140 million, less any previously repaid amount, if the change of control occurs on or before December 31, 2013, or required to repay \$150 million, less any previously repaid amount, if the change of control event occurs after December 31, 2013. The Company can prepay after October 1, 2013, an amount equal to \$150 million less any previously repaid amount.

The Company determined the redemption feature upon a change of control to be an embedded derivative requiring bifurcation. The fair value of the embedded derivative was calculated by determining the fair value of the debt with the change in control provision included and also without

the change in control provision. The difference between the two fair values of the debt was determined to be the fair value of the embedded derivative, and upon closing, the Company recorded a derivative liability of \$14.6 million as a reduction to the note payable. The fair value of this derivative liability is remeasured at each reporting period, with changes in fair value recognized in the statement of operations. The fair value of the derivative liability at September 30, 2013 was \$7.2 million and the Company recognized a gain on change in fair value of derivative liability of \$1.4 million and \$7.4 million for the three and nine

**Table of Contents**

month periods ended September 30, 2013, respectively. For the nine months ended September 30, 2013, the Company recorded \$9.7 million and \$2.2 million of cash and non-cash interest expense, respectively related to the BioPharma debt. For the three months ended September 30, 2013, the Company recorded \$2.7 million and \$0.6 million of cash and non-cash interest expense, respectively related to the BioPharma debt. The Company will periodically evaluate the remaining term of the agreement and the effective interest will be recalculated each period based on the Company's most current estimate of repayment.

The Company currently estimates that its Vascepa revenue levels will not be high enough in each quarter to support repayment to BioPharma in accordance with threshold amounts in the repayment schedule. For the three months ended September 30, 2013, revenues were below the contractual threshold amount such that a cash payment of \$0.8 million is due in November 2013 reflecting the calculated optional reduction amount as opposed to the contractual threshold payment of \$2.5 million. In accordance with the agreement with BioPharma, quarterly differences between the calculated optional reduction amounts and the repayment schedule amounts are rescheduled for payment beginning in the second quarter of 2017. Any such deferred repayments will remain subject to continued application of the quarterly ceiling in amounts due established by the calculated threshold based on quarterly Vascepa revenues. Additionally, the revised assumptions yielded a decrease in the calculated effective interest rate resulting in a decrease in interest expense during the three months ended September 30, 2013 as compared to the three months ended June 30, 2013 and March 31, 2013.

**Exchangeable Senior Notes**

In January 2012, the Company issued \$150.0 million in principal amount of 3.5% exchangeable senior notes due 2032, or the Senior Notes. The Senior 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 fully and unconditionally guaranteed by Amarin but not by any of the Company's subsidiaries. Corsicanto Limited has no assets, operations, revenues or cash flows other than those related to the issuance, administration and repayment of the Senior Notes. There are no significant restrictions on the ability of Amarin to obtain funds from Corsicanto Limited in the form of cash dividends, loans, or advances. Net proceeds to the Company, after payment of underwriting fees and expenses, were approximately \$144.3 million.

The Senior 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 Senior Notes' maturity on January 15, 2032. The Senior 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 Senior Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the repurchase date. The Senior 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 Senior Notes. It is the Company's current intention to settle these obligations in cash. If the Company elected physical settlement, the Senior Notes would initially be exchangeable into 17,021,280 ADSs. Based on the closing price of the Company's stock at September 30, 2013, the principal amount of the Senior Notes would exceed the value of the shares if converted on that date by \$42.4 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 Senior Notes. The Company is required to use commercially reasonable efforts to procure and maintain the listing of the Senior 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 Senior Notes are not freely tradable, as a result of restrictions pursuant to U.S. securities law or the terms of the Indenture or the Senior Notes, the Company shall pay additional interest on the Senior Notes at the rate of 0.50% per annum of the principal amount of Senior 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 Senior Notes are not freely tradable.

The Company may not redeem the Senior 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 Senior Notes. On or after January 19, 2017 and prior to the maturity date, the Company may redeem for cash all or part of the Senior Notes at a redemption price equal to 100% of the principal amount of the Senior Notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date. There is no prepayment penalty or sinking fund provided for the Senior Notes. If the Company undergoes a fundamental change, holders may require the Company to repurchase for cash all or part of their Senior Notes at a repurchase price equal to 100% of the principal amount of the Senior Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date. The Senior 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 Senior Notes and equal in right of payment to the Company's future unsecured indebtedness that is not so subordinated. The Senior Notes are effectively junior in right of payment to future secured indebtedness to the extent of the value of the assets securing such indebtedness.

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

The Senior Notes are exchangeable under certain circumstances. The Company calculated the fair value of the liability component of the Senior Notes to be \$126.2 million, and the excess of the principal amount of the debt over the liability component of \$23.8 million was allocated to the conversion option resulting in a discount on the debt. The discount created from allocating proceeds to the

**Table of Contents**

conversion option is being amortized to interest expense using the effective interest method over the Senior Notes' estimated remaining life, which was calculated to be a period of twenty-four months. The effective interest rate of the Senior Notes is 14.5%. As of September 30, 2013, the unamortized discount created from the allocation of the proceeds to the conversion option was \$3.9 million. The conversion option will not be subsequently remeasured as long as it continues to meet the criteria for equity classification.

The Company also recorded a debt discount to reflect the value of the underwriters' 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 Senior Notes of twenty-four months. As of September 30, 2013, the unamortized debt discount was \$0.8 million and was recorded as a direct reduction of the related debt on the balance sheet. The carrying value of the Notes, net of the unamortized discount, was \$145.3 million. During the three months ended September 30, 2013, the Company recognized interest expense of \$5.2 million related to the Notes, of which \$3.2 million represents amortization of the debt discount created upon allocation of proceeds to the conversion option, \$1.3 million represents contractual coupon interest, and \$0.7 million represents the amortization of the discount from the underwriters' discounts and offering costs. During the nine months ended September 30, 2013, the Company recognized interest expense of \$15.0 million related to the Notes, of which \$9.2 million represents amortization of the debt discount created upon allocation of proceeds to the conversion option, \$3.9 million represents contractual coupon interest, and \$1.9 million represents the amortization of the discount from the underwriters' discounts and offering costs. At September 30, 2013, the Company had accrued interest of \$1.1 million.

In January and July 2013, the interest payments due of \$2.6 million were paid as scheduled.

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

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

The Company's active pharmaceutical ingredient, or API, supply agreement with Nisshin Pharma, Inc. (Nisshin), provided for minimum supply purchase obligations on behalf of the Company to enable Amarin to maintain exclusivity with this supplier, and to prevent potential termination of the agreement based on Company estimated minimum purchase requirements. As of September 30, 2013, the API aggregate minimum purchase obligations under this supply agreement had been achieved and as a result, the Company has no future minimum purchase obligation from Nisshin.

In 2011, the Company entered into agreements with two additional suppliers, Chemport, Inc. (Chemport) and BASF (formerly Equateq Limited) for the supply of API materials for Vascepa. In 2012, the Company agreed to terms with a fourth API supplier, Slanmhor Pharmaceutical, Inc., or Slanmhor. 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. The Company is not obligated to pay in cash any shortfall in the minimum purchase obligations pursuant to the Chemport and BASF agreements. The agreement with Slanmhor contains a provision requiring the Company to pay Slanmhor in cash for any shortfall in the minimum purchase obligations, which will become effective upon the approval for manufacture by the FDA of supply from Slanmhor. Chemport and BASF were approved by the FDA to manufacture API for commercial sale in April 2013. The Company has begun to purchase commercial supply from Chemport. BASF must complete production of validation batches before the Company will begin to purchase commercial supply. The 2011 supply agreements include commitments for the Company to fund (i) development fees up to a maximum of \$0.5 million (ii) material purchases of up to \$5.0 million for initial raw materials, which amount will be credited against future API purchases and (iii) a raw material purchase commitment of \$1.1 million. Under these agreements, during the nine months ended September 30, 2013, the Company made payments of \$4.8 million and \$0.1 million to Chemport and BASF, respectively. The agreement with Slanmhor 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. The \$15.0 million commitment fee is contingent upon the mutually agreed upon expansion of Slanmhor's API manufacturing capacity. Under this agreement, during the nine months ended

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

September 30, 2013, the Company made payments of \$6.1 million to Slanmhor related to stability and technical batches and advances on future API purchases.

Under the 2004 share repurchase agreement with Laxdale Limited, or Laxdale, upon approval of Vascepa by the FDA on July 26, 2012, the Company was required to make a milestone payment to Laxdale of £7.5 million. The Company made this payment in 2012 and capitalized this Laxdale milestone (\$11.6 million on July 26, 2012) as an intangible asset. This long-term asset is being amortized over the estimated useful life of the intellectual property the Company acquired from Laxdale and the Company recognized amortization expense of \$0.5 million during the nine months ended September 30,

**Table of Contents**

2013. Also under the Laxdale agreement, upon receipt of marketing approval in Europe for the first indication for Vascepa (or first indication of any product containing Amarin Neuroscience intellectual property acquired from Laxdale in 2004), the Company must make an aggregate stock or cash payment to the former shareholders of Laxdale (at the sole option of each of the sellers) of £7.5 million (approximately \$12.1 million at September 30, 2013). Also under the Laxdale agreement, 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, 2013) for each of the two potential market approvals (i.e. £10 million maximum, or approximately \$16.1 million at September 30, 2013).

The Company has no provision for any of the obligations above since the amounts are either not probable or estimable at September 30, 2013.

**(8) Equity****Common stock**

On July 12, 2013, the Company completed a public offering of 21,700,000 ADSs. The underwriters purchased the ADSs from Amarin at a price of \$5.60 per ADS, resulting in net proceeds to Amarin of approximately \$121.2 million, after deducting estimated offering expenses payable by the Company. Amarin also granted the underwriters a 30-day option to purchase an additional 3,255,000 ADSs, which was not exercised. The stated use of proceeds in connection with this offering were as follows: primarily to continue the commercial launch of Vascepa capsules in the MARINE indication, prepare for and commercially launch Vascepa in the ANCHOR indication, if approved, advance the Company's REDUCE-IT cardiovascular outcomes trial, and for general corporate and working capital purposes.

During the nine months ended September 30, 2013 and 2012, the Company issued 386,000 and 3,107,913 shares, respectively, as a result of the exercise of stock options. Gross and net proceeds resulting from the exercise of stock options amounted to \$0.6 million for the nine months ended September 30, 2013. For the nine months ended September 30, 2012, gross proceeds amounted to \$7.9 million and net proceeds amounted to \$7.8 million resulting from the exercise of stock options. In addition, during the nine months ended September 30, 2013 and 2012, the Company issued 120,000 and 10,881,276 shares, respectively, as a result of the exercise of warrants. Gross and net proceeds resulting from the exercise of warrants amounted to \$0.1 million for the nine months ended September 30, 2013. For the nine months ended September 30, 2012, gross proceeds amounted to \$16.6 million and net proceeds amounted to \$16.5 million resulting from the exercise of warrants.

In August and September of 2013, the Company granted a total of 44,000 restricted stock units ( RSUs ) to several employees under the Amarin Corporation plc 2011 Stock Incentive Plan ( 2011 Plan ). As of September 30, 2013, no RSU s were forfeited and no shares were issued as a result of vesting. These RSUs vest upon the achievement of certain operational milestones and expire on December 31, 2013 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 Compensation Committee in shares or a combination of cash or shares. The fair value of the RSUs was 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 no expense during the nine months ended September 30, 2013 related to the vesting of these RSUs.

In July of 2013, the Company granted a total of 54,000 deferred stock units ( DSUs ) to members of the Company's Board of Directors under the Amarin Corporation plc 2011 Stock Incentive Plan ( 2011 Plan ). As of September 30, 2013, no DSU s were forfeited and no shares were issued as a result of vesting. The DSU s vest over a three year period. The DSUs will become fully vested upon a change of control of the Company. Upon termination of service to the Company, each Director shall be entitled to a payment equal to the fair market value of one share of Amarin common stock, which is required to be made in shares. The Company recorded expense during the nine months ended September 30, 2013 of \$47,000 related to the vesting of these DSUs.

In January 2013, the Company granted 454,875 RSUs to several employees under the 2011 Plan. As of September 30, 2013, 32,500 RSUs were forfeited and no shares were issued as a result of vesting. These RSUs vest upon the achievement of certain operational milestones and expire on August 3, 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 Compensation Committee in shares or a combination of cash or shares. The fair value of the RSUs was 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 no expense during the nine months ended September 30, 2013 related to the vesting of these RSUs.



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

In February 2012, the Company granted 584,400 RSUs to several employees under the 2011 Plan. As of September 30, 2013, a total of 90,684 RSUs were forfeited. These RSUs vest upon the achievement of certain regulatory and time-based milestones. The RSUs

**Table of Contents**

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 Compensation Committee in shares or a combination of cash or shares. During the nine months ended September 30, 2013 and 2012, the Company issued 93,048 and 97,398 shares, respectively, as a result of the vesting of these RSUs. The fair value of the RSUs was determined on the date of grant, and compensation expense related to the RSUs is recognized once the related milestone is deemed probable. During the nine months ended September 30, 2013 and 2012, the Company recorded expense of \$0.3 million and \$1.2 million, respectively, related to the vesting of these RSUs.

**(9) Subsequent Events**

On October 16, 2013, the Company announced that an advisory committee to the FDA voted 9 to 2 against recommending approval of the use of Vascepa capsules for the ANCHOR indication based on information presented at the advisory committee meeting. The FDA is scheduled to make its decision on whether to approve the ANCHOR sNDA on the December 20, 2013 PDUFA goal date for the application, however, the FDA could complete its review of the sNDA prior to this date and there can be no assurance that the FDA will complete its review of the sNDA by this date.

On October 22, 2013, in an effort to reduce operating expenses following the recommendation of the advisory committee to the FDA, the Company implemented a worldwide reduction in force of approximately fifty percent of its staff positions worldwide. The majority of affected staff members are sales professionals who have supported the initial commercial launch of Vascepa. The Company estimates that it will incur approximately \$3 million in charges related to the reduction in force, all of which includes cash expenditures for one-time termination benefits and associated costs. The Company expects to record the charges in the fourth quarter of 2013 and make the related payments by the end of the first quarter of 2014.

On October 29, 2013, the FDA notified the Company that it has rescinded the ANCHOR study Special Protocol Assessment, or SPA, agreement because in their view a substantial scientific issue essential to determining the effectiveness of Vascepa in the studied population from the ACCORD-Lipid and AIM-HIGH outcome trials, as well as the publicly presented results from the HPS2-THRIVE outcome trial, which the FDA stated in its October 29, 2013 notice to the Company, fail to support the hypothesis that a triglyceride-lowering drug significantly reduces the risk for cardiovascular events among statin-treated patients. Thus, the FDA stated that it no longer considers a change in serum triglyceride levels as sufficient to establish the effectiveness of a drug intended to reduce cardiovascular risk in subjects with serum triglyceride levels below 500 mg/dL.

On November 1, 2013, a purported investor of Amarin filed a putative class action lawsuit against Amarin and the Company's Chief Executive Officer in the U.S. District Court for the District of New Jersey, Steven Sklar v. Amarin Corporation plc and Joseph S. Zakrzewski, No. 13-cv-6954 (D.N.J. Nov. 1, 2013). The lawsuit alleges that, during the period July 9, 2009 through October 15, 2013, the Company misled investors regarding the FDA's willingness to approve Vascepa's ANCHOR indication and the potential relevance of data from the ongoing REDUCE-IT trial to that approval, thereby artificially inflating the price of the Company's securities. Based on these allegations, the suit asserts claims under the Securities Exchange Act of 1934 and seeks unspecified monetary damages and attorneys' fees and costs. The Company believes that it has valid defenses and will vigorously defend against the claims.

On November 5, 2013, a purported investor of Amarin filed a putative class action lawsuit against Amarin and certain of the Company's officers in the U.S. District Court for the Southern District of New York, Joseph A. Bove and Joseph J. Bove v. Amarin Corporation, PLC., Joseph S. Zakrzewski, John F. Thero, and Steven B. Ketchum, No. 13-CIV-7882 (S.D.N.Y. Nov. 5, 2013). The lawsuit alleges, similar to the *Sklar* case, that, during the period August 8, 2012 until October 16, 2013, the Company misled investors regarding the FDA's willingness to approve Vascepa's ANCHOR indication and the potential relevance of data from the ongoing REDUCE-IT trial to that approval, thereby artificially inflating the price of the Company's securities. Based on these allegations, the suit asserts claims under the Securities Exchange Act of 1934 and seeks unspecified monetary damages and attorneys' fees and costs. The Company believes that it has valid defenses and will vigorously defend against the claims.

**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, 2012 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 with expertise in lipid science focused on the commercialization and development of therapeutics to improve cardiovascular health. On July 26, 2012, we received U.S. Food and Drug Administration, or FDA, approval to market and sell our lead product Vascepa® (icosapent ethyl) capsules (formerly known as AMR 101) as an adjunct to diet to reduce triglyceride 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. Hypertriglyceridemia refers to a condition in which patients have high levels of triglycerides in the bloodstream. It is estimated 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 States have severely high triglyceride levels (TG  $\geq$ 500mg/dL), commonly known as very high triglyceride levels. According to *The American Heart Association Scientific Statement on Triglycerides*

---

**Table of Contents**

and *Cardiovascular Disease* (2011), triglycerides also 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 cholesterol, or HDL-C (often referred to as good cholesterol), and elevated levels of LDL-C (often referred to as bad cholesterol). Guidelines for the management of very high triglyceride levels suggest that reducing triglyceride levels is the primary goal in patients to reduce the risk of acute pancreatitis. The effect of Vascepa on cardiovascular mortality and morbidity, or the risk for pancreatitis, in patients with hypertriglyceridemia has not been determined.

Vascepa became commercially available in the United States by prescription in January 2013, when we commenced sales and shipments to its network of U.S.-based wholesalers and specialty pharmacy providers. On January 28, 2013, we commenced our full commercial launch of Vascepa in the United States for use in the MARINE indication with approximately 275 sales representatives. In October 2013, we reduced our number of sales representatives to approximately 130, excluding sales management, in the United States to focus on the sales territories that we believe have demonstrated the greatest potential for Vascepa sales growth.

We are also developing Vascepa for the treatment of patients with high triglyceride levels (TG  $\geq$ 200 mg/dL and  $<$ 500 mg/dL) who are also on statin therapy for elevated LDL-C levels. This indication is referred to as mixed dyslipidemia or the ANCHOR indication. In February 2013, we submitted a supplemental New Drug Application, or sNDA, to the FDA seeking approval of Vascepa for the ANCHOR indication.

On October 16, 2013, the FDA convened an advisory committee to review the Company's sNDA for the ANCHOR indication and the advisory committee voted 9 to 2 against recommending approval of the ANCHOR indication based on information presented at the meeting. The FDA will consider the recommendation of the advisory committee, but the final decision regarding the approval of the sNDA will be made by the FDA.

A Special Protocol Assessment, or SPA, agreement is an agreement with the FDA that Phase 3 trial protocol design, clinical endpoints, and planned statistical analyses are acceptable to support regulatory approval. A 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. On October 29, 2013, the FDA notified us that it rescinded the ANCHOR study SPA because the FDA determined that a substantial scientific issue essential to determining the effectiveness of Vascepa in the studied population was identified after testing began. Specifically, consistent with discussion at the advisory committee meeting, the FDA determined that results from outcome studies of other triglyceride lowering drugs failed to support the hypothesis that a triglyceride-lowering drug significantly reduces the risk for cardiovascular events among the population studied in the ANCHOR trial. Thus, the FDA stated that it no longer considers a change in serum triglyceride levels as sufficient to establish the effectiveness of a drug intended to reduce cardiovascular risk in subjects with serum triglyceride levels below 500 mg/dL. On November 7, 2013, we submitted to the FDA a formal appeal of its decision to rescind the SPA including documents outlining why we believe the SPA was wrongfully rescinded. There can be no assurance that the FDA will agree with our arguments. The ANCHOR indication sNDA is subject to a standard review and has been assigned a Prescription Drug User Fee Act, or PDUFA, date of December 20, 2013. The PDUFA date is the target date for the FDA to complete its review of the sNDA. The FDA could complete its review of the sNDA prior to this date and there can be no assurance that the FDA will complete its review of the sNDA by this date. If the FDA does not approve the ANCHOR indication, it would have a material adverse impact on our future results of operations and financial condition. Based on the recommendation of the advisory committee and the rescinding of the ANCHOR SPA, we believe there is a significant possibility that FDA may not approve the ANCHOR sNDA and require, as a condition of any possible approval, additional preclinical studies or clinical trials.

On October 22, 2013, in an effort to reduce operating expenses following the recommendation of the advisory committee to the FDA, we implemented a worldwide reduction in force of approximately fifty percent of our staff positions worldwide. The majority of affected staff members are sales professionals who have supported the initial commercial launch of Vascepa. We estimate that we will incur approximately \$3 million in charges related to the reduction in force, all of which includes cash expenditures for one-time termination benefits and associated costs. We expect to record the charges in the fourth quarter of 2013 and make the related payments by the end of the first quarter of 2014. As part of the reduction in force, we retained approximately 130 sales representatives in the United States in sales territories that we believe have demonstrated the greatest potential for Vascepa sales growth. We plan to have this team cover the target base of physicians responsible for the majority of Vascepa prescription volume and growth since its launch in early 2013. With these changes and resulting target base coverage, Amarin anticipates continued Vascepa revenue growth over time. Amarin further anticipates that such sales growth may be inconsistent from period to period.

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), which is designed to evaluate the efficacy of Vascepa in reducing major cardiovascular events in a high risk patient population on statin therapy. The final results of the REDUCE-IT study may be required for FDA approval of Vascepa for the ANCHOR indication. In September 2013, we announced that over 6,000 patients were, in aggregate, enrolled in REDUCE-IT. Amarin currently estimates that it will complete patient enrollment in this study in the first half of 2015. However, if we do not receive FDA approval of the ANCHOR indication, we plan to re-evaluate the REDUCE-IT study, including the likelihood of REDUCE-IT

providing clinically and commercially useful results, the likelihood of FDA approval for an expanded indication for Vascepa based on these results and whether it is advisable to continue or discontinue the study. We anticipate that in any such re-evaluation we will seek further feedback from the FDA. If continued, the REDUCE-IT study will be completed after reaching an aggregate number of cardiovascular events. Based on event rates in other outcomes studies, Amarin estimates completing the REDUCE-IT study in or about 2017. Based on the results of REDUCE-IT, we may seek additional indications for VASCEPA beyond the indications studied in the ANCHOR or MARINE trials.

---

## **Table of Contents**

In August 2013, we completed dosing of AMR102, a fixed dose combination of Vascepa and a leading statin product. The study is a randomized, open-label, single-dose, 4-way cross-over study to continue testing of the relative bioavailability of AMR102 capsules, Vascepa capsules with the selected statin taken concomitantly, Vascepa taken alone and the selected statin taken alone. We anticipate results from this study either in the fourth quarter of 2013 or in the first half of 2014. If we do not receive FDA approval for the ANCHOR indication, we may discontinue development of AMR102.

The potential efficacy and safety of Vascepa was studied in the MARINE trial and the ANCHOR trial, each of which were Phase 3 clinical trials. At a daily dose of 4 grams of Vascepa, the dose at which Vascepa is FDA-approved for the MARINE indication, these trials showed favorable clinical results in their respective patient populations in reducing triglyceride levels without increasing LDL-C levels in the MARINE trial and with a statistically significant decrease in LDL-C levels in the ANCHOR trial, in each case as compared to placebo. 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 these trials, the most commonly reported adverse reaction (incidence >2% and greater than placebo) in patients treated with Vascepa was arthralgia (joint pain) (2.3% for Vascepa vs. 1.0% for placebo).

### *Commercialization Update*

Vascepa became commercially available in the United States by prescription in January 2013 when we commenced sales and shipments to our network of U.S.-based wholesalers. On January 28, 2013, we commenced our full commercial launch of Vascepa in the United States. In preparation for our commercial launch, we hired and trained a direct sales force of approximately 275 sales representatives, which was subsequently reduced by approximately 50% in October 2013. We also employ various marketing and medical affairs personnel to support our commercialization of Vascepa.

In September 2013, we completed our eighth full calendar month of marketing and selling Vascepa. Based on monthly compilations of data provided by a third party, the estimated number of normalized total Vascepa prescriptions (TRx) for the first three quarters of 2013 post-launch of Vascepa were as follows: 10,484 (Q1); 47,335 (Q2); and 74,576 (Q3). Normalized total prescriptions represent the estimated total number of Vascepa prescriptions shipped to patients, calculated on a normalized basis (i.e., total capsules shipped divided by 120 capsules, or one month supply). The data reported above is based on information made available to us from a third party resource and may be subject to adjustment and may overstate or understate actual prescriptions.

As of November 1, 2013, over 13,000 clinicians had written prescriptions for Vascepa.

Although we believe these data are prepared on a period-to-period basis in a manner that is generally consistent and that such results are generally indicative of current prescription trends, these data are based on estimates and should not be relied upon as definitive. In addition, because of our limited selling history, during the nine months ended September 30, 2013, we only recognized revenue on product that was resold for purposes of filling prescriptions. Those prescription data may differ from data reported by other third parties.

Prior to commencing our U.S. commercial launch of Vascepa in January 2013, we had no revenue from Vascepa. Because of our limited selling history, we do not believe that we can provide a reasonably accurate forecast of Vascepa prescriptions or revenues. We provide no guidance regarding anticipated levels of Vascepa prescriptions or revenues and no such guidance should be inferred from the operating metrics described above. We believe that investors should view the above-referenced operating metrics with caution, as data for this limited period may not be representative of a trend consistent with the results presented or otherwise predictive of future results. Seasonal fluctuations in pharmaceutical sales, for example, may affect future prescription trends of Vascepa, as could changes in prescriber sentiment and other factors. We believe investors should consider our results over several quarters, or longer, before making an assessment about potential future performance.

The commercial launch of a new pharmaceutical product is a complex undertaking, and our ability to effectively and profitably launch Vascepa will depend in part on our ability to generate market demand for Vascepa through education, marketing and sales activities, our ability to achieve market acceptance of Vascepa, our ability to generate product revenue and our ability to receive adequate levels of reimbursement from third-party payers. See *Risk Factors Risks Related to the Commercialization and Development of Vascepa*.

### *Commercial Supply Update*

During the nine months ended September 30, 2013, we acquired approximately \$20.4 million of Vascepa active pharmaceutical ingredient, or API, of which \$16.7 million was capitalized to inventory as of September 30, 2013. The balance of such Vascepa API purchase costs was included as a component of research and development expense because it was received from suppliers that had not yet been qualified by the

FDA.

In April 2013, the FDA approved our sNDAs covering Chemport, Inc. and BASF (formerly Equateq Limited) as additional Vascepa API suppliers. We are working with Slanmhor Pharmaceuticals, Inc. to pursue FDA approval for Slanmhor to manufacture Vascepa API and submitted an sNDA in August 2013. Until an API supplier is approved, all Vascepa API purchased from such supplier is included as a component of research and development expense.

**Table of Contents**

The amount of supply purchases in 2014 and beyond will depend on the level of growth of Vascepa revenues, which will be significantly impacted by the outcome of the FDA's decision on approval of the ANCHOR indication. We anticipate that our gross margin from Vascepa sales will be lower in 2013 than in subsequent years due to multiple factors, including API supply pricing with our earliest approved supplier, Nisshin. This is the case particularly as it relates to our earliest volume of purchases from Nisshin being higher than supply pricing later agreed with other suppliers, tiered supply pricing at certain suppliers such that cost per kilogram of supply purchases are scheduled to decline as volume of purchases increase, recent improvement in currency exchange rates, geographic location of our suppliers, special initial stocking discounts provided to wholesalers and pharmacies to encourage them to stock Vascepa in advance of Vascepa's January 2013 commercial launch, and rebate cards offered to consumers filling prescriptions for Vascepa to reduce the size of the consumer's co-payment requirements while we work with payors to migrate Vascepa coverage from tier-3 to tier-2 in these payors' drug pricing systems. We anticipate rebate amounts that we will agree to provide payors for tier-2 insurance coverage on sales of Vascepa will cost us less than our current rebate card program.

*Financial Position*

We believe that our cash and cash equivalents balance of \$225.9 million at September 30, 2013, which includes \$121.2 million in net proceeds received from our offering of ADSs in July 2013, will be sufficient to fund our projected operations for at least the next twelve months.

**Financial Operations Overview**

*Revenue.* All of our revenue is derived from product sales of Vascepa, net of allowances, discounts, incentives, rebates, chargebacks and returns. We sell product to a limited number of major wholesalers, as well as selected regional wholesalers and specialty pharmacy providers, or collectively, our Distributors, who resell the product to retail pharmacies for purposes of their reselling the product to fill patient prescriptions. In accordance with GAAP, until we have the ability to reliably estimate returns of Vascepa from our Distributors, revenue will be recognized based on the resale of Vascepa for the purposes of filling patient prescriptions, and not based on sales from us to such Distributors. Consistent with industry practice, once we achieve sufficient history such that we can reliably estimate returns based on sales to our Distributors, we anticipate that our revenues will be recognized based on sales to our Distributors. We currently defer Vascepa revenue recognition until the earlier of the product being resold for purposes of filling patient prescriptions; and the expiration of the right of return (twelve months after the expiration date of the product). We also defer the related cost of product sales and record such amounts as finished goods inventory held by others until revenue related to such product sales is recognized. As of September 30, 2013, product returns were de minimus.

*Cost of Goods Sold.* Cost of goods sold includes the cost of API for Vascepa on which revenue was recognized during the period, as well as the associated costs for encapsulation, packaging, shipment, supply management, insurance and quality assurance. The cost of the API included in cost of goods sold reflects the average cost method of inventory valuation and relief. This average cost reflects the actual purchase price of Vascepa API, the majority of which through September 30, 2013 was from Nisshin, our first approved API supplier.

*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 qualifying contract manufacturers, services expenses incurred in developing and testing products and product candidates, salaries and related expenses for personnel, including stock-based compensation expense, costs of materials, depreciation, rent, utilities and other facilities costs. In addition, research and development expenses include the cost to support current development efforts, including patent costs and milestone payments. We expense research and development costs as incurred.

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

*Interest and Other (Expense) Income, Net.* Interest expense consists of interest incurred under lease obligations, interest incurred under our 3.5% exchangeable debt and interest incurred under our December 2012 financing arrangement with BioPharma Secured Debt Fund II Holdings Cayman LP, or BioPharma. Interest expense under our 3.5% exchangeable debt includes the amortization of the conversion option related to our exchangeable debt, the amortization of the related debt discount and debt obligation coupon interest. Interest income consists of interest earned on our cash and cash equivalents. Other (expense) income, net, consists primarily of foreign exchange losses and gains.



---

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

Our discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements and notes, which have been prepared in accordance with accounting principles generally accepted in the United States (GAAP). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expenses. On an ongoing basis, we evaluate our estimates and judgments, including those related to derivative financial liabilities. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. A summary of our significant accounting policies is contained in Note 2 to our consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our consolidated financial statements.

*Revenue Recognition* We sell Vascepa principally to a limited number of Distributors, that in turn resell Vascepa to retail pharmacies that subsequently resell it to patients and health care providers. In accordance with GAAP, our revenue recognition policy requires that: (i) there is persuasive evidence that an arrangement exists between us and the Distributor, (ii) delivery has occurred, (iii) collectability is reasonably assured and (iv) the price is fixed or determinable.

We began recognizing revenue from the sale of Vascepa following our commercial launch in the United States in January 2013. Prior to 2013, we recognized no revenue from Vascepa sales. In accordance with GAAP, until we have the ability to reliably estimate returns of Vascepa from our Distributors, revenue will be recognized based on the resale of Vascepa for the purposes of filling patient prescriptions, and not based on sales from us to such Distributors. Consistent with industry practice, once we achieve sufficient history such that we can reliably estimate returns based on sales to our Distributors, we anticipate that our revenues will be recognized based on sales to our Distributors. We currently defer Vascepa revenue recognition until the earlier of the product being resold for purposes of filling patient prescriptions; and the expiration of the right of return (twelve months after the expiration date of the product). We also defer the related cost of product sales and record such amounts as finished goods inventory held by others until revenue related to such product sales is recognized. As of September 30, 2013, we had experienced de minimis product returns.

We have written contracts with our Distributors, and delivery occurs when a Distributor receives Vascepa. We evaluate the creditworthiness of each of our Distributors to determine whether revenues can be recognized upon delivery, subject to satisfaction of the other requirements, or whether recognition is required to be delayed until receipt of payment. In order to conclude that the price is fixed or determinable, we must be able to (i) calculate our gross product revenues from the sales to Distributors and (ii) reasonably estimate our net product revenues. We calculate gross product revenues based on the wholesale acquisition cost that we charge our Distributors for Vascepa. We estimate our net product revenues by deducting from our gross product revenues (a) trade allowances, such as invoice discounts for prompt payment and distributor fees, (b) estimated government and private payor rebates, chargebacks and discounts, such as Medicaid reimbursements, (c) reserves for expected product returns and (d) estimated costs of incentives offered to certain indirect customers, including patients.

*Derivative Financial Liabilities* Derivative financial liabilities are initially recorded at fair value. They are subsequently held at fair value, with gains and losses arising for changes in fair value recognized in the statement of operations. The fair value of derivative financial liabilities is determined using valuation techniques; typically we use the Black-Scholes option pricing model. We use our judgment to select a variety of methods and make assumptions that are mainly based on market conditions existing at each balance sheet date. Fluctuations in the assumptions used in the valuation model would result in adjustments to the fair value of the warrant derivative liability reflected on our balance sheet and, therefore, our statement of operations. If we issue 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. For options and warrants treated as derivative financial liabilities, at settlement date the carrying value of the options and warrants are transferred to equity. The cash proceeds received from shareholders for additional shares are recorded in common stock and additional paid-in capital. We recorded a financial derivative related the change in control provision associated with our December 2012 debt financing. During 2013 we recorded a derivative on our forward foreign exchange contracts. The fair value of these derivatives could fluctuate based on changes in the assumptions used in the valuation models.

*Inventory Capitalization* Prior to July 26, 2012, when we received approval from the FDA to market and sell Vascepa in the United States for the MARINE indication, Vascepa was considered a product candidate under development. All supply of Vascepa purchased prior to July 26, 2012 was not capitalized and instead charged as a component of research and development expense in the period received. After Vascepa was approved, we began to capitalize inventory purchased from Nisshin, the API supplier approved in the NDA. Prior to April 2013, only Nisshin was an FDA-approved supplier of API for Vascepa. In April 2013, the FDA approved our sNDAs covering Chemport and BASF as additional Vascepa API suppliers. All supply from Chemport and BASF prior to FDA approval of these API suppliers was not capitalized and instead charged as a component of research and development expense in the period received. Subsequent to the approval of these suppliers, we capitalize API purchases from them. We are working with Slanmhor to pursue FDA approval for Slanmhor to manufacture Vascepa API and submitted an sNDA in August 2013. Until an API supplier is approved, all Vascepa API purchased from such supplier is included as a

component of research and development expense.

---

## **Table of Contents**

Upon sNDA approval of each additional supplier, we capitalize subsequent Vascepa API purchases from such supplier as inventory. Purchases of Vascepa API received and expensed before such regulatory approvals are not subsequently capitalized, and all such purchases are quarantined and not used for commercial supply until such time as the sNDA for the supplier that produced the API is approved.

### **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, 2013 versus September 30, 2012***

*Revenue.* We recorded revenue of \$8.4 million during the three months ended September 30, 2013. We commenced our full commercial launch of Vascepa in the United States for use in the MARINE indication on January 28, 2013. We recorded no revenue in 2012. All of our revenue in the three months ended September 30, 2013 was derived from product sales of Vascepa, net of allowances, discounts, incentives, rebates, chargebacks and returns.

We sell Vascepa to Distributors. In accordance with our revenue recognition policy, until we have more experience with the sale of Vascepa and can better estimate product returns, we currently recognize revenue only for product which has been used for of the purpose of filling prescriptions. During the three month period ended September 30, 2013, we invoiced Distributors for \$11.7 million. The excess of the amount billed and the amount recognized as revenue for the three months ended September 30, 2013, net of applicable discounts and rebates, has been recorded as deferred revenue.

During the three months ended September 30, 2013, our net product revenues included an adjustment for co-pay mitigation rebates provided by us to commercially insured patients. Such rebates are intended to offset the differential for patients of Vascepa not covered by commercial insurers at the time of launch on tier 2, resulting in higher co-pay amounts for such patients. Our cost for these co-payment mitigation rebates is up to \$75 dollars per prescription filled during 2013. Commencing in March and April 2013, certain third-party payors added Vascepa to their tier 2 coverage, which results in lower co-payments for patients covered by these third-party payors. As of November 1, 2013, approximately 92 million lives covered by medical insurance were under insurance plans that have added Vascepa to their tier 2 coverage. In connection with the start of such tier 2 coverage, we have agreed to pay customary rebates to these third-party payors on the resale of Vascepa to patients covered by these third-party payors.

As is typical for the pharmaceutical industry, the majority of Vascepa sales are to major commercial wholesalers which then resell Vascepa to retail pharmacies. As of November 1, 2013, over 13,000 clinicians had written prescriptions for Vascepa. As of November 1, 2013, we are not aware of any clinician who is responsible for 10% or more of the aggregate prescriptions written for Vascepa.

On October 22, 2013, in an effort to reduce operating expenses following the recommendation of the advisory committee to the FDA, we implemented a worldwide reduction in force including a reduction of approximately fifty percent of our sales representatives. Following the reduction in force, we retained approximately 130 sales representatives in the United States in sales territories which have demonstrated what we believe is the greatest potential for Vascepa sales growth. This team will cover the target base of physicians responsible for the majority of Vascepa prescription volume and growth since its launch in early 2013. With these changes and resulting target base coverage, we anticipate continued Vascepa revenue growth over time. We further anticipate that such revenue growth may be inconsistent from period to period.

*Cost of Goods Sold.* Cost of goods sold during the three months ended September 30, 2013 was \$3.7 million, and includes the cost of API for Vascepa on which revenue was recognized during the period, as well as the associated costs for encapsulation, packaging, shipment, supply management, insurance and quality assurance. The cost of the API included in cost of goods sold reflects the average cost of API included in inventory. This average cost reflects the actual purchase price of Vascepa API, as well as a portion of API carried at zero cost for material which was purchased prior to FDA approval of Vascepa on July 26, 2012 or was purchased prior to the sNDA approval of our suppliers.

The majority of API included in the calculation of the average cost of goods sold during the three months ended September 30, 2013 was sourced from one API supplier. The contracted cost of supply from this API supplier for initial purchase volumes is higher than the contracted cost from our other API suppliers. Contracted purchase costs from this initial API supplier reflect that they were working with Amarin prior to commencement of the MARINE and ANCHOR clinical trials and are anticipated to decline as additional API volume is purchased. In the future, we anticipate making continued purchases from this initial supplier at substantially lower unit pricing than the pricing of the initial purchases

from this supplier and to make additional lower unit cost purchases of Vascepa API from other API suppliers, including Chemport and BASF, both of which were approved by the FDA in April 2013 to produce Vascepa API. The Company began purchasing lower unit cost API from Chemport in the three months ended June 30, 2013.

**Table of Contents**

During the three months ended September 30, 2013, no product was sold that was previously expensed and thus had a carrying value of zero. We expect current inventories with a carrying value of zero to be utilized in 2014. The Company may have additional zero cost inventories in the future to the extent that we receive approval of the sNDA for our fourth commercial supplier. As of September 30, 2013, the Company maintained inventory with a carrying value of zero and an acquisition cost of \$0.6 million, which has an estimated net realizable value of \$2.6 million based on our average net selling price for the three months ended September 30, 2013.

Our gross margin improved from 45% and 48% in the three months ended March 31 and June 30, 2013, respectively, to 56% in the three months ended September 30, 2013, which was primarily driven by lower unit cost API purchases. In addition to expected continued lower average unit cost purchases of API, we also expect that API costs will be lower in the future due to recent improvements in foreign currency exchange rates and potential advantages derived from the geographical mix of our suppliers.

*Research and Development Expense.* Research and development expense for the three months ended September 30, 2013 was \$16.8 million, versus \$20.9 million in the prior year period, a decrease of \$4.1 million, or 19.6%. Research and development expenses for the three months ended September 30, 2013 and 2012 are summarized in the table below (in thousands):

	<b>Three Months Ended September 30,</b>	
	<b>2013</b>	<b>2012</b>
REDUCE-IT study (1)	\$ 9,126	\$ 9,922
Other clinical trial programs (2)	461	160
Pre-approval commercial supply (3)	2,623	5,826
Regulatory filing fees and expenses (4)	976	242
Internal staffing, overhead and other (5)	3,045	3,793
Research and development expense, excluding non-cash expense	16,231	19,943
Non-cash stock-based compensation (6)	590	970
Total research and development expense	\$ 16,821	\$ 20,913

The decrease in research and development expenses for the three months ended September 30, 2013, as compared to the same period in 2012, is primarily due to a decrease in pre-approval commercial supply purchases as described further below.

- (1) In December 2011, we announced commencement of patient dosing in our cardiovascular outcomes study of Vascepa, titled REDUCE-IT, which is designed to evaluate the efficacy of Vascepa in reducing major cardiovascular events in a high risk patient population on statin therapy. The study duration is dependent on the rate of clinical events in the study, which rate may be affected by the number of patients enrolled in the study and the epidemiology of the patients enrolled in the study. We manage the study through a contract research organization (CRO) through which all costs for this outcomes study are incurred with the exception of costs for clinical trial material (CTM) and costs for internal management. Our internal personnel are responsible for managing multiple projects and their costs are not specifically allocated to REDUCE-IT or any other individual project. In September 2013, we announced that, in aggregate, over 6,000 patients have been enrolled in REDUCE-IT. We estimate that we will complete patient enrollment in this study in the first half of 2015. The REDUCE-IT study will be completed after reaching an aggregate number of cardiovascular events. Based on event rates in other outcomes studies, we estimate completing the REDUCE-IT study in or about 2017. For 2013, we anticipate incurring expense through our CRO in connection with this trial of between \$30 million and \$40 million, inclusive of the amounts spent during the nine months ended September 30, 2013. Inclusive of CTM costs, we anticipate combined CRO and CTM costs in 2013 for REDUCE-IT will total approximately \$40 million to \$45 million, inclusive of the amounts spent during the nine months ended September 30, 2013. We expense costs for CTM upon receipt. The aggregate cost of this outcomes study will depend on the rate of clinical events in the study. We currently estimate that quarterly costs incurred for this study in the remainder of 2013 and 2014 will continue at approximately the same levels as we have incurred on a quarterly average in 2013. Excluding 2013 costs, based on our current assumptions of CRO and CTM costs, we estimate that aggregate remaining costs to complete the REDUCE-IT study and evaluate its results to likely exceed \$100 million. We anticipate that our costs for this outcomes study will continue to represent the most significant component of our research and development expenditures. However, if we do not receive FDA approval of the ANCHOR indication, we plan to re-evaluate the REDUCE-IT study, including the likelihood of REDUCE-IT providing clinically and commercially useful results, the likelihood of FDA approval for an

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

expanded indication for Vascepa based on these results and whether it is advisable to continue or discontinue the study. We anticipate that in any such re-evaluation we will seek further feedback from the FDA.

- (2) In 2012 and 2013, other clinical trial programs consisted of fixed-dose combination studies. In December 2012, we completed dosing and pharmacokinetic sampling in a study to test a fixed-dose combination of Vascepa capsules and a

**Table of Contents**

- leading statin which we refer to as AMR102. In August 2013, we completed dosing in a randomized, open-label, single-dose, 4-way cross-over study to continue testing of the relative bioavailability of AMR102 capsules, Vascepa capsules with a selected statin taken concomitantly, Vascepa taken alone and the selected statin taken alone. We anticipate results from this study either late in the second half of 2013 or in the first half of 2014. We expect that additional costs to complete the study, excluding costs of our internal personnel, will be less than \$1 million. Future costs related to the development of AMR102 beyond the ongoing study cannot be reasonably estimated until we evaluate the results of the ongoing study.
- (3) Until an API supplier is approved by the FDA to manufacture commercial supply of Vascepa, all Vascepa purchased from such supplier is included as a component of research and development expense. Upon approval of the supplier, we capitalize subsequent Vascepa API purchases from such supplier as inventory. Purchases of Vascepa API received and expensed before such regulatory approvals are not subsequently capitalized, and all such purchases are quarantined and not used for commercial supply until such time as the supplier that produced the API is approved. The commercial supply expense for the periods shown above represents inventory received from Nisshin prior to NDA approval of Vascepa on July 26, 2012 or received from our other suppliers prior to their sNDA approvals. In April 2013, sNDAs were approved for two of our additional suppliers, BASF and Chemport. An sNDA was submitted in August 2013 for Novasep as part of the Slanmhor consortium. The amount of commercial supply that we receive from Novasep prior to sNDA approval depends upon production schedules at Novasep and the timing of regulatory approval, and we are unable to estimate these amounts at this time. We will continue to expense inventory received from the unapproved supplier until such time as FDA approval is obtained. Additionally, during the three months ended September 30, 2013, we recorded an inventory reserve of \$1.8 million related to certain product in development that is not recoverable in its current form. This product is from a supplier from which no supply has yet been released for commercial use.
  - (4) The regulatory filing fees primarily represent costs incurred in connection with regulatory filings associated with requests for regulatory approvals, such as the sNDA for the ANCHOR indication and annual FDA fees for maintaining manufacturing sites. In the three months ended September, 30, 2013, such fees also include costs associated with preparing for the October 16, 2013 FDA advisory committee meeting.
  - (5) Internal staffing, overhead and other research and development expenses primarily relate to the costs of our personnel employed to managed research, development and regulatory affairs activities and related overhead costs including consulting and other professional fees that are not allocated to specific projects. Such costs also include costs related to qualifying suppliers and legal costs. We anticipate a reduction in such costs in 2014 compared to 2013 levels as a result of a company-wide reduction in force announced in October 2013.
  - (6) Non-cash stock-based compensation expense represents the costs associated with equity awards issued to internal staff supporting our research and development and regulatory functions.

*Selling, General and Administrative Expense.* Selling, general and administrative expense for the three months ended September 30, 2013 was \$28.3 million, versus \$13.4 million in the prior year period, an increase of \$14.9 million, or 111.2%. Selling, general and administrative expenses for the three months ended September 30, 2013 and 2012 are summarized in the table below (in thousands):

	<b>Three Months Ended September 30,</b>	
	<b>2013</b>	<b>2012</b>
Selling, general and administrative expenses, excluding non-cash expenses (1)	\$ 24,333	\$ 10,926
Non-cash stock based compensation expense (2)	3,665	3,665
Non-cash warrant related compensation expense (income) (3)	276	(1,194)
 Total selling, general and administrative expenses	 \$ 28,274	 \$ 13,397

- (1) Selling, general and administrative expense, excluding non-cash compensation charges for stock compensation and warrants, for the three months ended September 30, 2013 was \$24.3 million, versus \$10.9 million in the prior year period, an increase of \$13.4 million, or 122.9%. The increase was primarily due to cost increases in 2013 for sales force staffing, an increase in marketing program spending and increased general and administrative costs incurred in connection with the initial commercialization of Vascepa.
- (2) Stock based compensation expense for each of the three month periods ended September 30, 2013 and 2012 was \$3.7 million.
- (3) Warrant related compensation expense for the three months ended September 30, 2013 was \$0.3 million as compared to income of \$1.2 million in the prior year period. Warrant related compensation expense (income) reflects the non-cash change in fair value of the warrant derivative liability associated with warrants issued in October 2009 to three former employees of Amarin. The increase in the fair value of the warrants for the three months ended September 30, 2013 is due primarily to an increase in our stock price between June 30, 2013 and September 30, 2013. 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.



---

**Table of Contents**

Selling, general and administrative costs in 2013 have increased over 2012 levels as we continue to support the commercialization of Vascepa, including costs for market research, sales force staffing and support costs and investments in infrastructure. We anticipate a reduction in the level of such costs in 2014 as a result of the worldwide reduction in force announced in October 2013 and expected reductions in certain marketing program expenditures and other overhead costs.

*(Loss) Gain on Change in Fair Value of Derivative Liabilities.* (Loss) gain on change in fair value of derivative liabilities for the three months ended September 30, 2013 was a loss of \$1.4 million versus a gain of \$16.5 million in the prior year period. (Loss) gain on change in fair value of derivative liabilities is comprised of (i) the change in fair value of the warrant derivative liability, (ii) the change in fair value of the derivative liability related to the change in control provision associated with the December 2012 BioPharma financing and (iii) an unrealized loss on foreign exchange contracts.

The warrant 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, 2013 was \$36.0 million and we recognized a \$3.3 million loss on change in fair value of derivative liability for the three months ended September 30, 2013. The change in fair value of the warrant derivative liability is due primarily to the decrease or increase in the price of our common stock on the date of valuation.

Our December 2012 financing agreement with BioPharma contains a redemption feature whereby, upon a change of control, we would be required to pay \$140 million, less any previously repaid amount, if the change of control occurs on or before December 31, 2013, or required to repay \$150 million, less any previously repaid amount, if the change of control event occurs after December 31, 2013. The fair value of the derivative liability is recalculated at each reporting period using a probability-weighted model incorporating management estimates for potential change in control, and by determining the fair value of the debt with and without the change in control provision included. The difference between the two fair values of the debt was determined to be the fair value of the embedded derivative. At June 30, 2013, the fair value of the derivative was determined to be \$8.6 million, and at September 30, 2013, the fair value of the derivative was determined to be \$7.2 million. We recognized a \$1.4 million gain on change in fair value of derivative liability for the three months ended September 30, 2013.

We use foreign exchange forward contracts to hedge against changes in exchange rates for inventory purchases denominated in foreign currency. As of September 30, 2013 we had one outstanding foreign exchange forward contract with a notional amount of \$4.5 million. For the three months ended September 30, 2013, we recognized an unrealized gain of \$0.5 million related to the change in fair value of the foreign exchange forward contract derivative liability, which was included as a component of change in fair value of derivative liabilities. There is a balance of \$0.4 million within other current liabilities at September 30, 2013 representing the fair value of the outstanding forward exchange forward contract as of such date.

**Table of Contents**

*Interest Expense, net.* Net interest expense for the three months ended September 30, 2013 was \$8.4 million, versus \$4.6 million in the prior year period, an increase of \$3.8 million, or 82.6%. Net interest expense for the three months ended September 30, 2013 and 2012 is summarized in the table below (in thousands):

	<b>Three Months Ended September 30,</b>	
	<b>2013</b>	<b>2012</b>
<b>Exchangeable senior notes:</b>		
Amortization of debt discount created upon allocation of proceeds to the conversion option	\$ 3,213	\$ 2,785
Contractual coupon interest	1,313	1,298
Amortization of the discount from the underwriter's discounts and offering costs	646	560
<b>Total exchangeable senior notes interest expense</b>	<b>\$ 5,172</b>	<b>\$ 4,643</b>
<b>Long-term debt - BioPharma financing (1):</b>		
Cash interest - current	840	
Cash interest - deferred	1,819	
Non-cash interest	632	
<b>Total long-term debt interest expense</b>	<b>\$ 3,291</b>	<b>\$</b>
<b>Interest income (2)</b>	<b>(22)</b>	<b>(73)</b>
<b>Total interest expense, net</b>	<b>\$ 8,441</b>	<b>\$ 4,570</b>

- (1) Cash and non-cash interest expenses related to the BioPharma financing for the three months ended September 30, 2013 were \$2.7 million and \$0.6 million, respectively. These amounts reflect a change in the assumption from prior quarters that our Vascepa revenue levels will be high enough to support repayment to BioPharma in accordance with the repayment schedule without the optional reduction which is allowed to be elected by us if the threshold revenue levels are not achieved. For the three months ended September 30, 2013, our revenues were below the contractual threshold amount such that we have a cash payment of \$0.8 million due in November 2013 reflecting the calculated optional reduction amount as opposed to the contractual threshold payment of \$2.5 million. Additionally, the revised assumptions yielded a decrease in the calculated effective interest rate resulting in a decrease in interest expense during the three months ended September 30, 2013 as compared to the three months ended June 30, 2013 and March 31, 2013.
- (2) Interest income for the three months ended September 30, 2013 was \$22 thousand, versus \$73 thousand in the prior year period, a decrease of \$51 thousand, or 69.9%. Interest income represents income earned on cash balances.

*Other (Expense) Income, net.* Other (expense) income, net primarily consists of losses and gains on foreign exchange transactions, including realized gains and losses on foreign exchange forward contracts. Other expense for the three months ended September 30, 2012 included an unrealized loss due to the fluctuation in the exchange rate of the Laxdale accrual in the amount of \$0.5 million.

*Benefit from (Provision for) Income Taxes.* Benefit from (provision for) income taxes primarily consists of tax obligations for one of our subsidiaries. During the three months ended September 30, 2013 and 2012, we recorded a benefit from (provision for) income taxes of \$1.6 million and \$(3.6) million, respectively.

**Comparison of Nine Months Ended September 30, 2013 versus September 30, 2012**

*Revenue.* We recorded revenue of \$16.2 million during the nine months ended September 30, 2013. We commenced our full commercial launch of Vascepa in the United States for use in the MARINE indication on January 28, 2013. We recorded no revenue in 2012. All of our revenue in the nine months ended September 30, 2013 was derived from product sales of Vascepa, net of allowances, discounts, incentives, rebates, chargebacks and returns.

We sell Vascepa to Distributors. In accordance with our revenue recognition policy, until we have more experience with the sale of Vascepa and can better estimate product returns, we currently recognize revenue only for product which has been used for purposes of filling prescriptions.

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

During the nine month period ended September 30, 2013, we invoiced Distributors for \$25.2 million. The excess of the amount billed and the amount recognized as revenue for the nine months ended September 30, 2013, net of applicable discounts and rebates, has been recorded as deferred revenue.

During the nine months ended September 30, 2013, our net product revenues included an adjustment for co-pay mitigation rebates provided by us to commercially insured patients. Such rebates are intended to offset the differential for patients of Vascepa not covered by commercial insurers at the time of launch on tier 2, resulting in higher co-pay amounts for such patients. Our cost for these co-payment mitigation rebates is up to \$75 dollars per prescription filled during 2013. Commencing in March and April 2013, certain third-party payors added Vascepa to their tier 2 coverage, which results in lower co-payments for patients covered by these third-party payors. As of November 1, 2013, approximately 92 million lives covered by medical insurance were under insurance plans that have added Vascepa to their tier 2 coverage. In connection with the start of such tier 2 coverage, we have agreed to pay customary rebates to these third-party payors on the resale of Vascepa to patients covered by these third-party payors.

---

**Table of Contents**

As is typical for the pharmaceutical industry, the majority of Vascepa sales are to major commercial wholesalers which then resell Vascepa to retail pharmacies. As of November 1, 2013, over 13,000 clinicians had written prescriptions for Vascepa. As of November 1, 2013, we are not aware of any clinician who is responsible for 10% or more of the aggregate prescriptions written for Vascepa.

On October 22, 2013, in an effort to reduce operating expenses following the recommendation of the advisory committee to the FDA, we implemented a worldwide reduction in force including a reduction of approximately fifty percent of our sales representatives. Following the reduction in force, we retained approximately 130 sales representatives in the United States in sales territories which have demonstrated what we believe is the greatest potential for Vascepa sales growth. This team will cover the target base of physicians responsible for the vast majority of Vascepa prescription volume and growth since its launch in early 2013. With these changes and resulting target base coverage, Amarin anticipates continued Vascepa revenue growth over time. Amarin further anticipates that such sales growth may be inconsistent from period to period.

*Cost of Goods Sold.* Cost of goods sold during the nine months ended September 30, 2013 was \$7.8 million, and includes the cost of API for Vascepa on which revenue was recognized during period, as well as the associated costs for encapsulation, packaging, shipment, supply management, insurance and quality assurance. The cost of the API included in cost of goods sold reflects the average cost of API included in inventory. This average cost reflects the actual purchase price of Vascepa API, as well as a portion of API carried at zero cost for material which was purchased prior to FDA approval of Vascepa on July 26, 2012 or was purchased prior to the sNDA approval of our suppliers.

The majority of API included in the calculation of the average cost of goods sold during the nine months ended September 30, 2013 was sourced from one API supplier. The contracted cost of supply from this API supplier for initial purchase volumes is higher than the contracted cost from our other API suppliers. Contracted purchase costs from this initial API supplier reflect that they were working with Amarin prior to commencement of the MARINE and ANCHOR clinical trials and are anticipated to decline as additional API volume is purchased. In the future, we anticipate making continued purchases from this initial supplier at substantially lower unit pricing than the pricing of the initial purchases from this supplier and to make additional lower unit cost purchases of Vascepa API from other API suppliers, including Chemport and BASF, both of which were approved by the FDA in April 2013 to produce Vascepa API. We began purchasing lower unit cost API from Chemport in the three months ended June 30, 2013. During the nine months ended September 30, 2013, the cost basis of product sold that had a carrying value of zero was approximately \$4.0 million. Had such inventories been valued at acquisition cost, it would have resulted in an increase in cost of goods sold and a decrease in gross margin during such periods. We expect current inventories with a carrying value of zero to be utilized in 2014. We may have additional zero cost inventories in the future to the extent that we receive approval of the sNDA for our fourth commercial supplier. As of September 30, 2013, we maintained inventory with a carrying value of zero and an acquisition cost of \$0.6 million, which has an estimated net realizable value of \$2.6 million based on our average net selling price for the three months ended September 30, 2013.

Our gross margin improved from 45% and 48% in the three months ended March 31 and June 30, 2013, respectively, to 56% in the three months ended September 30, 2013, which was primarily driven by lower unit cost API purchases and resulted in a gross margin of 52% for the nine months ended September 30, 2013. In addition to expected continued lower average unit cost purchases of API, we also expect that API costs will be lower in the future due to recent improvements in foreign currency exchange rates and potential advantages derived from the geographical mix of our suppliers.

**Table of Contents**

*Research and Development Expense.* Research and development expense for the nine months ended September 30, 2013 was \$56.1 million, versus \$39.7 million in the prior year period, an increase of \$16.4 million, or 41.3%. Research and development expenses for the nine months ended September 30, 2013 and 2012 are summarized in the table below:

	Nine Months Ended September 30,	
	2013	2012
REDUCE-IT study (1)	\$ 34,154	\$ 15,941
Other clinical trial programs (2)	932	501
Pre-approval commercial supply (3)	5,783	11,503
Regulatory filing fees and expenses (4)	2,658	(1,098)
Internal staffing, overhead and other (5)	10,420	9,983
Research and development expense, excluding non-cash expense	53,947	36,830
Non-cash stock-based compensation (6)	2,201	2,905
Total research and development expense	\$ 56,148	\$ 39,735

The increase in research and development expenses for the nine months ended September 30, 2013, as compared to the prior year period, is primarily due to an increase in costs associated with the REDUCE-IT study as further described below.

- (1) In December 2011, we announced commencement of patient dosing in our cardiovascular outcomes study of Vascepa, titled REDUCE-IT, which is designed to evaluate the efficacy of Vascepa in reducing major cardiovascular events in a high risk patient population on statin therapy. The study duration is dependent on the rate of clinical events in the study, which rate may be affected by the number of patients enrolled in the study and the epidemiology of the patients enrolled in the study. We manage the study through a contract research organization (CRO) through which all costs for this outcomes study are incurred with the exception of costs for clinical trial material (CTM) and costs for internal management. Our internal personnel are responsible for managing multiple projects and their costs are not specifically allocated to REDUCE-IT or any other individual project. In September 2013, we announced that, in aggregate, over 6,000 patients have been enrolled in REDUCE-IT. We estimate that we will complete patient enrollment in this study in the first half of 2015. The REDUCE-IT study will be completed after reaching an aggregate number of cardiovascular events. Based on event rates in other outcomes studies, we estimate completing the REDUCE-IT study in or about 2017. For 2013, we anticipate incurring expense through our CRO in connection with this trial of between \$30 million and \$40 million, inclusive of the amounts spent during the nine months ended September 30, 2013. Inclusive of CTM costs, we anticipate combined CRO and CTM costs in 2013 for REDUCE-IT will total approximately \$40 million to \$45 million, inclusive of the amounts spent during the nine months ended September 30, 2013. We expense costs for CTM upon receipt. The aggregate cost of this outcomes study will depend on the rate of clinical events in the study. We currently estimate that quarterly costs incurred for this study in the remainder of 2013 and 2014 will continue at approximately the same levels as we have incurred on a quarterly average in 2013. Excluding 2013 costs, based on our current assumptions of CRO and CTM costs, we estimate that aggregate remaining costs to complete the REDUCE-IT study and evaluate its results to likely exceed \$100 million. We anticipate that our costs for this outcomes study will continue to represent the most significant component of our research and development expenditures. However, if we do not receive FDA approval of the ANCHOR indication, we plan to re-evaluate the REDUCE-IT study, including the likelihood of REDUCE-IT providing clinically and commercially useful results, the likelihood of FDA approval for an expanded indication for Vascepa based on these results and whether it is advisable to continue or discontinue the study. We anticipate that in any such re-evaluation we will seek further feedback from the FDA.
- (2) In 2012 and 2013, other clinical trial programs consisted of fixed-dose combination studies. In December 2012, we completed dosing and pharmacokinetic sampling in a study to test a fixed-dose combination of Vascepa capsules and a leading statin which we refer to as AMR102. In August 2013, we completed dosing in a randomized, open-label, single-dose, 4-way cross-over study to continue testing of the relative bioavailability of AMR102 capsules, Vascepa capsules with a selected statin taken concomitantly, Vascepa taken alone and the selected statin taken alone. We anticipate results from this study either late in the second half of 2013 or in the first half of 2014. We expect that additional costs to complete the study, excluding costs of our internal personnel, will be less than \$1 million. Future costs related to the development of AMR102 beyond the ongoing study cannot be reasonably estimated until we evaluate the results of the ongoing study.
- (3) Until an API supplier is approved by the FDA to manufacture commercial supply of Vascepa, all Vascepa purchased from such supplier is included as a component of research and development expense. Upon approval of the supplier, we capitalize subsequent Vascepa API

purchases from such supplier as inventory. Purchases of Vascepa API received and expensed before

**Table of Contents**

such regulatory approvals are not subsequently capitalized, and all such purchases are quarantined and not used for commercial supply until such time as the supplier that produced the API is approved. The commercial supply expense for the periods shown above represents inventory received from Nisshin prior to NDA approval of Vascepa on July 26, 2012 or received from our other suppliers prior to their sNDA approvals. In April 2013, sNDAs were approved for two of our additional suppliers, BASF and Chemport. A sNDA was submitted in August 2013 for Novasep as part of the Slanmhor consortium. The amount of commercial supply that we receive from Novasep prior to sNDA approval depends upon production schedules at Novasep and the timing of regulatory approval, and we are unable to estimate these amounts at this time. We will continue to expense inventory received from the unapproved supplier until such time as FDA approval is obtained. Additionally, during the nine months ended September 30, 2013, we recorded an inventory reserve of \$1.8 million related to certain product in development that is not recoverable in its current form. This product is from a supplier from which no supply has yet been released for commercial use.

- (4) The regulatory filing fees primarily represent costs incurred in connection with regulatory filings associated with requests for regulatory approvals, such as the sNDA for the ANCHOR indication and annual FDA fees for maintaining manufacturing sites. In the nine months ended September 30, 2013, such fees also include costs associated with preparing for the October 16, 2013 FDA advisory committee meeting. In the nine months ended September 30, 2012, the regulatory filing fees balance was a net credit as a result of the reimbursement of \$1.5 million in fees by the FDA related to the NDA filing for Vascepa.
- (5) Internal staffing, overhead and other research and development expenses primarily relate to the costs of our personnel employed to managed research, development and regulatory affairs activities and related overhead costs including consulting and other professional fees that are not allocated to specific projects. Such costs also include costs related to qualifying suppliers and legal costs. We anticipate a reduction in such costs in 2014 compared to 2013 levels as a result of a company-wide reduction in force announced in October 2013.
- (6) Non-cash stock-based compensation expense represents the costs associated with equity awards issued to internal staff supporting our research and development and regulatory functions.

*Selling, General and Administrative Expense.* Selling, general and administrative expense for the nine months ended September 30, 2013 was \$101.5 million, versus \$41.1 million in the prior year period, an increase of \$60.4 million, or 147.0%. Selling, general and administrative expenses for the nine months ended September 30, 2013 and 2012 are summarized in the table below:

	<b>Nine Months Ended September 30,</b>	
	<b>2013</b>	<b>2012</b>
Selling, general and administrative expenses, excluding non-cash expenses (1)	\$ 90,664	\$ 27,583
Non-cash stock based compensation expense (2)	12,017	10,439
Non-cash warrant related compensation (income) expense (3)	(1,179)	3,037
Total selling, general and administrative expenses	\$ 101,502	\$ 41,059

- (1) Selling, general and administrative expense, excluding non-cash compensation charges for stock compensation and warrants, for the nine months ended September 30, 2013 was \$90.7 million, versus \$27.6 million in the prior year period, an increase of \$63.1 million, or 228.6%. The increase was primarily due to cost increases in 2013 for sales force staffing, an increase in marketing program spending and increased general and administrative costs incurred in connection with the initial commercialization of Vascepa.
- (2) Stock based compensation expense for the nine months ended September 30, 2013 was \$12.0 million, versus \$10.4 million in the prior year period, an increase of \$1.6 million primarily reflecting an increase in the number of awards outstanding during the period ending September 30, 2013 versus the prior period.
- (3) Warrant related compensation (income) expense for the nine months ended September 30, 2013 was income of \$1.2 million, versus expense of \$3.0 million in the prior year period. Warrant related compensation (income) expense reflects the non-cash change in fair value of the warrant derivative liability associated with warrants issued in October 2009 to three former employees of Amarin. The decrease in the fair value of the warrants for the nine months ended September 30, 2013 is due primarily to a decrease in our stock price between December 31, 2012 and September 30, 2013. 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

**Table of Contents**

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.

Selling, general and administrative costs in 2013 have increased over 2012 levels as we continue to support the commercialization of Vascepa, including costs for market research, sales force staffing and support costs and investments in infrastructure. We anticipate a reduction in the level of such costs in 2014 as a result of the reduction in force announced in October 2013 and expected reductions in certain marketing program spend and other overhead costs.

*(Loss) Gain on Change in Fair Value of Derivative Liabilities.* (Loss) gain on change in fair value of derivative liabilities for the nine months ended September 30, 2013 was a gain of \$21.1 million versus a loss of \$68.7 million in the prior year period. (Loss) gain on change in fair value of derivative liabilities is comprised of (i) the change in fair value of the warrant derivative liability, (ii) the change in fair value of the derivative liability related to the change in control provision associated with the December 2012 BioPharma financing and (iii) an unrealized loss on foreign exchange contracts.

The warrant 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, 2012 was \$54.9 million and we recognized a \$14.1 million gain on change in fair value of derivative liability for the nine months ended September 30, 2013 for these warrants. 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 nine months ended September 30, 2012. The change in fair value of the warrant derivative liability is due primarily to the decrease or increase in the price of our common stock on the date of valuation.

Our December 2012 financing agreement with BioPharma contains a redemption feature whereby, upon a change of control, we would be required to pay \$140 million, less any previously repaid amount, if the change of control occurs on or before December 31, 2013, or required to repay \$150 million, less any previously repaid amount, if the change of control event occurs after December 31, 2013. The fair value of the derivative liability is recalculated at each reporting period using a probability-weighted model incorporating management estimates for potential change in control, and by determining the fair value of the debt with and without the change in control provision included. The difference between the two fair values of the debt was determined to be the fair value of the embedded derivative. At December 31, 2012, the fair value of the derivative was determined to be \$14.6 million, and at September 30, 2013, the fair value of the derivative was determined to be \$7.2 million. We recognized a \$7.4 million gain on change in fair value of derivative liability for the nine months ended September 30, 2013.

We use foreign exchange forward contracts to hedge against changes in exchange rates for inventory purchases denominated in foreign currency. As of September 30, 2013 we had one outstanding foreign exchange forward contract with a notional amount of \$4.5 million. For the nine months ended September 30, 2013, we recognized an unrealized loss of \$0.4 million related to the change in fair value of the foreign exchange forward contract derivative liability, which was included as a component of change in fair value of derivative liabilities and in other current liabilities at September 30, 2013.

*Interest Expense, net.* Net interest expense for the nine months ended September 30, 2013 was \$26.6 million, versus \$12.8 million in the prior year period, an increase of \$13.8 million, or 107.8%. Net interest expense for the nine months ended September 30, 2013 and 2012 is summarized in the table below (in thousands):

	<b>Nine Months Ended September 30,</b>	
	<b>2013</b>	<b>2012</b>
<b>Exchangeable senior notes:</b>		
Amortization of debt discount created upon allocation of proceeds to the conversion option	\$ 9,215	\$ 7,798
<b>Contractual coupon interest</b>	<b>3,938</b>	<b>3,806</b>
Amortization of the discount from the underwriter's discounts and offering costs	1,851	1,567
<b>Total exchangeable senior notes interest expense</b>	<b>\$ 15,004</b>	<b>\$ 13,171</b>

Long-term debt - BioPharma financing (1):



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

Cash interest - current	840	
Cash interest - deferred	8,854	
Non-cash interest	2,166	
Total long-term debt interest expense	\$ 11,860	\$
Interest income (2)	(218)	(333)
Total interest expense, net	\$ 26,646	\$ 12,838

**Table of Contents**

- (1) Cash and non-cash interest expenses related to the BioPharma financing for the nine months ended September 30, 2013 were \$9.7 million and \$2.2 million, respectively. These amounts reflect a change in the assumption from prior quarters that our Vascepa revenue levels will be high enough to support repayment to BioPharma in accordance with the repayment schedule without the optional reduction which is allowed to be elected by us if the threshold revenue levels are not achieved. For the three months ended September 30, 2013, our revenues were below the contractual threshold amount such that we have a cash payment of \$0.8 million due in November 2013 reflecting the calculated optional reduction amount as opposed to the contractual threshold payment of \$2.5 million. Additionally, the revised assumptions yielded a decrease in the calculated effective interest rate resulting in a decrease in interest expense during the three months ended September 30, 2013 as compared to the three months ended June 30, 2013 and March 31, 2013.
- (2) Interest income for the nine months ended September 30, 2013 was \$0.2 million, versus \$0.3 million in the prior year period, a decrease of \$0.1 million, or 33.3%. Interest income represents income earned on cash balances.

*Other (Expense) Income, net.* Other (expense) income, net primarily includes realized gains and losses on foreign exchange transactions, including foreign exchange forward contracts. Other expense for the nine months ended September 30, 2012 included an unrealized loss due to the fluctuation in the exchange rate of the Laxdale accrual in the amount of \$0.5 million.

*Benefit from (Provision for) Income Taxes.* Benefit from (provision for) income taxes primarily consists of tax obligations for one of our subsidiaries. During the nine months ended September 30, 2013 and 2012, we recorded a benefit from (provision for) income taxes of \$4.8 million and \$(5.9) million, respectively.

**Liquidity and Capital Resources**

Our sources of liquidity as of September 30, 2013 include cash and cash equivalents of \$225.9 million. On July 12, 2013, we completed a public offering of 21,700,000 American Depositary Shares, or ADSs. The underwriters purchased the ADSs from us at a price of \$5.60 per ADS, resulting in net proceeds to us of approximately \$121.2 million, after deducting estimated offering expenses payable by us. Our cash flows from operating, investing and financing activities, as reflected in the consolidated statements of cash flows, are summarized in the following table (in millions):

	Nine Months Ended September 30,	
	2013	2012
Cash (used in) provided by continuing operations:		
Operating activities	\$ (157.2)	\$ (78.5)
Investing activities	(0.0)	(1.7)
Financing activities	122.9	178.7
(Decrease) increase in cash and cash equivalents	\$ (34.3)	\$ 98.5

On December 6, 2012 we entered into a financing agreement with BioPharma. Under this agreement, we granted to BioPharma a security interest in future receivables and all related rights to Vascepa, in exchange for \$100 million received at the closing of the agreement which closing occurred in December 2012. We have agreed to repay BioPharma up to \$150 million of future revenue and receivables. The first repayment under the agreement is a repayment of \$0.8 million of interest due to BioPharma in November 2013, reflective of the option reduction described below. Additional quarterly repayments are due thereafter in accordance with the following schedule: \$2.5 million of interest in the first quarter of 2014; \$8.0 million per quarter in each of the next four quarters, \$10.0 million per quarter in each of the next four quarters, \$15.0 million per quarter in each of the next four quarters and a final payment of \$13.0 million due in May 2017. The quarterly repayments through the third quarter of September 2014 represent interest only. Quarterly payments do not begin to reduce the principal balance until the fourth quarter of 2014. For the three months ended September 30, 2013, revenues were below the contractual threshold amount such that a cash payment of \$0.8 million is due in November 2013 reflecting the calculated optional reduction amount as opposed to the contractual threshold payment of \$2.5 million. In accordance with the agreement with BioPharma, quarterly differences between the calculated optional reduction amounts and the repayment schedule amounts are rescheduled for payment beginning in the second quarter of 2017. Any such deferred payments will remain subject to continued application of the quarterly ceiling in amounts due established by the calculated threshold based on quarterly Vascepa revenues. Additionally, the revised assumptions yielded a decrease in the calculated effective interest rate resulting in a decrease in interest expense during the three months ended September 30, 2013 as compared to the three months ended June 30, 2013 and March 31, 2013. Except upon a change of control in Amarin, the agreement does not expire until \$150 million has been repaid. Under the agreement, upon a change of control, we would be required to pay \$140 million, less any previously repaid amount, if the change of control occurs on or before December 31, 2013, or required to repay \$150 million, less any previously repaid amount, if the change of control event occurs after December 31, 2013. We can prepay after October 1, 2013, an amount equal to \$150 million less any previously repaid amount. We currently estimate that Vascepa

revenue levels will not be high enough in each quarter to support repayment to BioPharma in accordance with threshold amounts in the repayment schedule.

**Table of Contents**

On January 9, 2012, Amarin, through our wholly-owned subsidiary Corsicanto Limited, or Corsicanto, 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 proceeds we received 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, us as guarantor, and Wells Fargo Bank, National Association, as trustee. The notes are the senior unsecured obligations of Corsicanto and are guaranteed by us. 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 our 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 our election, subject to certain conditions, in cash, ADSs or a combination of cash and ADSs.

As of September 30, 2013, we had cash and cash equivalents of \$225.9 million, a decrease of \$34.3 million from December 31, 2012. The decrease is primarily due to net cash used in operating activities in support of the commercial launch of Vascepa, net of proceeds from financing activities. We have incurred annual operating losses since our inception and, as a result, had an accumulated deficit of \$898.5 million as of September 30, 2013. We believe that our cash and cash equivalents balance of \$225.9 million at September 30, 2013 will be sufficient to fund our projected operations for at least the next twelve months. We estimate that our operating activities in the fourth quarter of 2013 will result in a net use of cash no more than reported for the third quarter of 2013. We also estimate that during 2014 our operating activities will result in a net use of cash of not more than \$80 million.

**Contractual Obligations**

The following table summarizes our contractual obligations at September 30, 2013 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	2013	2014 to 2015	2016 to 2017	After 2017
Contractual Obligations:					
Purchase obligations (1)	\$	\$	\$	\$	\$
Operating lease obligations (2)	3.3	0.2	1.6	1.4	0.1
Interest payment obligations exchangeable debt (3)	2.6		2.6		
Principal & Interest payment obligations BioPharma (4)	150.0	0.8	64.5	84.7	
Total contractual cash obligations	\$ 155.9	\$ 1.0	\$ 68.7	\$ 86.1	\$ 0.1

- (1) We have agreements with API suppliers which include minimum annual purchase levels to enable Amarin to maintain exclusivity with each respective supplier, and to prevent potential termination of the agreements based on our estimated minimum purchase requirements. Except under our API agreement with Slanmhor, we are not obligated to pay in cash any shortfall in the minimum purchase obligations pursuant to its supply agreements.
- (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.
- (4) Represents principal and interest payments that we anticipate paying under the terms of the agreement entered into with BioPharma. Under this agreement, we granted to BioPharma a security interest in future receivables and all rights to Vascepa, in exchange for \$100 million received at the closing of the agreement which closing occurred in December 2012. We have agreed to repay BioPharma up to \$150

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

million of future revenue and receivables. The first repayment under the agreement is a payment of \$0.8 million of interest due to BioPharma in November 2013, which is reflective of the option reduction described below. Additional quarterly repayments are due thereafter in accordance with the following schedule: \$2.5 million of interest in the first quarter of 2014; \$8.0 million per quarter in each of the next four quarters, \$10.0 million per quarter in each of the next four

**Table of Contents**

quarters, \$15.0 million per quarter in each of the next four quarters and a final payment of \$13.0 million due in May 2017. The quarterly repayments through the third quarter of September 2014 represent interest only. Quarterly payments do not begin to reduce the principal balance until the fourth quarter of 2014. In accordance with the agreement with BioPharma, quarterly differences between the calculated optional reduction amounts and the repayment schedule amounts are rescheduled for payment beginning in the second quarter of 2017 subject at that time to continued application of the quarterly ceiling in amounts due established by the calculated threshold based on quarterly Vascepa revenues. In 2014 and beyond, the table above reflects payment in full of the scheduled quarterly amounts without such potential elected reductions.

We do not enter into financial instruments for trading or speculative purposes. At September 30, 2013, we had one outstanding forward exchange contract with a notional amount of \$4.5 million to hedge payments made in foreign currency for API supply. As of September 30, 2013 we recorded an unrealized loss of \$0.4 million for one outstanding foreign exchange contract.

The above table also does not reflect potential material purchases under our API supply agreements with the consortium led by Slanmhor Pharmaceuticals. In April 2013, we announced the approval by the FDA of the sNDAs covering two of our API suppliers, Chemport, Inc. and BASF (formerly Equateq Limited). These commercial supply agreements provide access to additional API supply that is incremental to supply from Nissin, our other existing FDA-approved API supplier. Each of these additional 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 us. 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 us to maintain supply exclusivity with each respective supplier, and to prevent potential termination of the agreements and because the agreements with Chemport and BASF do not require any shortfall in the minimum purchase commitments to be paid in cash, have been excluded from the table above. The sNDA for the consortium led by Slanmhor, our intended fourth API supplier, is not yet approved, and as such any minimum purchase commitments that could result in a future cash obligation have also been excluded from the above table. The two supply agreements entered into in 2011 with BASF and Chemport 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. Under these agreements, during the nine months ended September 30, 2013 we purchased approximately \$20.4 million of Vascepa API.

The agreement with Slanmhor 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. The \$15.0 million commitment fee is contingent upon the mutually agreed upon expansion of Slanmhor's API manufacturing capacity. Under this agreement, during the nine months ended September 30, 2013 we made payments of \$6.1 million to Slanmhor related to stability and technical batches and advances on future API purchases.

Under the 2004 share repurchase agreement with Laxdale Limited, or Laxdale, upon approval of Vascepa by the FDA on July 26, 2012, we were required to make a milestone payment to Laxdale of £7.5 million. We made this payment in 2012 and capitalized this Laxdale milestone payment of \$11.6 million as a component of other long term assets. This long-term asset is being amortized over the estimated useful life of the intellectual property we acquired from Laxdale and we recognized amortization expense of \$0.5 million during the nine months ended September 30, 2013. Also under the Laxdale agreement, upon receipt of marketing approval in Europe for the first indication for Vascepa (or first indication of any product containing Amarin Neuroscience intellectual property acquired from Laxdale in 2004), we must make an aggregate stock or cash payment to the former shareholders of Laxdale (at the sole option of each of the sellers) of £7.5 million (approximately \$12.1 million at September 30, 2013). Also under the Laxdale agreement, 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), 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, 2013) for each of the two potential market approvals (i.e. £10 million maximum, or approximately \$16.1 million at September 30, 2013).

In addition to the obligations in the table above, we have recorded a liability of approximately \$0.8 million for uncertain tax positions that is classified in long-term liabilities at September 30, 2013. We are not able to reasonably estimate in which future periods these amounts will ultimately be settled.

**Off-Balance Sheet Arrangements**

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

**Shelf Registration Statement**

On March 29, 2011, we filed with the Securities and Exchange Commission 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

## **Table of Contents**

Depository 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***

There have been no material changes with respect to the information appearing in PART II, Item 7A Quantitative and Qualitative Disclosures about Market Risk of our Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 28, 2013.

### **Item 4. *Controls and Procedures***

#### **Evaluation of Disclosure Controls and Procedures**

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

As of September 30, 2013, our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities and Exchange Act of 1934). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer have concluded based upon the evaluation described above that, as of September 30, 2013, our disclosure controls and procedures were effective at the reasonable assurance level.

#### **Changes in Internal Control over Financial Reporting**

During the quarter ended September 30, 2013, there have been no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15(d)-15(f) promulgated under the Securities Exchange Act of 1934, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.



**Table of Contents****PART II****Item 1. Legal Proceedings**

On November 1, 2013, a purported investor of Amarin filed a putative class action lawsuit against Amarin and our Chief Executive Officer in the U.S. District Court for the District of New Jersey, Steven Sklar v. Amarin Corporation plc and Joseph S. Zakrzewski, No. 13-cv-6954 (D.N.J. Nov. 1, 2013). The lawsuit alleges that, during the period July 9, 2009 through October 15, 2013, we misled investors regarding the FDA's willingness to approve Vascepa's ANCHOR indication and the potential relevance of data from the ongoing REDUCE-IT trial to that approval, thereby artificially inflating the price of our securities. Based on these allegations, the suit asserts claims under the Securities Exchange Act of 1934 and seeks unspecified monetary damages and attorneys' fees and costs. We believe that we have valid defenses and we will vigorously defend against the claims.

On November 5, 2013, a purported investor of Amarin filed a putative class action lawsuit against Amarin and certain of our officers in the U.S. District Court for the Southern District of New York, Joseph A. Bove and Joseph J. Bove v. Amarin Corporation, PLC., Joseph S. Zakrzewski, John F. Thero, and Steven B. Ketchum, No. 13-CIV-7882 (S.D.N.Y. Nov. 5, 2013). The lawsuit alleges, similar to the *Sklar* case, that, during the period August 8, 2012 until October 16, 2013, we misled investors regarding the FDA's willingness to approve Vascepa's ANCHOR indication and the potential relevance of data from the ongoing REDUCE-IT trial to that approval, thereby artificially inflating the price of our securities. Based on these allegations, the suit asserts claims under the Securities Exchange Act of 1934 and seeks unspecified monetary damages and attorneys' fees and costs. We believe that we have valid defenses and we will vigorously defend against the claims.

In addition to the above, in the ordinary course of business, we are from time to time involved in lawsuits, claims, investigations, proceedings, and threats of litigation relating to intellectual property, commercial arrangements and other matters. While the outcome of these proceedings and claims cannot be predicted with certainty, as of September 30, 2013, 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 proceedings 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, our ability to successfully commercially launch Vascepa, the progress and timing of our clinical programs, the safety and efficacy of our product candidates, risks associated with regulatory filings, risks associated with determinations made by regulatory agencies, the potential clinical benefits and market potential of our 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 Securities and Exchange Commission on February 28, 2013.*

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

***\*Our ability to generate increased revenue over the next few years depends, in part, on FDA approval for the use of Vascepa in the ANCHOR indication in the United States and we may be delayed in obtaining, or never obtain, such approval. In October 2013 an advisory committee convened by the FDA voted 9 to 2 against recommending approval of Vascepa in the ANCHOR indication, as a result of which there is a significant risk that FDA will not approve Vascepa for this indication.***

While we are currently marketing Vascepa for use in the MARINE indication in the United States, our ability to commercialize Vascepa in the ANCHOR indication in the United States or market Vascepa for either indication outside of the United States is dependent upon receiving additional regulatory approvals. In April 2013, the FDA accepted our Supplemental New Drug Application, or sNDA, which seeks approval for the use of Vascepa in patients with high triglyceride levels (TG  $\geq$ 200 mg/dL and <500 mg/dL) who are also on statin therapy for elevated LDL-C levels, which we refer to as the ANCHOR indication, and the FDA has assigned the sNDA a Prescription Drug User Fee Act, or PDUFA, date of December 20, 2013 for the completion of its review. The PDUFA date is the goal date for the FDA to complete its review of the sNDA. The FDA may complete its review of the sNDA earlier than this date and there can be no assurance that the FDA will complete its

review by this date.

On June 18, 2013, the FDA informed us that it planned to convene an advisory committee meeting on October 16, 2013 to review the sNDA for the ANCHOR indication. On October 11, 2013, the FDA posted on its website executive summary briefing documents from both the FDA and Amarin for the advisory committee consideration. Included in these materials was the voting question posed to the advisory committee, which was stated in its entirety as follows: Taking into account the described efficacy and safety data for Vascepa, do you believe that its effects on the described lipid/lipoprotein parameters are sufficient to grant approval for co-administration with statin therapy for the treatment of patients with mixed dyslipidemia and CHD or CHD risk equivalent prior to the completion of REDUCE-IT? On October 16, 2013, the advisory committee voted 9 to 2 against recommending approval of Vascepa, based on the question posed to the advisory committee by the FDA.

During the advisory committee meeting, based in part on the briefing materials prepared by the FDA for the meeting, the advisory committee reviewed the safety and efficacy data observed in the ANCHOR trial. This included a discussion regarding observed nominally statistically significant changes from baseline in an adverse direction, while on background statin therapy, in certain lipid parameters, including TGs, in the placebo group, raising the possibility that the mineral oil placebo used in the ANCHOR trial (and in the REDUCE-IT trial) was not biologically inert and might be viewed as artificially exaggerating the clinical effect of Vascepa when measured against placebo in the ANCHOR trial. Because no strong evidence for biological activity of mineral oil was identified by the FDA in the MARINE trial, ultimately it was concluded that the between-group differences likely provided the most appropriate descriptions of the treatment effect of Vascepa and that whatever factor(s) led to the within-group changes over time in the

---

**Table of Contents**

placebo group were likely randomly distributed to all treatment groups. Thus, FDA approved Vascepa for use in the MARINE indication in July 2012. Following this discussion at the advisory committee meeting, while no formal vote was taken related to the inert nature of the placebo, we believe that the consensus of the advisory committee, although not unanimous, and the FDA was that, based on the information made available to the advisory committee and FDA at the meeting, Vascepa appeared to be safe and effective for the reduction of TGs in patients with mixed dyslipidemia on statin therapy.

However, there was also extensive discussion during the advisory committee meeting regarding the expected clinical benefit of a reduction in TGs in this patient population. That is, whether the clinical data derived from the ANCHOR trial, without more, was a sufficient basis for approval. In particular, the advisory committee and FDA noted the lack of prospective, controlled clinical trial data demonstrating that pharmacological reduction of TGs in patients with mixed dyslipidemia on statin therapy significantly reduces residual cardiovascular risk in these patients. The FDA noted that prior clinical outcomes studies conducted by others, albeit in different patient populations, evaluating different drugs with different mechanisms of action, failed to demonstrate a statistically significant reduction in cardiovascular events following concomitant use of drug therapy in patients on statin therapy. We believe that the negative vote of the advisory committee was principally due to the lack of recent conclusive data in these clinical outcomes studies in favor of the hypothesis that TG reduction will result in reduced cardiovascular risk. The FDA is not bound by the recommendations of the advisory board, but it generally follows such recommendations.

A Special Protocol Assessment, or SPA, agreement is an agreement with the FDA that Phase 3 trial protocol design, clinical endpoints, and planned statistical analyses are acceptable to support regulatory approval. A 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. On October 29, 2013, the FDA notified us that it rescinded the SPA agreement we entered into for the ANCHOR trial protocol because the FDA determined that a substantial scientific issue essential to determining the effectiveness of Vascepa in the studied population was identified after testing began. Specifically, consistent with discussion at the advisory committee meeting, the FDA determined that results from outcome studies of other triglyceride lowering drugs failed to support the hypothesis that a triglyceride-lowering drug significantly reduces the risk for cardiovascular events among the population studied in the ANCHOR trial. Thus, the FDA stated that it no longer considers a change in serum triglyceride levels as sufficient to establish the effectiveness of a drug intended to reduce cardiovascular risk in subjects with serum triglyceride levels below 500 mg/dL. On November 7, 2013, we submitted to the FDA a formal appeal of its decision to rescind the SPA including documents outlining why we believe the SPA was wrongfully rescinded. There can be no assurance that the FDA will agree with our arguments.

Based on the recommendation of the advisory committee and the rescinding of the ANCHOR SPA, we believe there is a significant possibility that the FDA may not approve the ANCHOR sNDA and require, as a condition of any possible approval, additional preclinical studies or clinical trials, including the REDUCE-IT cardiovascular outcomes trial. If we do not receive FDA approval of the ANCHOR indication, we plan to re-evaluate the REDUCE-IT study, including the likelihood of REDUCE-IT providing clinically and commercially useful results, the likelihood of FDA approval for an expanded indication for Vascepa based on these results and whether it is best to continue or discontinue the study. We anticipate that in any such re-evaluation we will seek further feedback from the FDA. The aggregate cost to complete REDUCE-IT is estimated to exceed \$100 million which is a significant financial burden given our current financial position. To the extent the FDA conditions approval of Vascepa for the ANCHOR indication on its review of the data from the REDUCE-IT trial, Vascepa may never be approved for this indication. Any delay in obtaining, or an inability to obtain, marketing approval in this indication would prevent us from growing revenue and achieving profitability and could have a material adverse effect on our operations and financial condition, including our ability to reach profitability.

Even if we obtain additional regulatory approvals for Vascepa, the timing or scope of any approvals may prohibit or reduce our ability to commercialize the product 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 from the FDA in July 2012 for the MARINE indication, may prove to not have the scope or breadth needed for us to successfully commercialize Vascepa or become profitable.

***\*Our SPA for ANCHOR has been rescinded and our SPA for REDUCE-IT is not a guarantee of FDA approval of Vascepa for the proposed REDUCE-IT indication.***

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 with the FDA. In each case, 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. A 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.

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

On October 29, 2013, the FDA notified us that it rescinded the ANCHOR study SPA because the FDA determined that a substantial scientific issue essential to determining the effectiveness of Vascepa in the studied

**Table of Contents**

population was identified after testing began. Specifically, consistent with discussion at the advisory committee meeting, the FDA determined that results from outcome studies of other triglyceride lowering drugs failed to support the hypothesis that a triglyceride-lowering drug significantly reduces the risk for cardiovascular events among the population studied in the ANCHOR trial. Thus, the FDA stated that it no longer considers a change in serum triglyceride levels as sufficient to establish the effectiveness of a drug intended to reduce cardiovascular risk in subjects with serum triglyceride levels below 500 mg/dL.

Thus, even though we have received regulatory approval of Vascepa for the MARINE indication under an SPA, our ANCHOR SPA was rescinded and there is no assurance that the FDA will not rescind our REDUCE-IT SPA. Any delay in obtaining, or an inability to obtain, marketing approval in either the ANCHOR or REDUCE-IT indications would prevent us from growing revenue and could have a material adverse effect on our operations and financial condition, including our ability to reach profitability.

***\*If we do not obtain FDA approval of the ANCHOR indication, we may choose to discontinue our ongoing REDUCE-IT outcome study of Vascepa, which is designed to determine whether Vascepa is effective in reducing major cardiovascular events in a high risk patient population on statin therapy and our development of AMR102, a fixed dose combination of Vascepa and a leading statin product.***

Our ongoing REDUCE-IT cardiovascular outcome study was designed to determine whether Vascepa, when added to statin therapy, would reduce the risk of major cardiovascular events in an at-risk patient population. We expect the ongoing incremental cost of the REDUCE-IT study to us over the next several years will exceed \$100 million as the study currently involves over 450 clinical trial sites in eleven countries. The timing of completion of the REDUCE-IT study is based on the rate of cardiovascular events for patients in the study. If it takes longer for such events to accrue than we expect, the trial could take longer to complete and cost more than we currently expect. AMR102, a fixed dose combination of Vascepa and a leading statin product, is in early stage development with relatively minimal current expense associated with ongoing development, but significant expense associated with development over the next several years. We have not been profitable in any of the last five fiscal years. Our cash and cash equivalents at September 30, 2013 was \$225.9 million. For the fiscal year ended December 31, 2012, we reported a loss of approximately \$179.2 million. For the nine months ended September 30, 2013, we reported a loss of approximately \$150.8 million and we had an accumulated deficit at September 30, 2013 of \$898.5 million. For the nine months ended September 30, 2013, net revenue from the sale of Vascepa based on the MARINE indication was \$16.2 million. Given the substantial ongoing cost of the REDUCE-IT cardiovascular outcome study, our current capital resources and the current sales of Vascepa resulting from FDA approval of Vascepa for use in the MARINE indication, we may not be able to continue the study with our current financial resources and anticipated revenues from Vascepa without the additional revenues that may be available to us from the sale of Vascepa following an FDA approval of the ANCHOR indication. If we do not receive FDA approval of the ANCHOR indication, we plan to re-evaluate the REDUCE-IT study, including the likelihood of REDUCE-IT providing clinically and commercially useful results, the likelihood of FDA approval for an expanded indication for Vascepa based on these results and whether it is advisable to continue or discontinue the study. We anticipate that in any such re-evaluation we will seek further feedback from the FDA. If we do not receive FDA approval of the ANCHOR indication and do not continue the ongoing REDUCE-IT trial or our development of AMR102, our ability to generate revenue now and over the next several years will be substantially dependent on sales of Vascepa resulting from FDA approval of Vascepa for use in the MARINE indication. Accordingly, our prospects for substantially increasing future revenue from sales of Vascepa beyond what might be expected from the MARINE indication labeling alone will be substantially diminished.

***We are dependent upon the success of Vascepa, which we launched commercially in the MARINE indication in January 2013.***

As a result of our reliance on a single product and our primary focus on the U.S. market in the near-term, much of our near-term results and value as a company depends on our ability to execute our commercial strategy for Vascepa in the United States, which we only recently launched in January 2013. If commercialization efforts for Vascepa in the MARINE indication or, if approved, the ANCHOR indication, are not successful, 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 or do so in a timely manner without suffering material adverse effects on our business. As a result, the lack of alternative products we develop could constrain our ability to generate revenues and achieve profitability.

---

## Table of Contents

*\*We launched Vascepa in the MARINE indication in the United States in January 2013 with our own, newly established sales and marketing teams and distribution channels and we may not be successful. Historical results may not be consistent with or predictive of future results.*

In late January 2013, we began selling and marketing Vascepa in the United States through our own, newly established sales and marketing teams and through a newly established third-party commercial distribution infrastructure. We hired key personnel in these areas over the last several years and hired and trained a professional sales force in early January 2013. On October 22, 2013, following an FDA advisory committee recommendation against approval for the ANCHOR indication, we announced a plan to reduce our workforce and our team of sales professionals in half. The commercial launch of a new pharmaceutical product is a complex undertaking for a company to manage, and we have very limited experience as a company operating in this area. Factors related to building and managing our own sales and marketing organization that can inhibit our efforts to successfully commercialize Vascepa on our own include:

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

our inability to adequately train our sales and marketing personnel, in particular as it relates to various healthcare regulatory requirements applicable to the marketing and sale of pharmaceutical products, and our inability to adequately monitor compliance with these requirements;

the inability of our new sales personnel, working for us as a new market entrant, to obtain access to or persuade adequate numbers of physicians to prescribe Vascepa;

the effect of our recent reduction in force on our ability to contact potential purchasers of Vascepa in an efficient manner;

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 operating a new independent sales and marketing organization.

In addition, we believe that investors should view with caution both the results for the nine months ended September 30, 2013, as data for this limited period may not be representative of a trend consistent with the results presented or otherwise predictive of future results, especially in light of the recent negative advisory committee vote and the approximately 50% reduction in our sales force. We commenced our commercial launch of Vascepa on January 28, 2013. Accordingly, there is a very limited amount of information available at this time to determine the actual number of total prescriptions for Vascepa. We believe investors should consider our results for the nine months ended September 30, 2013 together with results over several future quarters, or longer, before making an assessment about potential future performance.

In addition to the factors identified above, seasonal fluctuations in pharmaceutical sales, for example, may affect future prescription trends of Vascepa. Moreover, in accordance with our revenue recognition policy and U.S. Generally Accepted Account Principles, or GAAP, until we have more experience with the commercialization of Vascepa and can reasonably estimate any product returns, we plan to recognize revenue based on the resale of Vascepa for the purposes of filling prescriptions, and not based on sales from us to such distributors. Accordingly, because of our limited selling history, during the nine months ended September 30, 2013, we only recognized revenue on product that we could substantiate being resold by retailers, such as pharmacies, for purposes of filling prescriptions. These prescription data may differ from the data reported by third parties. The value of product shipped to distributors but not resold by the distributors to retailers has been deferred until we have evidence that the product was resold by retailers or until we gain sufficient history with our customers to be able to estimate product returns. This is the case even where invoices for such shipments have been collected in full. From launch through September 30, 2013, the Company had experienced a de minimus quantity of product returns.

We have to compete with other pharmaceutical and life sciences companies to recruit, hire, train and retain sales and marketing personnel, and turnover in our sales force and marketing personnel following our recent approximately 50% worldwide reduction in force could negatively affect sales of Vascepa. If we are not successful in our efforts to market and sell Vascepa on our own, market acceptance of Vascepa may be

harmed, our anticipated revenues will be materially and negatively affected, and we may need additional funding or seek a strategic licensing or co-promotion transaction as a means of raising additional funds.

***\*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.***

We only recently began marketing and selling Vascepa for use in the MARINE indication in January 2013. Vascepa may 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:

the perceived efficacy, safety and potential advantages of Vascepa, as compared to alternative treatments;

---

**Table of Contents**

our ability to offer Vascepa for sale at competitive prices;

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 scope, effectiveness and strength of product education, marketing and distribution support, including our sales and marketing team (which was affected by our recent reduction in force);

publicity concerning Vascepa or competing products;

sufficient third-party coverage or reimbursement; and

the actual efficacy of the product and the prevalence and severity of any side effects, including any limitations or warnings contained in Vascepa's approved labeling.

*\*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, and greater 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 and also generic versions of these products. 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 AbbVie, Inc., which currently markets Tricor and Trilipix for the treatment of severe hypertriglyceridemia and mixed dyslipidemia and Niaspan, which is primarily used to raise HDL-C, but is also used to lower triglycerides. In March 2011, Pronova BioPharma Norge AS, now owned by BASF, 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/BASF 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. In addition, in April 2009, Pronova/BASF filed a patent infringement lawsuit in Delaware against Teva Pharmaceuticals USA Inc and Par Pharmaceutical Inc, to prevent them from bringing out a generic version of Lovaza. In September 2013, U.S. Court of Appeals for the Federal Circuit ruled that one of these patents was invalid. Pronova/BASF appealed this decision in October 2013. Because the other patent has expired, this decision could potentially clear the way for third parties to market a generic version of the product. 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 and marketed, would compete with Vascepa. These include a free fatty acid form of omega-3 (comprised of 55% EPA and 20% DHA) developed by Omthera Pharmaceuticals, which in April 2012 announced its top-line Phase 3 clinical trial results. In July 2013, Omthera Pharmaceuticals announced the submission of an



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

NDA to the U.S. Food and Drug Administration, or FDA, seeking approval of its drug candidate for the treatment of severe hypertriglyceridemia. Later in July 2013, AstraZeneca PLC acquired Omthera Pharmaceuticals. We expect AstraZeneca will utilize its substantial commercial resources to seek to market Omthera Pharmaceuticals product, if approved. We also understand that another company, Trygg Pharma AS, has completed a Phase 3 study of an omega-3 based drug candidate for severe hypertriglyceridemia, but we believe Trygg has not yet announced results from that study. It is possible that Trygg Pharma has filed for FDA approval of its product candidate. In addition, Acasti Pharma, a subsidiary of Neptune Technologies & Bioresources Inc., announced in late 2012 that it intends to conduct a Phase 3 clinical program to assess the safety and efficacy of its omega-3 prescription drug candidate derived from krill oil for the treatment of hypertriglyceridemia. We believe

**Table of Contents**

Resolvyx 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 Matinas BioPharma, Inc. is developing an omega-3-based therapeutic for the treatment of severe hypertriglyceridemia and mixed dyslipidemia. Matinas BioPharma, Inc. has reported that it is preparing to file an Investigational New Drug Application with the FDA and conduct a human study in 2013. Isis Pharmaceuticals recently announced favorable Phase 2 results of ISIS-APOCIII<sub>Rx</sub>, a drug candidate administered through weekly subcutaneous injections, in patients with high triglycerides and type 2 diabetes. Isis is also evaluating ISIS-APOCIII<sub>Rx</sub> in a separate Phase 2 study in patients with moderate to severe high triglycerides and has announced plans to report data from this study in the summer of 2013.

***\*Competitors may seek approval of generic versions of Vascepa.***

In April 2013, the FDA published draft guidance for companies that may seek to develop generic versions of Vascepa. If an application for a generic version of Vascepa were filed and if new chemical entity, or NCE, exclusivity is not granted to Vascepa, the FDA may accept the filing for review and we would likely engage in costly litigation with the applicant to protect our patent rights. If the generic filer is ultimately successful in patent litigation against us, meets the requirements for a generic version of Vascepa to the satisfaction of the FDA (after any applicable regulatory exclusivity period and, typically, the litigation-related 30-month stay period expires), and is able to supply the product in significant commercial quantities, the generic company could, with the market introduction of a generic version of Vascepa, limit our U.S. sales, which would have an adverse impact on our business and results of operations. In addition, even if a competitor's effort to introduce a generic product is ultimately unsuccessful, the perception that such development is in progress and/or news related to such progress could materially affect the perceived value of our company and its stock price.

***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.***

Our only current product, Vascepa, is a prescription-only omega-3 fatty acid. Mixtures of omega-3 fatty acids are naturally occurring substances contained 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 due to reduced market acceptance.

***If we are not successful marketing and selling Vascepa on our own, we may need to find collaborative partners to help market and sell the product.***

If we are not successful marketing and selling Vascepa on our own, we may need to find collaborative partners to help market and sell the product or otherwise outsource these functions to third parties. Until such time as we choose to, and actually do, complete a strategic transaction with a third party to market and sell Vascepa, if ever, we will continue to market and sell Vascepa on our own. We are actively exploring collaboration opportunities for the continued marketing and sale of Vascepa as we approach the potential approval of Vascepa in the ANCHOR indication, assuming its regulatory approval.

We may choose not to enter into a collaboration to help market and sell Vascepa or, if we determine such a collaborative partner is necessary we may not be successful in finding a collaborative partner, or may be delayed in doing so. 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. 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 that were to occur, depending on Vascepa revenues, we may have to curtail the continued development of Vascepa for approval for additional indications 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, depending on Vascepa's revenues, we may need to obtain additional capital, which may not be available to us on acceptable terms, or at all, or which may not be possible due to our other financing arrangements, including our Purchase and Sale Agreement with BioPharma Secured Debt Fund II Holdings Cayman, L.P., or BioPharma. If we do not generate sufficient funds from the sale of Vascepa or, to the extent needed to supplement funds generated from product revenue, cannot raise sufficient funds, we may not be able to devote resources sufficient to market and sell Vascepa on our own in a manner required to realize the full market potential of Vascepa.

**Table of Contents**

*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 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 including direct-to-consumer advertising and promotional activities involving the Internet, 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. Industry-sponsored scientific and educational activities also must comply with FDA and other requirements. 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 also are subject to the new federal transparency requirements under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, which require manufacturers of certain drugs, devices, biologics, and medical supplies to report to the Centers for Medicare & Medicaid Services, or CMS, information related to payments and other transfers of value to physicians and teaching hospitals and physician ownership and investment interests. 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 commercial value of Vascepa may be negatively affected by the advisory committee recommendation against approval of Vascepa in the ANCHOR indication or any subsequent rejection of the pending FDA application with the FDA for the use of Vascepa in the ANCHOR indication.*

Though we are restricted from promoting Vascepa under applicable law for any indication other than the FDA-approved MARINE indication, healthcare professionals are not restricted from prescribing Vascepa for such so-called off-labeled uses. A significant amount of the sales of Vascepa may, in fact, be attributable to so-called off-labeled uses of the drug. We expect that among the off-labeled uses of Vascepa are uses that would fall into, or be closely related to, the proposed ANCHOR indication. The recent negative recommendation of the advisory committee meeting against approval of Vascepa in the ANCHOR indication, the recent rescission by the FDA of the ANCHOR SPA, and/or a subsequent decision by the FDA to not approve Vascepa in the ANCHOR indication may negatively and materially affect the perception of the utility of Vascepa for use in the ANCHOR indication or for other purposes and thus negatively and materially affect sales of Vascepa.

---

## **Table of Contents**

***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 received FDA marketing approval for Vascepa for the MARINE indication, physicians may still prescribe Vascepa to their patients for use in the treatment of conditions that are not included as part of the indication statement in our FDA-approved Vascepa 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.

In addition, incentives exist under applicable laws that encourage competitors, 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. These incentives could also lead to suits that we have mischaracterized a competitor's product in the marketplace and may, as a result, be sued for alleged damages to our competitors. 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.

***\*The REDUCE-IT cardiovascular outcomes trial may fail to show that Vascepa can reduce major cardiovascular events in an at-risk patient population on statin therapy, and the long-term clinical results of Vascepa may not be consistent with the clinical results we observed in our Phase 3 clinical trial, in which case our sales of Vascepa may then suffer.***

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. The REDUCE-IT study is designed to evaluate the efficacy of Vascepa in reducing major cardiovascular events in an at-risk patient population on statin therapy.

Outcomes studies of certain other lipid-modifying therapies have failed to achieve the endpoints of such studies. For example, in 2010, the results of the ACCORD-Lipid trial were published. This trial studied the effect of adding fenofibrate onto open-label simvastatin therapy on cardiovascular outcomes. The addition of fenofibrate did not show any treatment benefit on cardiovascular outcomes over simvastatin monotherapy in this study. In 2011, the results of the AIM-HIGH trial were published. This trial studied the effect of adding a second lipid-altering agent, extended-release niacin, to simvastatin therapy on cardiovascular outcomes in people at high risk for cardiovascular events. No significant incremental treatment benefit with extended-release niacin was observed. In addition, 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. This 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 these studies may not be directly applicable to the use of Vascepa over time. For instance, the outcomes studies for fenofibrates and niacin were conducted in patient populations in which the majority of patients studied had triglycerides below 200 mg/dL and fenofibrates and niacin are believed to work differently than Vascepa in the body and do not have as favorable a side-effect profile, and 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. In addition, in May 2013, *The New England Journal of Medicine* published the results of an outcome study of 1 gram per day of an omega-3 acid ethyl ester composition. In that study, the composition failed to show a benefit in reducing the rate of death from cardiovascular causes or hospitalization for cardiovascular causes when administered to patients with cardiovascular risk factors under different study conditions than in the REDUCE-IT study. Vascepa is comprised of highly-pure ethyl-EPA, and has been approved by the FDA for use in patients with severe hypertriglyceridemia at a dose of 4 grams per day.

The only other outcomes study involving the use of a highly-pure formulation of ethyl-EPA, called the Japan EPA Lipid Intervention Study (JELIS), suggested that use of a highly-pure formulation of ethyl-EPA in Japan, when used in conjunction with statins, reduced cardiovascular events by 19% compared to the use of statins alone. However, there are several limitations to the JELIS study. First, the patient population was exclusively Japanese, the majority of the participants were women, and at baseline patients had a much higher LDL, limiting its generalizability to the intended target population. Second, a low dose of statins was used. It is unknown whether the positive treatment effects would have persisted if these patients had been optimally treated with statins using contemporary LDL targets in the United States. Third, JELIS was an open-label trial, which could influence patient and



## **Table of Contents**

physician behavior and reporting of symptoms, decisions regarding hospitalization, and referral of events for adjudication. This may be particularly relevant since hospitalizations for unstable angina was a primary contributor of the overall positive result, and is considered a softer endpoint than fatal cardiovascular events.

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 cGMPs for use in clinical trials;

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.



---

## **Table of Contents**

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 establishing an infrastructure for commercializing Vascepa, we may encounter difficulties in managing our growth and expanding our operations successfully.*

We only recently hired and trained a professional sales force of approximately 275 sales representatives and commenced our commercial launch of Vascepa in the MARINE indication in the United States in early January 2013. The process of establishing a commercial infrastructure is difficult, expensive and time-consuming. Our recent worldwide reduction in force, which included the termination of approximately 50% of the then-staffed sales force, will likely make this process more difficult. 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, including the need to identify, recruit, maintain and integrate additional employees. Our future financial performance and our ability to commercialize Vascepa and to compete effectively will depend, in part, on our ability to manage our future growth effectively. To that end, we must be able to manage our development efforts effectively, and hire, train, integrate and retain 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**

*\*If we do not realize the expected benefits from recent worldwide reductions in our workforce and from future cost savings initiatives that we may implement, the value of our company and our assets and the market price of our ADSs could materially decline.*

On October 22, 2013, we announced a plan to reduce our worldwide workforce by approximately 50%. We cannot guarantee that we will be able to realize the cost savings and other anticipated benefits from our recent worldwide reductions in force. If we experience excessive unanticipated inefficiencies or incremental costs in connection with restructuring activities, such as unanticipated inefficiencies caused by reducing headcount, we may be unable to meaningfully realize cost savings and we may incur expenses in excess of what we anticipate. Either of these outcomes could prevent us from meeting our strategic objectives and could adversely affect our results of operations and financial condition.

*\*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.

---

**Table of Contents**

We initially purchased 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 was approved by the FDA as a Vascepa API supplier as part of our FDA marketing approval for the MARINE indication in July 2012. In April 2013, we announced the approval by the FDA of Chemport, Inc. and BASF (formerly Equateq Limited) as additional Vascepa API suppliers. We now plan to use and purchase additional commercial supply from Chemport and BASF in addition to Nisshin. Each of the API manufacturers obtains supply of the key raw material to manufacture API from other third party sources of supply.

While we have contractual freedom to source the API for Vascepa and have entered into supply agreements with multiple suppliers who also rely on other third party suppliers of the key raw material to manufacture the API for Vascepa, Nisshin currently supplies a large majority of our API for Vascepa. Our strategy in adding API suppliers beyond Nisshin has been to expand manufacturing capacity and to partially mitigate the risk of reliance on one supplier. Both Chemport and BASF continue to expand their API manufacturing capacity and bring to three the number of qualified worldwide suppliers of API for Vascepa.

Also, in December 2012 we announced the addition of an exclusive consortium of companies led by Slanmhor Pharmaceutical, Inc., or Slanmhor, to our planned API global supply chain for Vascepa. Slanmhor was spun-out from Ocean Nutrition Canada, or ONC, prior to the May 2012 acquisition of ONC by Royal DSM N.V., a global leader in life sciences and materials sciences. Amarin now has a total of four suppliers for Vascepa API to utilize in supporting the global commercialization of Vascepa, subject to appropriate regulatory approval of Slanmhor. We intend to submit an additional sNDA for Slanmhor after it successfully completes the qualification process.

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 was approved as one of our API supplier in April 2013, is a privately-held company and their commitment to Vascepa supply has required them to seek additional resources. 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, Chemport and BASF. 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.

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 may not be able to maintain our exclusivity with our third-party Vascepa suppliers if we do not meet minimum purchase obligations due to lower than anticipated sales of Vascepa.***

Our agreements with our suppliers include minimum purchase obligations and limited exclusivity provisions based on such minimum purchase obligations. If we do not meet the respective minimum purchase obligations in our supply agreements, our suppliers will be free to sell the active pharmaceutical ingredient of Vascepa to potential generic competitors of Vascepa. While we anticipate that potential FDA regulatory exclusivity and intellectual property barriers to entry will be the primary means to protect the commercial potential of Vascepa, the availability of Vascepa active pharmaceutical ingredient from our suppliers to our potential competitors would make our competitors' entry into the market easier and more attractive.

***We do not have sufficient experience with the commercial sale of Vascepa, and such inexperience may cause us to 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 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



---

**Table of Contents**

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, or cGMPs, and comparable requirements of foreign regulatory bodies. There are a limited number of manufacturers that operate under these cGMPs 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, Nisshin 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, Chemport and BASF, or other potential API suppliers, we may be delayed in successfully supplying the product to meet anticipated demand 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 cGMPs, 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 have plans to file a supplemental NDA to add Slanmhor as an additional API supplier for Vascepa. If Slanmhor cannot establish, to the satisfaction of the FDA, that it is in substantial compliance with cGMPs, and that the product manufactured at its site meets 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 if such supply cannot be satisfied by our other three API suppliers.

Furthermore, the FDA and foreign regulatory agencies require that we be able to consistently produce the API 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. 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 commercial supply of Vascepa 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.

***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 trials. 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.

## Table of Contents

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

*\*We are dependent on patents, proprietary rights and confidentiality to protect the commercial potential of Vascepa.*

Because of the significant time and expense involved in developing new products and obtaining regulatory approvals, it is very important to obtain patent and preserve 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.

As of October 31, 2013, we had 37 patent applications in the United States that have been either issued or allowed and more than 30 additional patent applications are pending in the United States. Of such 37 allowed and issued applications, we currently have:

2 issued U.S. patents directed to a pharmaceutical composition of Vascepa in a capsule that have terms that expire in 2020 and 2030, respectively,

1 issued U.S. patent covering a composition containing highly pure EPA that expires in 2021,

24 U.S. patents covering the use of Vascepa in either the MARINE or anticipated ANCHOR indication that have terms that expire in 2030,

9 additional patent applications for which the United States Patent and Trademark Office, or USPTO, has issued a Notice of Allowance each of which with terms that expire in 2030 and are related to the use of Vascepa in either the MARINE or anticipated ANCHOR indication, and

1 additional patent application for which the USPTO has issued a Notice of Allowance with a term that expires in 2030 related to the use of a pharmaceutical composition comprised of free fatty acids to treat the ANCHOR patient population.

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. In October 2013, we submitted additional information to the USPTO related to the October 16, 2013 FDA advisory committee meeting in all pending patent applications that are related to the use of Vascepa for the ANCHOR indication, including five for which we had already received a Notice of Allowance. This information has thus far been considered by the USPTO in one of the cases, resulting in a re-issuance of the Notice of Allowance. No assurance can be given that applications with issued notices of allowance will be issued as patents or that any of our pending patent applications will issue as patents. No assurance can be given that, if and when issued, our patents will prevent competitors from competing with Vascepa.

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

We are also pursuing patent applications related to Vascepa in multiple jurisdictions outside the United States. We may be dependent in some cases upon third party licensors to pursue filing, prosecution and maintenance of patent rights or applications

---

## **Table of Contents**

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 went 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 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.

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, for example, by requesting a reexamination of our patent at the USPTO, or by filing an opposition in a foreign patent office, even if the opposition or challenge has little or no merit. Such proceedings are generally highly technical, expensive, and time consuming, and there can be no assurance that such a challenge would not result in the narrowing or complete revocation of any patent of ours that was so challenged.

***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 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, and 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 sNDA 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. Furthermore, third parties may attempt to submit publications for consideration by the patent office during





---

**Table of Contents**

examination of our patent applications. Providing such additional evidence and publications 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 an 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. 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 have not been told and do not know what determination the FDA will reach regarding the pending exclusivity request for Vascepa or when the FDA will make such determination. Based on our communications with the FDA, we cannot make a reliable prediction as to when the FDA will communicate a determination on the matter. 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.

NCE marketing exclusivity, if granted, would preclude approval during the five-year exclusivity period of certain 505(b)(2) applications or 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. A three-year period of exclusivity is granted under the Hatch-Waxman Amendments for a drug product that contains an active moiety that has been previously approved when the application contains reports of new clinical investigations (other than bioavailability studies) conducted by the sponsor that were essential to approval of the application. Our MARINE trial was a new clinical investigation that was essential to the approval of our new drug application. We are entitled to at least three-year exclusivity even if the FDA determines that the EPA moiety was previously approved in Lovaza because our MARINE clinical investigation was essential for the approval of our new drug product, Vascepa.

Such three-year 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.

## **Table of Contents**

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

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



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

Under current UK legislation, a company incorporated in England and Wales, or which is centrally managed and controlled in the UK, is regarded as resident in the UK for taxation purposes. Under current Irish legislation, a company is regarded as resident for tax purposes in 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 UK and Ireland then the provisions of article 4(3) of the Double Tax Convention between the UK 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. Furthermore, the lessened probability that we will obtain FDA approval for the ANCHOR indication could have an adverse impact on our ability to retain and recruit qualified personnel. In addition, on October 22, 2013, we eliminated approximately fifty percent of our staff positions worldwide as part of a restructuring following the FDA advisory committee's recommendation against the potential Vascepa label expansion. Even though all employees were offered severance pay in exchange for signing a comprehensive release of claims, this restructuring could lead to claims by former employees related to their termination. The restructuring could also have an adverse impact on our ability to retain and recruit qualified personnel. The failure to recruit key scientific, technical and management personnel would be detrimental to our ability to implement our business plan.

**Risks Related to our Financial Position and Capital Requirements*****We have a history of operating losses and anticipate that we will incur continued losses for an indefinite period of time.***

We have not been profitable in any of the last five fiscal years. For the fiscal years ended December 31, 2012, 2011, and 2010, we reported losses of approximately \$179.2 million, \$69.1 million and \$249.6 million, respectively, and we had an accumulated deficit at December 31, 2012 of \$747.6 million. For the nine months ended September 30, 2013 and 2012, we reported losses of approximately \$150.8 million and \$168.6 million, respectively, and we had an accumulated deficit at September 30, 2013 of \$898.5 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. Additionally, as a result of our significant expenses relating to research and development and to commercialization, we expect to continue to incur significant operating losses for an indefinite period, even after we begin to generate revenues from our commercialization of 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. Our historic 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 2014 and the remainder of 2013 in connection with our REDUCE-IT cardiovascular 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.



---

**Table of Contents**

*Although we began generating revenue from Vascepa in January 2013, we may never be profitable.*

Our ability to become profitable depends upon our ability to generate revenue. In January 2013, we began to generate revenue from the marketing of Vascepa for use in the MARINE indication, but we may not be able to generate sufficient revenue to attain profitability. Our ability to generate profits on sales of Vascepa is subject to the market acceptance and commercial success of Vascepa and our ability to manufacture commercial quantities of Vascepa through third parties at acceptable cost levels, and may also depend upon our ability to enter into one or more strategic collaborations to effectively market and sell Vascepa.

Even though Vascepa has been approved by the FDA for marketing in the United States in the MARINE indication, it may not gain market acceptance or achieve commercial success and it may never be approved for the ANCHOR indication or any other indication. In addition, we anticipate continuing to incur 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 historical financial results do not form an accurate basis for assessing our current business.*

As a consequence of the many years developing Vascepa for commercialization and the recent commercial launch of Vascepa in the MARINE indication in the United States, 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 continue 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.

*\*Our operating results are unpredictable and may fluctuate. If our operating results are below the expectations of securities analysts or investors, the trading price of our stock could decline.*

Our operating results are difficult to predict and will likely fluctuate from quarter to quarter and year to year, and Vascepa prescription figures will likely fluctuate from month to month. Due to the recent approval by the FDA of Vascepa and the lack of historical sales data, Vascepa sales will be difficult to predict from period to period and as a result, you should not rely on Vascepa sales results in any period as being indicative of future performance, and sales of Vascepa may be below the expectation of securities analysts or investors in the future. We believe that our quarterly and annual results of operations may be affected by a variety of factors, including:

the level of demand for Vascepa;

the extent to which coverage and reimbursement for Vascepa is available from government and health administration authorities, private health insurers, managed care programs and other third-party payers;

the timing, cost and level of investment in our sales and marketing efforts to support Vascepa sales and the resulting effectiveness of those efforts;

additional developments regarding our intellectual property portfolio and regulatory exclusivity protections, if any;

the results of our sNDA application for the ANCHOR indication and the results of the REDUCE-IT study or post-approval studies for Vascepa;

outcomes of litigation and other legal proceedings, regulatory matters and tax matters;

whether we continue the REDUCE-IT study; and.

the impact of the restructuring of the company implemented on October 22, 2013.



## **Table of Contents**

***\*We may 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. We believe that our cash and cash equivalents balance of \$225.9 million at September 30, 2013 will be sufficient to fund our projected operations for at least the next twelve months.

In order to fully realize the market potential of Vascepa, we may need to enter into a strategic collaboration or raise additional capital. We may also need additional capital to fully complete our REDUCE-IT cardiovascular outcomes trial.

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

revenue generated from the commercial sale of Vascepa in the MARINE indication and, subject to FDA approval, the ANCHOR indication;

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 of sales and marketing capabilities, and 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, and the terms of any such collaboration;

the continued cost associated with our REDUCE-IT cardiovascular outcomes study, if we continue that study;

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; and

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

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

***\*As a result of recent worldwide reductions in our workforce, we are in the process of reallocating certain employment responsibilities and may outsource certain corporate functions. As a result, we may be more dependent on third parties to perform these corporate functions than we have been in the past.***

As a result of the recent worldwide reductions in our workforce, we have been required to outsource certain corporate functions. This has made us more dependent on third-parties for the performance of these functions. Our ongoing results of operations could be adversely affected to the extent that we are unable to effectively reallocate employee responsibilities, retain key employees, maintain effective internal control over financial reporting and effective disclosure controls and procedures, establish and maintain agreements with competent third-party contractors on terms that are acceptable to us, and effectively manage the work performed by any retained third-party contractors.

---

**Table of Contents**

*Continued negative economic conditions would likely have a negative effect 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.

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

To the extent we are permitted under our Purchase and Sale Agreement with BioPharma, 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, 2013, there were warrants outstanding for the purchase of up to 9,816,826 ADSs each representing one of our ordinary shares, with a weighted average exercise price of \$1.44 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 beyond the rights we have already relinquished, 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.

## **Table of Contents**

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 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, 2013 we had 172,664,013 common shares outstanding including 172,195,467 shares held as ADSs and 468,546 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;

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.

#### ***A share price of less than \$1.00 may impact our NASDAQ listing.***

As of the date of this Quarterly Report, our ADSs are currently trading above \$1.00; however, recent market activity has resulted in a decrease in our stock price, and our stock price may fall below the \$1.00 threshold. If our closing bid price is less than \$1.00 for 30 consecutive trading days, we would receive a NASDAQ staff deficiency letter indicating that we are not in compliance with the minimum bid price requirement for continued listing. Such a letter would trigger an automatic 180 calendar day period within which the company could regain compliance. Compliance is regained at any time during this period if the Amarin closing bid price is \$1.00 per share or more for a minimum of 10

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

consecutive trading days. If we do not regain compliance during this period, our ADSs could be delisted from The NASDAQ Global Market, transferred to a listing on The NASDAQ Capital Market, or delisted from the NASDAQ markets altogether. The failure to maintain our listing on The NASDAQ Global Market could harm the liquidity of our ADSs and could have an adverse effect on the market price of our ADSs.

**Table of Contents**

***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 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.

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

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.

We believe it prudent to assume that we were classified as a PFIC in 2012. However, it is possible that, because of the commencement of sales and marketing of Vascepa, we may not be classified as a PFIC in 2013 or in future years, although there can be no assurance in this regard.

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 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.

***Failure to meet our obligations under our Purchase and Sale Agreement with BioPharma could adversely affect our financial results and liquidity.***

Pursuant to our December 2012 Purchase and Sale Agreement with BioPharma, we are obligated to make payments to BioPharma based on the amount of our net product sales of Vascepa and any future products based on ethyl-EPA, or covered products, subject to certain quarterly caps.

Pursuant to this agreement, we may not, among other things: (i) incur indebtedness greater than a specified amount, which we refer to as the Indebtedness Covenant; (ii) pay a dividend or other cash distribution, unless we have cash and cash equivalents in excess of a specified amount after such payment; (iii) amend or restate our memorandum and articles of association unless such amendments or restatements do not affect BioPharma's interests under the transaction; (iv) encumber any of the collateral securing our performance under the agreement; and (v) abandon certain patent rights, in each case without the consent of BioPharma.

Upon a transaction resulting in a change of control of Amarin, as defined in the agreement, BioPharma will be automatically entitled to receive any amounts not previously paid, up to our maximum repayment obligation. As defined in the agreement, change of control includes, among other things, (i) a greater than 50 percent change in the ownership of Amarin, (ii) a sale or disposition of any collateral securing our debt with BioPharma and (iii), unless BioPharma has been paid a certain amount under the indebtedness, the licensing of Vascepa to a third party for sale in the United States. The acceleration of the payment obligation in the event of a change of control transaction may make us less attractive to potential acquirers, and the payment of such funds out of our available cash or acquisition proceeds would reduce acquisition proceeds for our stockholders.

To secure our obligations under the agreement, we granted BioPharma a security interest in our rights in patents, trademarks, trade names, domain names, copyrights, know-how and regulatory approvals related to the covered products, all books and records

---

**Table of Contents**

relating to the foregoing and all proceeds of the foregoing, which we refer to as the collateral. If we (i) fail to deliver a payment when due and do not remedy that failure within specific notice period, (ii) fail to maintain a first-priority perfected security interest in the collateral in the United States and do not remedy that failure after receiving notice of such failure or (iii) become subject to an event of bankruptcy, then BioPharma may attempt to collect the maximum amount payable by us under this agreement (after deducting any payments we have already made).

There can be no assurance that we will not breach the covenants or other terms of, or that an event of default will not occur under, this agreement and, if a breach or event of default occurs, there can be no assurance that we will be able to cure the breach within the time permitted. Any failure to pay our obligations when due, any breach or default of our covenants or other obligations, or any other event that causes an acceleration of payment at a time when we do not have sufficient resources to meet these obligations, could have a material adverse effect on our business, results of operations, financial condition and future viability.

***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



## **Table of Contents**

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.

### ***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.



---

**Table of Contents**

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 (or on a poll shareholders representing 75% of the ordinary shares voting (in person or by proxy)), 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.

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 voting at the meeting and representing 75% of the ordinary shares voting 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.

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.

***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 affect 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.

***U.S. holders of the ADSs or ordinary shares may be subject to U.S. federal 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 5. Other Information**

None

**Item 6. Exhibits**

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

<b>Exhibit Number</b>	<b>Description</b>
31.1	Certification of Chief Executive Officer (Principal Executive Officer) pursuant to Section 302 of Sarbanes-Oxley Act of 2002
31.2	Certification of President (Principal Financial Officer) pursuant to Section 302 of Sarbanes-Oxley Act of 2002
32.1	Certification of Chief Executive Officer (Principal Executive Officer) and President (Principal Financial Officer) pursuant to Section 906 of Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

**Table of Contents**

**SIGNATURE**

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

AMARIN CORPORATION PLC

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

(On behalf of the Registrant)

Date: November 7, 2013