

AMARIN CORP PLC\UK  
Form 10-Q  
November 06, 2014  
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, 2014

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)

**England and Wales**  
(State or Other Jurisdiction of

**Not applicable**  
(I.R.S. Employer

Incorporation or Organization)

Identification No.)

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

**Dublin 2, Ireland**  
(Zip Code)

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

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer  (Do not check if smaller reporting company)

Smaller reporting company

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

174,146,088 shares held as American Depository Shares (ADS), each representing one Ordinary Share, 50 pence par value per share, and 464,363 ordinary shares, were outstanding as of November 1, 2014.

**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, 2014 and December 31, 2013</u>	1
<u>Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2014 and 2013</u>	2
<u>Condensed Consolidated Statement of Changes in Deficit at September 30, 2014</u>	3
<u>Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2014 and 2013</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>	24
Item 3. <u>Quantitative and Qualitative Disclosures about Market Risk</u>	41
Item 4. <u>Controls and Procedures</u>	42
<b><u>PART II Other Information</u></b>	
Item 1. <u>Legal Proceedings</u>	43
Item 1A. <u>Risk Factors</u>	44
Item 6. <u>Exhibits</u>	68
<u>SIGNATURES</u>	69

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

	<b>September 30, 2014</b>	<b>December 31, 2013</b>
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 135,435	\$ 191,514
Restricted cash	600	1,000
Accounts receivable	6,667	3,645
Inventory, current	11,886	21,209
Deferred tax assets	471	471
Other current assets	2,980	1,563
<b>Total current assets</b>	<b>158,039</b>	<b>219,402</b>
Property, plant and equipment, net	424	579
Inventory, long-term		5,482
Deferred tax assets	11,862	11,944
Other non-current assets	4,823	4,360
Intangible asset, net	10,225	10,709
<b>TOTAL ASSETS</b>	<b>\$ 185,373</b>	<b>\$ 252,476</b>
<b>LIABILITIES AND STOCKHOLDERS DEFICIT</b>		
Current Liabilities:		
Accounts payable	\$ 6,059	\$ 6,375
Current portion of long-term debt	13,790	12,974
Warrant derivative liability	121	6,894
Deferred revenue		1,703
Accrued expenses and other current liabilities	15,365	9,594
<b>Total current liabilities</b>	<b>35,335</b>	<b>37,540</b>
Long-Term Liabilities:		
Exchangeable senior notes	120,487	149,317
Long-term debt	89,152	87,717
Long-term debt derivative liabilities	9,000	11,100
Other long-term liabilities	640	658
<b>Total liabilities</b>	<b>254,614</b>	<b>286,332</b>
Commitments and contingencies (Note 7)		
Stockholders' Deficit:		

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

Common stock, £0.50 par, unlimited authorized; 174,610,451 issued, 174,590,372 outstanding at September 30, 2014; 172,691,063 issued, 172,670,984 outstanding at December 31, 2013	143,113	141,477
Additional paid-in capital	738,440	738,754
Treasury stock; 20,079 shares at September 30, 2014 and December 31, 2013	(217)	(217)
Accumulated deficit	(950,577)	(913,870)
 Total stockholders' deficit	 (69,241)	 (33,856)
 <b>TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT</b>	 <b>\$ 185,373</b>	 <b>\$ 252,476</b>

See notes to 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,	
	2014	2013	2014	2013
Product revenues	\$ 14,149	\$ 8,403	\$ 37,722	\$ 16,245
Less: Cost of goods sold	5,366	3,682	14,637	7,813
Gross margin	8,783	4,721	23,085	8,432
Operating expenses:				
Selling, general and administrative	19,270	28,274	60,949	101,502
Research and development	14,457	16,821	37,891	56,148
Total operating expenses	33,727	45,095	98,840	157,650
Operating loss	(24,944)	(40,374)	(75,755)	(149,218)
Gain (loss) on change in fair value of derivative liabilities	4,466	(1,402)	11,870	21,059
Gain on extinguishment of debt			38,034	
Interest expense, net	(4,876)	(8,441)	(13,565)	(26,646)
Other (expense) income, net	(247)	(302)	3,994	(838)
Loss from operations before taxes	(25,601)	(50,519)	(35,422)	(155,643)
(Provision for) benefit from income taxes	(449)	1,635	(1,285)	4,827
Net loss	\$ (26,050)	\$ (48,884)	\$ (36,707)	\$ (150,816)
Loss per share:				
Basic	\$ (0.15)	\$ (0.29)	\$ (0.21)	\$ (0.96)
Diluted	\$ (0.17)	\$ (0.29)	\$ (0.25)	\$ (1.02)
Weighted average shares:				
Basic	174,502	170,187	173,426	157,105
Diluted	175,141	170,187	174,305	163,487

See notes to condensed consolidated financial statements.

**Table of Contents**

## AMARIN CORPORATION PLC

**CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN DEFICIT**

(Unaudited, in thousands, except share amounts)

	Common Shares	Common Stock	Additional Paid- in Capital	Treasury Shares	Accumulated Deficit	Total
<b>At December 31, 2013</b>	<b>172,691,063</b>	<b>\$ 141,477</b>	<b>\$ 738,754</b>	<b>\$ (217)</b>	<b>\$ (913,870)</b>	<b>\$ (33,856)</b>
Exercise of stock options	234,500	193	114			307
Exercise of warrants	1,684,888	1,443	208			1,651
Reacquisition of conversion option in convertible notes			(10,100)			(10,100)
Tax benefits realized from stock-based compensation			1			1
Stock-based compensation			6,272			6,272
Refund of equity issuance costs			3,191			3,191
Loss for the period					(36,707)	(36,707)
<b>At September 30, 2014</b>	<b>174,610,451</b>	<b>\$ 143,113</b>	<b>\$ 738,440</b>	<b>\$ (217)</b>	<b>\$ (950,577)</b>	<b>\$ (69,241)</b>

See notes to condensed consolidated financial statements.

**Table of Contents**

## AMARIN CORPORATION PLC

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

(Unaudited, in thousands)

	Nine months ended September 30,	
	2014	2013
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (36,707)	\$ (150,816)
Adjustments to reconcile loss to net cash used in operating activities:		
Depreciation and amortization	155	179
Stock-based compensation	6,272	14,170
Stock-based compensation warrants	(503)	(1,179)
Excess tax benefit from stock-based awards	(1)	(966)
Current portion of long-term debt	816	8,381
Amortization of debt discount and debt issuance costs	4,039	13,232
Amortization of intangible asset	484	485
Gain on changes in fair value of derivative liabilities	(11,870)	(21,059)
Gain on extinguishment of debt	(38,034)	
Deferred income taxes	82	(6,389)
Shares issued for services		27
Change in lease liability		3
Changes in assets and liabilities:		
Restricted cash	400	(1,400)
Accounts receivable	(3,022)	(3,721)
Inventories	14,805	(5,821)
Other current assets	(1,371)	(283)
Other non-current assets	2,017	(384)
Deferred revenue	(1,703)	
Accounts payable and other current liabilities	5,456	(1,714)
Net cash used in operating activities	(58,685)	(157,255)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchases of equipment		(14)
Net cash used in investing activities		(14)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from issuance of common stock, net of transaction costs		121,206
Refund of equity issuance costs	3,191	
Proceeds from exercise of stock options, net of transaction costs	307	627
Proceeds from exercise of warrants, net of transaction costs	1,651	120
Debt issuance costs	(2,480)	
Excess tax benefit from stock-based awards	1	966
Payments under capital leases	(64)	(7)
Net cash provided by financing activities	2,606	122,912
NET DECREASE IN CASH AND CASH EQUIVALENTS	(56,079)	(34,357)



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

CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	191,514	260,242
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 135,435	\$ 225,885
Supplemental disclosure of cash flow information:		
Cash paid during the year for:		
Interest	\$ 8,622	\$ 5,250
Income taxes	\$ 581	\$ 1,395
Supplemental disclosure of non-cash items:		
Reacquisition of conversion option in convertible notes	\$ 10,100	\$
See notes to condensed consolidated financial statements.		

---

**Table of Contents**

AMARIN CORPORATION PLC

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

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

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

**Nature of Business**

Amarin Corporation plc (Amarin or the Company) is a biopharmaceutical company with expertise in lipid science focused on the commercialization and development of therapeutics to improve cardiovascular health.

The Company's lead product, Vascepa® (icosapent ethyl) capsules, is approved by the U.S. Food and Drug Administration, or FDA, for use as an adjunct to diet to reduce triglyceride levels in adult patients with severe (TG  $\geq$ 500mg/dL) hypertriglyceridemia. Vascepa is available in the United States by prescription only. The Company began selling and marketing Vascepa in the United States in January 2013. 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. The Company markets Vascepa through its sales force of approximately 150 sales professionals, including sales representatives and their managers. In March 2014, the Company entered into a co-promotion agreement with Kowa Pharmaceuticals America, Inc., or Kowa Pharmaceuticals America, under which approximately 250 Kowa Pharmaceuticals America sales representatives began to devote a substantial portion of their time to promoting Vascepa starting in May 2014 in conjunction with the promotion of Kowa Pharmaceutical America's primary product, a branded statin for patients with high cholesterol. The Company operates in one business segment.

The Company is also developing Vascepa for potential additional indications for use. In particular, the Company is conducting a cardiovascular outcomes study of Vascepa, titled REDUCE-IT (Reduction of Cardiovascular Events with EPA Intervention Trial). The REDUCE-IT study, the results of which are currently blinded to the Company, is designed to evaluate the efficacy of Vascepa in reducing major cardiovascular events in a high risk patient population on statin therapy.

**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, or the SEC. Certain information in the footnote disclosures of the financial statements 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, 2013, or the 2013 Form 10-K, filed with the SEC. The balance sheet amounts at December 31, 2013 in this report were derived from the Company's audited 2013 consolidated financial statements included in the 2013 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, or 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, 2014 and September 30, 2013, respectively, are not necessarily indicative of the results for the entire fiscal year or any future period.

The accompanying consolidated financial statements of the Company and subsidiaries have been prepared on a basis which assumes that the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The Company's business operations are focused 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. The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

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

At September 30, 2014, the Company had cash and cash equivalents of \$135.4 million. The Company's consolidated balance sheets also include 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. The outstanding January 2012 exchangeable senior notes, or the 2012 Notes, and May 2014 exchangeable senior notes, or the 2014 Notes, may be redeemed on or after January 19, 2017 and January 19, 2019, respectively, at the option of the holders and it is not puttable by the holders prior to these dates except upon the occurrence of certain contingent

**Table of Contents**

events. The 2012 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. The 2014 Notes are exchangeable under certain circumstances into ADSs. 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 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.

**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 in January 2013. Prior to 2013, the Company recognized no revenue from Vascepa sales. In accordance with GAAP, until the Company had the ability to reliably estimate returns of Vascepa from its Distributors, revenue was 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. Beginning in January 2014, the Company concluded that it had developed sufficient history such that it can reliably estimate returns and as a result, began to recognize revenue based on sales to its Distributors. The change in revenue recognition methodology resulted in the recognition of previously deferred revenue. At December 31, 2013, the Company had deferred approximately \$1.7 million in amounts billed to Distributors that was not recognized as revenue. This change in revenue recognition methodology resulted in the recognition of such deferred revenues in the three months ended March 31, 2014.

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.

*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 while the fees for distribution services are based on contractual rates agreed with the respective Distributors. 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.

**Table of Contents**

**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, 2014, the Company had experienced a de minimis quantity of product returns. The Company estimates future product returns on sales of Vascepa based on: (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 adjusts its accruals for co-pay mitigation rebates based on actual redemption activity and estimates regarding the portion of issued co-pay mitigation rebates that it estimates will 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 was 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 December 31, 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, 2014 and 2013 (in thousands):

	Trade Allowances	Rebates, Chargebacks and Discounts	Product Returns	Other Incentives	Total
<b>Balance at January 1, 2014</b>	\$ 1,071	\$ 1,137	\$ 72	\$ 189	\$ 2,469
Provision related to current period sales	5,514	8,335	270	3,845	17,964
Provision related to prior period sales			12		12
Credits/payments made for current period sales	(4,120)	(5,876)		(3,759)	(13,755)
Credits/payments made for prior period sales	(925)	(911)			(1,836)
<b>Balance at September 30, 2014</b>	\$ 1,540	\$ 2,685	\$ 354	\$ 275	\$ 4,854

**Table of Contents**

	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>

The following table summarizes product revenue recognized and deferred during the nine months ended September 30, 2014 and 2013 (in thousands):

	September 30, 2014	September 30, 2013
Product revenue recognized	\$ 37,722	\$ 16,245
Deferred product revenue		1,617
	<b>\$ 37,722</b>	<b>\$ 17,862</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, 2014 and 2013 (in thousands):

	September 30, 2014	September 30, 2013
Cost of goods sold expensed	\$ 14,637	\$ 7,813
Finished goods inventory held by others		641
	<b>\$ 14,637</b>	<b>\$ 8,454</b>

**Cash and Cash Equivalents**

Cash and cash equivalents consist of cash, deposits 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.

**Accounts Receivable**

Accounts receivable, comprised of trade receivables, are generally due within 30 days and are stated at amounts due from customers. The Company does not currently maintain an allowance for doubtful accounts and has not historically experienced any credit losses.

**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 reduce the carrying value of such inventory to 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. The Company expenses inventory identified for use as marketing samples when they are packaged. The 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 or was purchased prior to the sNDA approval of the Company's suppliers.





**Table of Contents****Property, Plant and Equipment**

The Company states property, plant and equipment at cost and provides for depreciation and amortization using the straight-line method by charges to operations in amounts that depreciate the cost of the fixed asset over its estimated useful life. The estimated useful lives, by asset classification, are as follows:

<b>Asset Classification</b>	<b>Useful Lives</b>
Computer equipment and software	3 - 5 years
Furniture and fixtures	5 years
Leasehold improvements	Lesser of useful life or lease term

Upon retirement or sale of assets, the cost of the assets disposed and the related accumulated depreciation are removed from the balance sheet and any resulting gain or loss is credited or expensed to operations. Repairs and maintenance costs are expensed as incurred.

**Long-Lived Asset Impairment**

The Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Recoverability of these assets is determined by comparing the forecasted undiscounted net cash flows of the operation to which the assets relate to their carrying amount. If impairment is indicated, the assets are written down to fair value. Fair value is determined based on discounted forecasted cash flows or appraised values, depending on the nature of the assets.

**Intangible Asset, net**

Intangible assets consist of a milestone payment paid to the former shareholders of Laxdale Limited related to the 2004 acquisition of the 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 over the estimated useful life and no degradation of the cash flows over time is currently anticipated.

**Deferred Revenue**

Deferred revenue represents product shipments to Distributors for which the Company has invoiced the Distributors but not recognized as revenue because the product was not reported to the Company as having been resold for the purpose of filling prescriptions. Commencing on January 1, 2014, the Company recognizes revenue based on product shipments to its Distributors and as a result, no deferred revenue was recorded as of September 30, 2014.

**Research and Development Costs**

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

**Selling, General and Administrative Costs**

The Company charges selling, 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 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 (income) from non-cash changes in the fair value of a derivative liability associated with warrants issued in October 2009 to former officers of Amarin which is recorded as compensation expense (income).

**Income Taxes**

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

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

**Table of Contents**

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.

The Company regularly assesses the realizability of deferred tax assets. Changes in historical earnings performance and future earnings projections, among other factors, may cause the Company to adjust its valuation allowance on deferred tax assets, which would impact the Company's income tax expense in the period in which it is determined that these factors have changed.

**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 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 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. However, in certain periods in which there is a gain recorded pursuant to the change in fair value of a derivative liability, for diluted earnings per share purposes, the impact of such gains is reversed and the treasury stock method is used to determine diluted earnings per share.

The calculation of net loss and the number of shares used to compute basic and diluted loss per share for the three and nine months ended September 30, 2014 and 2013 are as follows:

<b>In thousands</b>	<b>Three months ended</b>		<b>Nine months ended</b>	
	<b>September 30, 2014</b>	<b>September 30, 2013</b>	<b>September 30, 2014</b>	<b>September 30, 2013</b>
Net loss - basic	\$ (26,050)	\$ (48,884)	\$ (36,707)	\$ (150,816)
Gain on warrant derivative liability	(4,392)		(6,773)	(15,256)
Net loss - diluted	(30,442)	(48,884)	(43,480)	(166,072)
Net loss per share - basic	(0.15)	(0.29)	(0.21)	(0.96)
Weighted average shares outstanding - basic	174,502	170,187	173,426	157,105
Effect of dilutive warrants	639		879	6,382
Weighted average shares outstanding - diluted	175,141	170,187	174,305	163,487
Net loss per share - diluted	(0.17)	(0.29)	(0.25)	(1.02)

**Table of Contents**

For the three and nine months ended September 30, 2014 and 2013, the following potentially dilutive securities were not included in the computation of net loss per share because the effect would be anti-dilutive:

In thousands	Three months ended		Nine months ended	
	September 30, 2014	September 30, 2013	September 30, 2014	September 30, 2013
Stock options	11,246	10,866	11,246	10,866
Restricted stock and restricted stock units	2,262	824	2,262	824
Warrants		9,817		1,702
Exchangeable senior notes (if converted)	49,215	17,021	49,215	17,021

**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 each period in which 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 conversion features in both the 2012 Notes and 2014 Notes qualify for the exception from derivative accounting in accordance with ASC 815-40. The 2012 Notes may be settled, at the Company's discretion, in any combination of ADSs or cash upon conversion and have been accounted for in accordance with ASC 470-20. Under ASC 470-20, the fair value of the liability component of the 2012 Notes was determined and deducted from the initial proceeds to determine the proceeds allocated to the conversion option, which has been recorded in equity. The difference between the initial fair value of the liability component and the amount repayable was amortized over the expected term of the instrument. The conversion feature in the 2014 Notes may only be settled in ADSs upon conversion and has been accounted for as part of the debt host.

The conversion options in both the 2012 Notes and 2014 Notes continue to be evaluated on a quarterly basis to determine if they still receive an exception from derivative accounting in accordance with ASC 815-40. The 2014 Notes were recognized initially at fair value as part of an extinguishment of a portion of the 2012 Notes (see further discussion in Note 6). As a result, the debt was initially recognized at a discount of \$27.9 million. This discount will be amortized through interest expense over the expected term of the note.

**Stock-Based Compensation**

Stock-based compensation cost is generally measured at the grant date, based on the fair value of the award, and is recognized as compensation cost over the requisite service period. Equity awards granted for which the grant date fair value is not determinable are marked to fair value each reporting period over the requisite service period.

**Concentration of Credit Risk**

Financial instruments that potentially subject the Company to credit risk consist primarily of cash and cash equivalents and accounts receivable. The Company maintains substantially all of its cash and cash equivalents in financial institutions believed to be of high-credit quality.

A significant portion of the Company's sales are to wholesalers in the pharmaceutical industry. The Company monitors the creditworthiness of customers to whom it grants credit terms and has not experienced any credit losses. The Company does not require collateral or any other security to support credit sales. The Company's top three customers accounted for 95% and 96% of gross product sales for the nine months ending September 30, 2014 and 2013, respectively and represented 96% and 98% of the gross accounts receivable balance as of September 30, 2014 and September 30, 2013, respectively.

**Foreign Currency**

All subsidiaries use the United States dollar as their 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, 2014 and December 31, 2013, there were no outstanding foreign exchange contracts.

**Table of Contents****Debt Issuance Costs**

Debt issuance costs are initially capitalized as a deferred cost within other non-current assets and amortized to interest expense using the effective interest method over the expected term of the related debt. Unamortized debt issuance costs related to extinguishment of debt are expensed at the time the debt is extinguished and recorded in other (expense) income, net in the consolidated statements of operations.

**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, 2014 and December 31, 2013 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, 2014</b>		
		<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>
<b>Asset:</b>				
Cash equivalents money markets	\$ 65.1	\$ 65.1	\$	\$
<b>Liabilities:</b>				
Warrant derivative liability	\$ 0.1	\$	\$	\$ 0.1
Long-term debt derivative liabilities	\$ 9.0	\$	\$	\$ 9.0

<i>In millions</i>	<b>Total</b>	<b>December 31, 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	\$ 6.9	\$	\$	\$ 6.9
Long-term debt derivative liability	\$ 11.1	\$	\$	\$ 11.1

The carrying amounts of cash, cash equivalents, accounts payable and accrued liabilities approximate fair value because of their short-term nature. The estimated fair value of debt is based on the Level 1 quoted prices for the exchangeable senior notes and based on Level 3 inputs for the remainder of the Company's long-term debt. The carrying amounts and the estimated fair values of debt instruments as of September 30, 2014 and December 31, 2013, are as follows:

<b>In thousands</b>	<b>September 30, 2014</b>		<b>December 31, 2013</b>	
	<b>Carrying Value</b>	<b>Estimated Fair Value</b>	<b>Carrying Value</b>	<b>Estimated Fair Value</b>
Long-term debt December 2012 financing	\$ 89,152	\$ 79,400	\$ 87,717	\$ 75,700
2012 Notes	31,266	24,100	149,317	106,600
2014 Notes	89,221	78,700		

**Table of Contents**

The carrying value of the 2012 Notes at September 30, 2014 and December 31, 2013 includes a debt discount of zero and \$0.7 million, respectively, which is being amortized as non-cash interest expense over the expected term of the 2012 Notes. The carrying value of the 2014 Notes at September 30, 2014 includes a debt discount of \$29.5 million which is being amortized as non-cash interest expense over the expected term of the 2014 Notes. The change in the estimated fair values of these liabilities from December 31, 2013 to September 30, 2014 is largely related to the issuance of the 2014 Notes and the quoted bond prices.

**Warrant Derivative Liability**

At September 30, 2014, the fair value of the warrant derivative liability was determined to be \$0.1 million using the Black-Scholes option valuation model applying the following assumptions: (i) risk-free rate of 0.02%, (ii) remaining term of 0.04 years, (iii) no dividend yield, (iv) volatility of 123% and (v) the stock price on the date of measurement. As of December 31, 2013, the fair value of the warrant derivative liability was determined to be \$6.9 million using the Black-Scholes option valuation model applying the following assumptions: (i) risk-free rate of 0.12%, (ii) remaining term of 0.8 years, (iii) no dividend yield, (iv) volatility of 99% and (v) the stock price on the date of measurement. The \$6.8 million decrease in the fair value of the warrant liability during the nine months ended September 30, 2014 was recognized as: (i) a \$6.3 million gain on change in fair value of the remaining derivative liability and (ii) \$0.5 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, 2014. 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 (\$1.20 based on the \$1.09 market price of the stock at September 30, 2014) on which the September 30, 2014 valuation was based, the value of the derivative liability would have increased by \$0.1 million. Such increase would have been reflected as additional loss on change in fair value of derivative liabilities within the statement of operations. Significant increases (decreases) in this input in isolation would result in a significantly higher (lower) fair value asset measurement.

**Long Term Debt Derivative Liabilities**

The Company's December 2012 financing agreement with BioPharma Secured Debt Fund II Holdings Cayman LP (discussed in Note 6 below) 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 was determined to be the fair value of the embedded derivative. At September 30, 2014, the fair value of the derivative was determined to be \$4.6 million, and the debt was valued by comparing debt issues of similar companies with (i) remaining terms of between 2.5 and 3.9 years, (ii) coupon rates of between 9.8% and 10.8% and (iii) market yields of between 8.9% and 17.2%. The Company recognized a \$6.5 million gain on change in fair value of derivative liability for the nine months ended September 30, 2014. The Company recognized a \$7.4 million gain on change in fair value of derivative liability for the nine months ended September 30, 2013. At December 31, 2013, the fair value of the derivative was determined to be \$11.1 million, and the debt was valued by comparing debt issues of similar companies with (i) remaining terms of between 3.3 and 6.6 years, (ii) coupon rates of between 9.9% and 12.5% and (iii) market yields of between 9.0% and 29.4%.

The Company's 2014 Notes contain a redemption feature whereby, upon occurrence of a change in control, the Company would be required to repurchase the notes. The Company determined this redemption feature to be an embedded derivative, requiring bifurcation in accordance with ASC 815. The derivative 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 of the probability of a change in control occurring, and by determining the fair value of the debt with and without the change in control provision included. The difference between the two was determined to be the fair value of the embedded derivative. At September 30, 2014, the fair value of the derivative was determined to be \$4.4 million, and the debt was valued by using (i) the remaining term of the notes, (ii) a bond yield of 22.6%, (iii) a risk-free interest rate of 3.2% and (iv) volatility of 83.0%. The Company recognized a \$0.9 million loss on change in fair value of derivative liability for the nine months ended September 30, 2014.



**Table of Contents**

The change in the fair value of derivative liabilities is as follows (in thousands):

	October 2009 Warrants	Long-Term Debt Derivative Liabilities	Totals
<b>Balance at December 31, 2013</b>	<b>\$ 6,894</b>	<b>\$ 11,100</b>	<b>\$ 17,994</b>
Record initial fair value of derivative liability on 2014 senior notes		3,500	3,500
Gain on change in fair value of derivative liabilities	(6,270)	(5,600)	(11,870)
Compensation income for change in fair value of warrants issued to former employees	(503)		(503)
<b>Balance at September 30, 2014</b>	<b>\$ 121</b>	<b>\$ 9,000</b>	<b>\$ 9,121</b>

	October 2009 Warrants	Long-Term Debt Derivative Liability	Foreign Exchange Contracts	Totals
<b>Balance at December 31, 2012</b>	<b>\$ 54,854</b>	<b>\$ 14,577</b>	<b>\$</b>	<b>\$ 69,431</b>
(Gain) loss on change in fair value of derivative liability	(14,077)	(7,377)	395	(21,059)
Compensation income for change in fair value of warrants issued to former employees	(1,179)			(1,179)
<b>Balance at September 30, 2013</b>	<b>\$ 39,598</b>	<b>\$ 7,200</b>	<b>\$ 395</b>	<b>\$ 47,193</b>

**Segment and Geographical Information**

Operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated on a regular basis by the chief operating decision-maker, or decision making group, in deciding how to allocate resources to an individual segment and in assessing performance of the segment. The Company currently operates in one business segment, which is the development and commercialization of Vascepa. A single management team that reports to the Company's chief decision maker, who is the Chief Executive Officer, comprehensively manages the business. Accordingly, the Company does not have separately reportable segments.

**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 considered the following recent accounting pronouncements which were not yet adopted as of September 30, 2014:

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606). This amendment provides principles for recognizing revenue for the transfer of promised goods or services to customers with the consideration to which the entity expects to be entitled in exchange for those goods or services. This amendment will be effective for the Company's fiscal year beginning January 1, 2017. Early adoption is not permitted. The Company is currently evaluating the accounting, transition and disclosure requirements of the standard and cannot currently estimate the financial statement impact of adoption.

In June 2014, the FASB issued guidance for accounting for share-based payments when the terms of an award provide that a performance target could be achieved after the requisite service period. The standard states that a performance target in a share-based payment that affects vesting and that could be achieved after the requisite service period should be accounted for as a performance condition. As such, the performance target should not be reflected in estimating the grant-date fair value of the award. The Company is required to adopt this standard in the first quarter of fiscal 2016 and early adoption is permitted. This standard will not have an impact on the Company's condensed consolidated financial

statements.

In August 2014, the FASB issued ASU No. 2014-15, Presentation of Financial Statements - Going Concern, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (Subtopic 205-40). ASU 2014-15 requires management to assess an entity's ability to continue as a going concern by incorporating and expanding upon certain principles that are currently in U.S. auditing standards. Specifically, the ASU (i) provides a definition of the term substantial doubt, (ii) requires an evaluation every reporting period including interim periods, (iii) provides principles for considering the mitigating effect of management's plans, (iv)

**Table of Contents**

requires certain disclosures when substantial doubt is alleviated as a result of consideration of management's plans, (v) requires an express statement and other disclosures when substantial doubt is not alleviated and (vi) requires an assessment for a period of one year after the date that the financial statements are issued (or available to be issued). This standard is effective for the fiscal years ending after December 15, 2016, and for annual periods and interim periods thereafter. Early application is permitted. The Company is currently evaluating the accounting, transition and disclosure requirements of the standard and cannot currently estimate the financial statement impact of adoption.

The Company believes that the impact of other recently issued but not yet adopted accounting pronouncements will not have a material impact on consolidated financial position, results of operations, and cash flows, or do not apply to the Company's operations.

**Table of Contents****(3) Intangible Assets**

Intangible assets consist of technology rights for Vascepa and have an estimated remaining useful life of 15.8 years. The carrying value as of September 30, 2014 and December 31, 2013 is as follows (in thousands):

	September 30, 2014	December 31, 2013
Technology rights	\$ 11,624	\$ 11,624
Accumulated amortization	(1,399)	(915)
	\$ 10,225	\$ 10,709

**(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 (in thousands):

	September 30, 2014	December 31, 2013
Raw materials, current	\$ 3,813	\$ 4,246
Work in process	3,308	11,310
Finished goods	4,765	5,026
Finished goods inventory held by others		627
Total inventory, current	11,886	21,209
Raw materials, long-term		5,482
Total inventory	\$ 11,886	\$ 26,691

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

The Company had 8,087,388 warrants to purchase common shares outstanding at September 30, 2014 at a weighted-average exercise price of \$1.50 as described below.

***October 2009 Warrants 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 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.

In conjunction with the October 2009 financing, the Company issued an additional 0.9 million warrants to three former officers. 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.

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

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 derivative 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.

As of September 30, 2014, October 2009 warrants remained outstanding to purchase up to an aggregate of 8,087,388 of the ordinary shares of the Company at \$1.50 per share. In October 2014, the Company and the holders of the remaining October 2009 Warrants mutually agreed to extend the expiration date of such warrants from October 16, 2014 to February 27, 2015.

**Table of Contents****July 2009 Warrants**

The Company issued several warrants in July 2009. As of September 30, 2014, there are no July 2009 warrants outstanding, while at December 31, 2013 these warrants were classified as equity instruments and are included in the Company's consolidated balance sheet within additional paid-in-capital. During the nine months ended September 30, 2014, 1,684,888 of the July 2009 warrants were exercised, resulting in proceeds to the Company of \$1.7 million. 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 Secured Debt Fund II Holdings Cayman LP, or 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 million received at the closing of the agreement which occurred in December 2012. The Company has agreed to repay BioPharma up to \$150 million of future revenue and receivables. As of September 30, 2014, the net remaining amount to be repaid to BioPharma is \$145.8 million. During the three and nine months ended September 30, 2014, the Company made repayments under the agreement of \$1.3 million and \$3.4 million to BioPharma, respectively, and an additional \$1.4 million is scheduled to be paid in November 2014. These payments, each representing 10% of net revenues for the respective periods, were calculated based on the threshold limitation, as described below, as opposed to the scheduled quarterly repayments. Additional quarterly repayments, subject to the threshold limitation, are scheduled to be paid thereafter in accordance with the following schedule: \$8.0 million in the first quarter of 2015, \$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. All such payments reduce the remainder of the \$150 million in aggregate payments to BioPharma. 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 and 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 in aggregate has been repaid. The Company can prepay an amount equal to \$150 million less any previously repaid amount.

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 the threshold amounts in the repayment schedule. For each quarterly period since the inception of the debt, revenues were below the contractual threshold amount such that cash payments were calculated for each period reflecting the optional reduction amount as opposed to the contractual threshold payment due for each quarterly period. The payment of \$1.4 million for the third quarter of 2014 is due in November 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. Any such deferred repayments will remain subject to continued application of the quarterly ceiling in amounts due established by the calculated threshold limitation based on quarterly Vascepa revenues. No additional interest expense or liability is incurred as a result of such deferred repayments. These estimates will be reevaluated each reporting period by the Company and adjusted if necessary.

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 Company recognized a gain on change in fair value of derivative liability of \$6.5 million and \$7.4 million during the nine months ended September 30, 2014 and 2013, respectively.

During the nine months ended September 30, 2014, the Company recorded \$5.5 million and \$1.4 million of cash and non-cash interest expense, respectively, on the BioPharma debt. During 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. 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.

To secure the obligations under the agreement with BioPharma, the Company granted BioPharma a security interest in the Company's patents, trademarks, trade names, domain names, copyrights, know-how and regulatory approvals related to the covered products, all books and records relating to the foregoing and all proceeds of the foregoing, referred to collectively as the collateral. If the Company (i) fails to deliver a payment

when due and does not remedy that failure within a specific notice period, (ii) fails to maintain a first-priority perfected security interest in the collateral in the United States and does not remedy that failure after receiving notice of such failure or (iii) becomes subject to an event of bankruptcy, then BioPharma may attempt to collect the maximum amount payable by the Company under this agreement (after deducting any payments the Company has already made).

**Table of Contents****January 2012 Exchangeable Senior Notes**

In January 2012, the Company issued \$150.0 million in principal amount of 3.5% exchangeable senior notes due 2032, a portion of which were subsequently exchanged (see discussion of May 2014 Exchangeable Senior Notes below). The 2012 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 other subsidiaries. Corsicanto Limited has no assets, operations, revenues or cash flows other than those related to the issuance, administration and repayment of the 2012 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 2012 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 2012 Notes' maturity on January 15, 2032. The 2012 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 2012 Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the repurchase date. The 2012 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 2012 Notes. If the Company elected physical settlement, the net remaining outstanding portion of the 2012 Notes would be exchangeable into 3,547,916 ADSs after the May 2014 exchange of a portion of the 2012 Notes (see below for further discussion of the May 2014 exchange).

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 2012 Notes. The Company is required to use commercially reasonable efforts to procure and maintain the listing of the 2012 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 2012 Notes are not freely tradable, as a result of restrictions pursuant to U.S. securities law or the terms of the Indenture or the 2012 Notes, the Company shall pay additional interest on the 2012 Notes at the rate of 0.50% per annum of the principal amount of 2012 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 2012 Notes are not freely tradable.

The Company may not redeem the 2012 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 2012 Notes. On or after January 19, 2017 and prior to the maturity date, the Company may redeem for cash all or part of the 2012 Notes at a redemption price equal to 100% of the principal amount of the 2012 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 2012 Notes. If the Company undergoes a change in control, holders may require the Company to repurchase for cash all or part of their 2012 Notes at a repurchase price equal to 100% of the principal amount of the 2012 Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the change in control repurchase date. The 2012 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 2012 Notes and equal in right of payment to the Company's future unsecured indebtedness that is not so subordinated. The 2012 Notes are effectively junior in right of payment to future secured indebtedness to the extent of the value of the assets securing such indebtedness.

The 2012 Notes are exchangeable under certain circumstances. At the time of issuance, the Company calculated the fair value of the liability component of the outstanding 2012 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 and corresponding increase in equity as a result of the cash settlement feature. The discount created from allocating proceeds to the conversion option is being amortized to interest expense using the effective interest method over the 2012 Notes' estimated remaining life, which was calculated to be a period of twenty-four months. As of September 30, 2014, the discount created from the allocation of the proceeds to the conversion option was fully amortized. 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 underwriter's discounts and offering costs. A portion of the debt discount from underwriter's discounts and offering costs was allocated to the equity and liability components of the 2012 Notes in proportion to the proceeds allocated to each component. The portion of the debt discount from underwriter's discounts and offering costs allocated to the liability component was amortized as interest expense over the estimated life of the 2012 Notes of twenty-four months. As of September 30, 2014, the debt discount was fully amortized and the carrying value of the 2012 Notes was \$31.3 million after an exchange of a portion of the 2012 Notes (see below for further discussion of the May 2014 exchange).

**May 2014 Exchangeable Senior Notes**



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

In May 2014, the Company entered into separate, privately negotiated exchange agreements with certain holders of the 2012 Notes pursuant to which Corsicanto exchanged \$118.7 million in aggregate principal amount of the existing 2012 Notes for \$118.7 million in aggregate principal amount of new 3.50% May 2014 Exchangeable Senior Notes due 2032, following which \$31.3 million in aggregate principal amount of the 2012 Notes remained outstanding with terms unchanged (the 2012 Notes and 2014 Notes are referred to collectively as the Notes ).

**Table of Contents**

The 2014 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, 2014, and ending upon the 2014 Notes' maturity on January 15, 2032, unless earlier repurchased or redeemed by Corsicanto or exchanged by the holders. At any time after the issuance of the 2014 Notes and prior to the close of business on the second business day immediately preceding January 15, 2032, holders may exchange the 2014 Notes at their option. If prior to January 15, 2018, a make-whole fundamental change (as defined in the Indenture) occurs or the Company elects to redeem the 2014 Notes in connection with certain changes in tax law, in each case as described in the Indenture, and a holder elects to exchange its 2014 Notes in connection with such make-whole fundamental change or election, as the case may be, such holder may be entitled to an increase in the exchange rate as described in the Indenture. In the event of physical settlement, the 2014 Notes would be exchangeable into 45,666,925 ADSs. The exchange rate will initially be 384.6154 ADSs per \$1,000 principal amount of the 2014 Notes (equivalent to an initial exchange price of approximately \$2.60 per ADS, or the Exchange Price), subject to adjustment in certain circumstances. The exchange rate is subject to adjustment from time to time upon the occurrence of certain events, including, but not limited to, the payment of cash dividends.

Prior to January 19, 2018, the Company may not redeem the 2014 Notes at its option other than in connection with certain changes in the tax law of a relevant taxing jurisdiction that results in additional amounts (as defined in the Indenture) becoming due with respect to payments and/or deliveries on the 2014 Notes. On or after January 19, 2018, the Company may redeem for cash all or a portion of the 2014 Notes at a redemption price of 100% of the aggregate principal amount of the 2014 Notes to be redeemed, plus accrued and unpaid interest to, but not including, the redemption date. If a fundamental change (as defined in the Indenture) occurs, holders may require the Company to repurchase all or part of their 2014 Notes for cash at a fundamental change repurchase price equal to 100% of the aggregate principal amount of the 2014 Notes to be repurchased, plus accrued and unpaid interest to, but not including, the fundamental change repurchase date. In addition, holders of the 2014 Notes may require the Company to repurchase all or any portion of the 2014 Notes on each of January 19, 2019, January 19, 2024 and January 19, 2029 for cash at a price equal to 100% of the aggregate principal amount of the 2014 Notes to be repurchased, plus accrued and unpaid interest to, but not including, the repurchase date.

The Company may elect at its option to cause all or any portion of the 2014 Notes to be mandatorily exchanged in whole or in part at any time prior to the close of business on the business day preceding January 15, 2032 if the Daily VWAP (as defined in the Indenture) equals or exceeds 110% of the Exchange Price then in effect for at least 20 VWAP Trading Days (as defined in the Indenture) in any 30 VWAP Trading Day period. The Company may only exercise its optional exchange rights upon satisfaction of specified equity conditions, including that the ADSs issuable upon exchange of the 2014 Notes be eligible for resale without registration by non-affiliates and listed on The NASDAQ Global Market, its related exchanges or the New York Stock Exchange. If Corsicanto elects to exercise its optional exchange rights on or prior to January 15, 2018, each holder whose 2014 Notes are exchanged will upon exchange receive a specified number of additional ADSs as set forth in the Indenture. Upon such a declaration of acceleration, such principal and accrued and unpaid interest, if any, will be due and payable immediately. Upon the occurrence of certain events of bankruptcy, insolvency or reorganization involving Corsicanto, 100% of the principal of and accrued and unpaid interest, if any, on all of the 2014 Notes will become due and payable automatically. Notwithstanding the foregoing, the Indenture will provide that, to the extent Corsicanto elects and for up to 360 days, the sole remedy for an event of default relating to certain failures by Corsicanto or the Company, as the case may be, to comply with certain reporting covenants in the Indenture consists exclusively of the right to receive additional interest on the 2014 Notes. Additional covenants pertaining to the 2012 Notes (as described above for the January 2012 Exchangeable Senior Notes) are also applicable to the May 2014 Notes.

As a result of the note exchange (as described above), the Company assessed both quantitative and qualitative aspects of the features of the 2014 Notes as compared to the 2012 Notes. Such assessment resulted in the conclusion that the features of the 2014 Notes represent a substantive modification from the 2012 Notes as the terms of the exchange resulted in a substantive modification to the embedded conversion feature within the 2012 Notes, and as such should be accounted for as an extinguishment of debt. In accordance with ASC 470-20, the Company extinguished the 2012 Notes by recording a gain on extinguishment of the liability component of \$38.0 million and repurchase of the conversion option in equity through a reduction to additional paid-in capital of \$10.1 million. The 2014 Notes were recorded at fair value of \$90.8 million representing a \$27.9 million discount to par. In addition the Company recognized \$2.5 million in underwriter's fees and offering costs and recognized those costs as deferred assets. The Company further allocated \$3.5 million of the \$90.8 million fair value of the 2014 Notes to the derivative liability related to the fundamental change redemption feature (as described above), which will be measured at fair value on an ongoing basis. During the three months ended September 30, 2014, the Company recognized a \$1.1 million loss on the change in fair value of the redemption feature and recorded a related long-term debt derivative liability of \$4.4 million.

Because the conversion option in the 2014 Notes receives an exception from derivative accounting and only requires gross physical settlement in shares, the embedded option does not require separate accounting and is therefore accounted for as part of the debt host at amortized cost. The debt discount is being amortized as interest expense over the estimated life of the 2014 Notes and recognized in the statement of operations as interest expense. As of September 30, 2014, the carrying value of the 2014 Notes was \$89.2 million. During the nine months ended September 30, 2014, the Company recognized interest expense of \$6.7 million related to the 2014 Notes, of which \$2.8 million represents amortization of the debt discount and \$3.9 million represents contractual coupon interest. At



**Table of Contents**

September 30, 2014 and December 31, 2013, the Company had accrued interest of \$1.1 and \$2.4 million, respectively, which is included in other current liabilities. The Company made the contractual interest payments due on the Notes in the nine months ended September 30, 2014 and 2013 of \$5.3 million.

**(7) Commitments and Contingencies****Litigation**

On November 1, 2013, a purported investor of Amarin filed a putative class action lawsuit captioned *Steven Sklar v. Amarin Corporation plc et al.*, No. 13-cv-6954 (D.N.J. Nov. 1, 2013) in the U.S. District Court for the District of New Jersey. Substantially similar lawsuits, captioned *Bove v. Amarin Corporation plc*, Civ. No. 13-07882 (AT) (S.D.N.Y. Nov. 5, 2013), *Bentley v. Amarin Corporation plc*, Civ. No. 13-08283 (AT) (S.D.N.Y. Nov. 20, 2013) and *Siegel v. Amarin Corporation plc*, No. 3:13-cv-07210 (D.N.J. Nov. 27, 2013), were subsequently filed in the U.S. District Court for the District of New Jersey and U.S. District Court for the Southern District of New York. On December 9, 2013, the cases filed in the Southern District of New York were transferred to the District of New Jersey and all such cases are now consolidated as *In re Amarin Corporation plc, Securities Litigation*, No. 3:13-cv-06663 (D.N.J. Nov. 1, 2013). The plaintiffs assert claims under the Securities Exchange Act of 1934 and allege that Amarin and certain of its current and former officers and directors made misstatements and omissions regarding the FDA's willingness to approve Vascepa's ANCHOR indication and related contributing factors and the potential relevance of data from the ongoing REDUCE-IT trial to that approval. The lawsuit seeks unspecified monetary damages and attorneys' fees and costs. The Company believes that it has valid defenses and will vigorously defend against this class action suit, but cannot predict the outcome. The Company is unable to reasonably estimate the loss exposure, if any, associated with the claims. The Company has insurance coverage that is anticipated to cover any significant loss exposure that may arise from this action after payment by the Company of the associated deductible obligation under such insurance coverage.

On February 27, 2014, the Company commenced a lawsuit against the FDA that challenges FDA's denial of the Company's request for five-year NCE exclusivity for Vascepa based on its reading of the relevant statute, the Company's view of FDA's inconsistency with past actions in this area and the retroactive effect of what the Company believes is a new policy at FDA as it relates to Vascepa situation. The Company's complaint requests that the court vacate FDA's decision, declare that Vascepa is entitled to the benefits of five-year statutory exclusivity, bar the FDA from accepting any ANDA or similar application for which Vascepa is the reference-listed drug until after the statutory exclusivity period and set aside what the Company contends are due to the denial of five-year exclusivity to Vascepa prematurely accepted pending ANDA applications.

On March 4, 2014, the Company filed a lawsuit for patent infringement of U.S. Patent No. 8,663,662 in the U.S. District Court for the District of Delaware against AstraZeneca Pharmaceuticals LP and its subsidiary, Omthera Pharmaceuticals, Inc., captioned *Amarin Pharmaceuticals Ireland Limited v. Omthera Pharmaceuticals, Inc. et al.*, Civ. A. No. 1:14-cv-00279 (D.Del.). On June 23, a second complaint was filed against AstraZeneca and Omthera, captioned *Amarin Pharmaceuticals Ireland Limited v. Omthera Pharmaceuticals, Inc. et al.*, Civ. A. No. 1:14-cv-00791 (D.Del.). That second complaint replaced the first complaint, which was voluntarily dismissed on June 27, and was filed in order to expedite the progress of this litigation on the merits. The focus of the lawsuit is the commercial marketing of Epanova® (omega-3-carboxylic acids) capsules in the United States. Epanova was approved by the FDA in May 2014 with substantially the same indication as Vascepa and is expected to compete with Vascepa. The Company is seeking damages and injunctive relief in the litigation. The Company intends to litigate the case vigorously, but cannot predict the outcome of this lawsuit.

In March, April, and May 2014, the Company received paragraph IV certification notices from six companies contending to varying degrees that certain of its patents are invalid, unenforceable and/or will not be infringed by the manufacture, use, sale or offer for sale of a generic form of Vascepa as described in those companies' abbreviated new drug applications, or ANDAs. The Company has commenced patent infringement lawsuits against each of these ANDA applicants. In each of the lawsuits, Amarin is seeking, among other remedies, an order enjoining the defendants from marketing generic versions of Vascepa before the last to expire of the asserted patents expires in 2030. In April 2014, Amarin filed lawsuits against Apotex, Inc. and Apotex Corporation, or collectively, Apotex, in the U.S. District Court for the District of New Jersey and the U.S. District Court for the Northern District of Illinois. The cases against Apotex are captioned *Amarin Pharma, Inc. et al. v. Apotex, Inc. et al.*, Civ. A. No. 14-2550 (D.N.J.) and *Amarin Pharma, Inc. et al. v. Apotex, Inc. et al.*, Civ. A. No. 14-2958 (N.D. Ill.). In April 2014, Amarin also filed lawsuits against Roxane Laboratories, Inc., or Roxane, in the U.S. District Court for the District of New Jersey and the U.S. District Court for the Northern District of Ohio. The cases against Roxane are captioned *Amarin Pharma, Inc. et al. v. Roxane Laboratories, Inc.*, Civ. A. No. 14-2551 (D.N.J.) and *Amarin Pharma, Inc. et al. v. Roxane Laboratories, Inc.*, Civ. A. No. 14-901 (N.D. Ohio). Amarin voluntarily dismissed the Northern District of Ohio case against Roxane on May 7, 2014. In April 2014, Amarin also filed a lawsuit against Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd., or collectively, Dr. Reddy's, in the U.S. District Court for the District of New Jersey. The case against Dr. Reddy's is captioned *Amarin Pharma, Inc. et al. v. Dr. Reddy's Laboratories, Inc. et al.*, Civ. A. No. 14-2760 (D.N.J.). In May 2014, Amarin also filed a lawsuit against Watson Laboratories, Inc. and Actavis plc, or Watson, in the U.S. District Court for the District of New Jersey. One of the Company's directors, Patrick J. O. Sullivan, is also a director of Actavis plc. The case against



## Table of Contents

Watson is captioned *Amarin Pharma, Inc. et al. v. Watson Laboratories, Inc. et al.*, Civ. A. No. 14-3259 (D.N.J.). On July 17, 2014, Amarin agreed to dismiss Actavis plc but the lawsuit against Watson remains pending. In June 2014, Amarin also filed a case against Teva Pharmaceuticals USA, Inc., or Teva, in the U.S. District Court for the District of New Jersey. The case against Teva is captioned *Amarin Pharma, Inc. et al. v. Teva Pharmaceuticals USA, Inc.*, Civ. A. No. 14-3558 (D.N.J.). In June 2014, Amarin also filed a lawsuit against Andrx Labs, LLC, Andrx Corporation, and Actavis plc, or collectively, Andrx, in the U.S. District Court for the District of New Jersey. The case against Andrx is captioned *Amarin Pharma, Inc. et al. v. Andrx Labs, LLC et. al.*, Civ. A. No. 14-3924 (D.N.J.). As a result of the 30-month stay associated with the filing of these lawsuits under the Hatch-Waxman Act, the FDA cannot grant final approval to any ANDA before September 2016, unless there is an earlier court decision holding that the subject patents are not infringed and/or are invalid. The Company intends to vigorously enforce its intellectual property rights relating to Vascepa, but cannot predict the outcome of these lawsuits.

In addition to the above, in the ordinary course of business, the Company is 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, 2014, the Company was not party to any legal or arbitration proceedings that may have, or have had in the recent past, significant effects on the Company's financial position or profitability. No governmental proceedings are pending or, to its knowledge, contemplated against the Company. The Company is not a party to any material proceedings in which any director, member of senior management or affiliate is either a party adverse to the Company or its subsidiaries or has a material interest adverse to the Company or its subsidiaries.

### Milestone and Supply Purchase Obligations

The Company entered into several product development agreements with, subject to performance obligations, certain milestone and supply purchase obligations, as detailed below:

The Company entered into its initial Vascepa API supply agreement with Nisshin Pharma, Inc., or Nisshin, in 2010. In 2011, the Company entered into agreements with two additional suppliers, Chemport, Inc., or Chemport, and BASF (formerly Equateq Limited) for the supply of API. In 2012, the Company agreed to terms with a fourth API supplier, a consortium of companies led by Slanmhor Pharmaceutical, Inc. (Slanmhor). These agreements included requirements for the suppliers to meet certain product specifications and qualify their materials and facilities with applicable regulatory authorities including the FDA. The Company has incurred certain costs associated with the qualification of product produced by these suppliers as described below.

Chemport was approved by the FDA to manufacture API for commercial sale in April 2013. The Company began purchasing commercial supply from Chemport in 2013. The agreement with Chemport contains a provision requiring the Company to pay Chemport in cash for any shortfall in the minimum purchase obligations. The 2011 supply agreement with Chemport includes commitments for the Company to fund (i) certain development fees, (ii) material purchases for initial raw materials, which amount will be credited against future API purchases and (iii) a raw material purchase commitment. During the nine months ended September 30, 2014, the Company made payments of \$3.3 million to Chemport.

Chemport together with Nisshin are currently the two manufacturers from which the Company purchases API. The Company has no royalty, milestone or minimum purchase commitments with Nisshin.

The API supply agreement with BASF terminated in February 2014. In April 2014, the Company reached a settlement agreement with BASF under which it received a refund for material purchases of \$3.0 million, included as other income in the statement of operations. The Company made payments of \$3.1 million to BASF related to development and supply commitments through September 30, 2014.

The Company made payments of \$6.2 million to the Slanmhor consortium related to development fees and other provisions through September 30, 2014 and during the nine months ended September 30, 2014 and 2013, made payments of \$0.4 million and \$6.1 million, respectively, to the Slanmhor consortium related to stability and technical batches and advances on anticipated future API purchases.

Pursuant to the agreements with our suppliers, there is a total of \$54.5 million that is potentially payable over the term of such agreements based on minimum purchase obligations.

Concurrent with its entry into one of its API supply agreements, the Company agreed to make a non-controlling minority share equity investment in the supplier of \$3.3 million. The Company invested \$1.7 million under this agreement in July 2011 and the remaining \$1.6 million during 2012. In September 2013, the Company entered into an equity sale and purchase agreement between

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

this supplier and a third party in which the Company agreed to sell approximately \$1.3 million of its investment in the supplier to the third party at cost. This transaction closed in the first quarter of 2014. The carrying amount of the investment of \$2.0 million and \$3.3 million as of September 30, 2014 and December 31, 2013, respectively, is included in other long term assets and is accounted for under the cost method.

Under the 2004 share repurchase agreement with Laxdale Limited, or Laxdale, 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

**Table of Contents**

shareholders of Laxdale (at the sole option of each of the sellers) of £7.5 million (approximately \$12.2 million at September 30, 2014). 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, 2014) for each of the two potential market approvals (i.e. £10 million maximum, or approximately \$16.2 million at September 30, 2014).

The Company has no provision for any of the obligations above since the amounts are either not probable or able to be estimated at September 30, 2014.

**(8) Equity**

During the three months ended September 30, 2014, the Company received a refund of \$3.2 million for UK stamp duty taxes paid in prior periods related to the issuance of common stock. Such proceeds were recorded as an increase to additional paid-in capital.

During the nine months ended September 30, 2014 and 2013, the Company issued 234,500 and 386,000 shares, respectively, as a result of the exercise of stock options, resulting in gross and net proceeds of \$0.3 million and \$0.6 million, respectively, for each period. In addition, during the nine months ended September 30, 2014 and 2013, the Company issued 1,684,888 and 120,000 shares, respectively, as a result of the exercise of warrants, resulting in gross and net proceeds of \$1.7 million and \$0.1 million, respectively.

On March 11, 2014, the Company granted a total of 173,348 restricted stock units, or RSUs, and 205,890 stock options to members of the Company's Board of Directors under the Amarin Corporation plc 2011 Stock Incentive Plan, or the 2011 Plan. The RSUs vest in equal installments over a three year period commencing with each installment vesting each year upon the earlier of the anniversary of the grant date or the Company's annual general meeting of shareholders in such anniversary year. The RSUs 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 stock options vest in full upon the earlier of the anniversary of the grant date or the Company's annual general meeting of shareholders in such anniversary year. The stock options will become fully vested upon a change of control of the Company.

On January 8, 2014, the Company granted a total of 2,082,000 RSUs and 2,605,500 stock options to employees under the 2011 Plan. The RSUs vest annually over a three year period and the stock options vest monthly over a four year period, with both becoming fully vested upon a change of control of the Company.

In January 2013, the Company granted 454,875 RSUs to several employees under the 2011 Plan. The terms of these RSUs provided for vesting upon the achievement of certain operational milestones. In the year ended December 31, 2013, as a result of the operational milestones not being achieved, all of these RSUs were forfeited and no shares were issued as a result of vesting.

**(9) Co-Promotion Agreement**

On March 31, 2014, the Company entered into a Co-Promotion Agreement, or the Agreement, with Kowa Pharmaceuticals America related to the commercialization of Vascepa® in the United States. Under the terms of the Agreement, Amarin granted to Kowa Pharmaceuticals America the right to be the sole co-promoter, together with the Company, of Vascepa in the United States during the term. The initial term of the Agreement extends through 2018.

During the term, Kowa Pharmaceuticals America and Amarin have agreed to use commercially reasonable efforts to promote, detail and optimize sales of Vascepa in the United States. The performance requirements include a negotiated minimum number of details to be delivered by each party in the first and second position, the use of a negotiated number of minimum sales representatives from each party, including no less than 250 Kowa Pharmaceuticals America sales representatives, and minimum levels of Vascepa revenues beginning in 2015. Kowa Pharmaceuticals America has agreed to continue to bear the costs incurred for its sales force associated with the commercialization of Vascepa and to pay for certain incremental costs associated with the use of its sales force, such as sample costs and costs for promotional and marketing materials. Amarin will continue to recognize all revenue from sales of Vascepa and will use commercially reasonable efforts to maintain a minimum amount of inventory of Vascepa for use in the United States.



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

Amarin will continue to recognize all revenue from sales of Vascepa under the Agreement. In exchange for Kowa Pharmaceuticals America's co-promotional services, Kowa Pharmaceuticals America is entitled to a quarterly co-promotion fee based on a percentage of aggregate Vascepa gross margins. The percentage of aggregate Vascepa gross margins earned by Kowa Pharmaceuticals America is scheduled to increase during the Agreement's term, from the high single digits in 2014, to mid-teen percent levels in 2015, and to the low twenty percent levels in 2018. The co-promotion fee also varies based on sales levels and whether the FDA has approved an ANCHOR indication labeling expansion for Vascepa or has permitted the use of data generated to support obtaining FDA approval of the ANCHOR indication in the promotion of Vascepa, in which case the co-promotion fee would be decreased if specified requirements are met. In the event of a change of control (as defined) or termination of the agreement, the Company would be required to make certain tail payments based on a specified percentage of revenues.

**Table of Contents**

**(10) Subsequent Events**

The Company has evaluated subsequent events from September 30, 2014 through the date of the issuance of these condensed consolidated financial statements.

## Table of Contents

### **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, 2013 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.

Our lead product, Vascepa® (icosapent ethyl) capsules, is approved by the U.S. Food and Drug Administration, or FDA, for use as an adjunct to diet to reduce triglyceride levels in adult patients with severe (TG  $\geq$ 500mg/dL) hypertriglyceridemia. Vascepa is available in the United States by prescription only. We began selling and marketing Vascepa in the United States in January 2013. We sell 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. We market Vascepa through our sales force of approximately 150 sales professionals, including sales representatives and their managers. In March 2014, we entered into a co-promotion agreement with Kowa Pharmaceuticals America, Inc. (Kowa Pharmaceuticals America) under which approximately 250 Kowa Pharmaceuticals America sales representatives began to devote a substantial portion of their time to promoting Vascepa starting in May 2014. We operate in one business segment.

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 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.

The potential efficacy and safety of Vascepa (known in its development stage as AMR 101) was studied in two Phase 3 clinical trials, the MARINE trial and the ANCHOR trial. At a daily dose of 4 grams of Vascepa, the dose at which Vascepa is FDA approved, 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, relative 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 Vascepa-treated patients was arthralgia (joint pain) (2.3% for Vascepa vs. 1.0% for placebo).

We are also developing Vascepa for the treatment of patients with high (TG  $\geq$  200 mg/dL and  $<$ 500 mg/dL) triglyceride levels who are also on statin therapy for elevated low-density lipoprotein cholesterol, or LDL-C, levels which we refer to as mixed dyslipidemia. We refer to this second proposed indication for Vascepa as the ANCHOR indication. The FDA has stated that it views the proposed ANCHOR indication as ostensibly and impliedly an indication to reduce cardiovascular risk. In addition, 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).

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

---

**Table of Contents**

We have a pending supplemental new drug application, or sNDA, with the FDA that seeks marketing approval of Vascepa for use in the ANCHOR indication. On October 16, 2013, the FDA convened an advisory committee to review our sNDA. This advisory committee was not asked by the FDA to evaluate whether Vascepa is effective in lowering triglycerides in the studied population, the ANCHOR indication as specified in the sNDA. Rather, the advisory panel was asked whether Vascepa has been demonstrated to improve cardiovascular outcomes or whether approval of the ANCHOR indication should wait for successful completion of the REDUCE-IT study, the first prospective study of cardiovascular outcomes in patients who have high triglyceride levels despite statin therapy. The advisory committee voted 9 to 2 against recommending approval of the ANCHOR indication based on information presented at the meeting. The FDA considers the recommendation of advisory committees, but final decisions on the approval of new drug applications are made by the FDA.

The ANCHOR clinical study was conducted under a special protocol assessment, or SPA, agreement with the FDA. The law governing SPA agreements requires that if the results of the trial conducted under the SPA substantiate the hypothesis of the protocol covered by the SPA, the FDA must use the data from the protocol as part of the primary basis for approval of the product. A SPA agreement is not a guarantee of FDA approval of the related new drug application. A SPA agreement 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 of the drug after the study begins that rises to the level of a public health concern, or if the study sponsor fails to follow the protocol that was agreed upon with the FDA. On October 29, 2013, the FDA rescinded the ANCHOR study SPA agreement 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. As a basis for this determination, the FDA communicated that it determined that the cumulative 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 while information we submitted supports testing the hypothesis that Vascepa 4 grams/day versus placebo reduces major adverse cardiovascular events in statin-treated subjects with residually high triglyceride levels, as is being studied in the Vascepa REDUCE-IT cardiovascular outcomes study, the FDA no longer considers a change in serum triglyceride levels alone as sufficient to establish the effectiveness of a drug intended to reduce cardiovascular risk in subjects with serum triglyceride levels below 500 mg/dL. Beginning in November 2013, we sought reconsideration and appealed the SPA rescission decision to three levels of increasing authority within the FDA and were denied each time, most recently in September 2014. Based on FDA's repeated position in its appeal denials and its internal consultation with FDA officials at higher levels, we informed the FDA that we did not intend to appeal the SPA rescission further.

The FDA did not take action on the ANCHOR sNDA by the Prescription Drug User Fee Act, or PDUFA, goal date for completion of FDA's review, December 20, 2013. Given our determination to not appeal the SPA rescission further, we expect the FDA to take action on our pending ANCHOR sNDA in the near future.

We are currently focused on the ongoing REDUCE-IT cardiovascular outcomes study of Vascepa. REDUCE-IT, a multinational, prospective, randomized, double-blind, placebo-controlled study, is the first prospective cardiovascular outcomes study of any drug in a population of patients who, despite stable statin therapy, have elevated triglyceride levels. Based on the results of REDUCE-IT, we plan to seek additional indications for Vascepa beyond the indications studied in the ANCHOR and MARINE trials. In REDUCE-IT, cardiovascular event rates for patients on stable statin therapy plus four grams per day of Vascepa will be compared to cardiovascular event rates for patients on stable statin therapy plus placebo. The REDUCE-IT study is designed to be completed after reaching an aggregate number of cardiovascular events. Based on projected event rates, we estimate the REDUCE-IT study can be completed in or about 2017 with results then expected to be available in 2018. An interim review of the efficacy results of the trial is scheduled to occur upon reaching 60% of the target aggregate number of cardiovascular events. We currently expect this interim review by the independent data monitoring committee (DMC) to occur during 2016. The DMC has been more frequently examining interim reviews of the safety data from the study. Amarin remains blinded to all data from the study. Approximately 90% of the 8,000 patients targeted for enrollment in the REDUCE-IT study have been enrolled.

Based on our communications with the FDA, we currently expect that final positive results from the REDUCE-IT outcomes study will be required for label expansion for Vascepa. There can be no assurance that we will be successful in our efforts to obtain a label expansion reflecting the ANCHOR clinical trial whether or not we obtain final positive results from the REDUCE-IT outcomes study. If the FDA does not approve the ANCHOR indication, it could have a material impact on our future results of operations and financial condition.

On October 22, 2013, in an effort to reduce operating expenses following the recommendation of the advisory committee to the FDA against approval of the ANCHOR indication, we implemented a worldwide reduction in force of approximately 50% of our staff positions. The majority of affected staff members were sales professionals who supported the initial commercial launch of Vascepa. We incurred approximately \$2.8 million in charges related to the reduction in force, all of which includes cash expenditures for one-time termination benefits and associated costs. The charges were recorded in the fourth quarter of 2013 and the related payments were made by the first half of 2014. As part of the reduction in force, we retained approximately 130 sales representatives, excluding sales management, in the United States in sales territories that we believe have demonstrated the greatest potential for Vascepa sales growth. This team covers 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 the resulting target base coverage, as well as the addition of the promotional efforts of 250 sales representatives from Kowa Pharmaceuticals America that began in May 2014, we

anticipate continued Vascepa revenue growth over time. We also anticipate that such sales growth may be inconsistent from period to period.

## **Table of Contents**

### *Commercialization Strategy*

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. 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 now market Vascepa in the United States through our sales force of approximately 150 sales professionals and their managers. Commencing in the middle of the second quarter of 2014, in addition to promotion by our sales representatives, approximately 250 Kowa Pharmaceuticals America sales representatives began promoting Vascepa. We also employ various marketing personnel to support our commercialization of Vascepa. Our clinical and commercial supply is provided to us under agreements with various third-party suppliers. As of November 1, 2014, over 23,000 clinicians had written prescriptions for Vascepa.

Under the co-promotion agreement with Kowa Pharmaceuticals America, under which promotion commenced in May 2014, both parties have agreed to use commercially reasonable efforts to promote, detail and optimize sales of Vascepa in the United States and have agreed to specific performance requirements detailed in the related agreement. The performance requirements include a negotiated minimum number of sales details to be delivered by each party in the first and second position, the use of a negotiated number of minimum sales representatives from each party, including no less than 250 Kowa Pharmaceuticals America sales representatives and the achievement of minimal levels of Vascepa revenue in 2015 and beyond. Kowa Pharmaceuticals America has also agreed to continue to bear the costs incurred for its sales force associated with the commercialization of Vascepa and to pay for certain incremental costs associated with the use of its sales force, such as sample costs and costs for promotional and marketing materials. We will continue to recognize all revenue from sales of Vascepa. In exchange for Kowa Pharmaceuticals America's co-promotional services, Kowa Pharmaceuticals America is entitled to a quarterly co-promotion fee based on a percentage of aggregate Vascepa gross margins that increases during the term. The percentage of aggregate Vascepa gross margins earned by Kowa Pharmaceuticals America is scheduled to increase from the high single digits in 2014, to mid-teen percent levels in 2015, and to the low twenty percent levels in 2018, subject to certain adjustments.

Based on monthly compilations of data provided by a third party, Symphony Health Solutions, the estimated number of normalized total Vascepa prescriptions for the three months ended September 30, 2014 was approximately 132,000 as compared to 110,000 and 93,000 prescriptions in the three months ended June 30, 2014 and March 31, 2014, respectively. According to data from another third party, IMS Health, the estimated number of normalized total Vascepa prescriptions for the three months ended September 30, 2014 was approximately 113,000 as compared to 93,000 and 78,000 prescriptions in the three months ended June 30, 2014 and March 31, 2014, respectively. 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's 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. Timing of shipments to wholesalers, as used for revenue recognition, and timing of prescriptions as estimated by these third parties may differ from period to period.

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 we had limited selling history during the year ended December 31, 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, changes in the size of our sales force, our co-promotion agreement, and uncertainty regarding resolution of the ANCHOR sNDA with the FDA, we do not believe that we can provide a reasonably accurate forecast of Vascepa revenues. While we expect to be able to grow Vascepa revenues, we provide no quantified 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.

We secured managed care coverage for over 200 million lives, including as of November 1, 2014 over 119 million lives covered on Tier 2.

---

## **Table of Contents**

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*.

### *Research and Development Update*

In September 2014, we announced our continued commitment to completing the ongoing REDUCE-IT cardiovascular outcomes study. This multinational, prospective, randomized, double-blind, placebo-controlled study is the first prospective cardiovascular outcomes study of any drug in a population of patients who, despite stable statin therapy, have elevated triglyceride levels.

We have over 7,100 patients enrolled in the REDUCE-IT study. We currently estimate that we will complete patient enrollment in this study within 2015. The REDUCE-IT study is designed to be completed after reaching an aggregate number of cardiovascular events. Based on projected event rates, we estimate the REDUCE-IT study can be completed in or about 2017 with results then expected to be available in 2018. Based on the results of REDUCE-IT, we may seek additional indications for Vascepa beyond the indications studied in the ANCHOR or MARINE trials. An interim review of the efficacy results of the trial is scheduled to occur upon reaching 60% of the target aggregate number of cardiovascular events. We currently expect this interim review by the independent data monitoring committee (DMC) to occur during 2016. As is typical, the statistical threshold for defining overwhelming efficacy on the primary endpoint at the interim analysis is considerably higher than the threshold for defining statistical significance at the end of the study. Amarin remains blinded to all data from the study.

Our scientific rationale for the REDUCE-IT study is supported by (i) epidemiological data that suggests elevated triglyceride levels correlate with increased cardiovascular disease risk, (ii) genetic data that suggests triglyceride and/or triglyceride-rich lipoproteins (as well as low-density lipoprotein cholesterol (LDL cholesterol), known as bad cholesterol) are independently in the causal pathway for cardiovascular disease and (iii) clinical data that suggest substantial triglyceride reduction in patients with elevated baseline triglyceride levels correlates with reduced cardiovascular risk.

### *Commercial Supply Update*

During 2013 and the nine months ended September 30, 2014, all of our active pharmaceutical ingredient, or API, was acquired through two suppliers, Nisshin and Chemport. On April 30, 2014, the Company reached a settlement agreement with a former supplier, BASF, under which the Company received a refund for previous material purchases of \$3.0 million, included as other income in the statement of operations. The amount of supply we seek to purchase in 2014 and beyond will depend on the level of growth of Vascepa revenues. Much of the inventory sold in 2014 was purchased in 2013 from Nisshin at a price which is higher than expected future average API costs.

### *Financial Position*

We believe that our cash and cash equivalents balance of \$135.4 million at September 30, 2014 is 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. The Company commenced its commercial launch in the United States in January 2013. In accordance with GAAP, until we had the ability to reliably estimate returns of Vascepa from our Distributors, revenue was recognized based on the resale of Vascepa for the purposes of filling patient prescriptions, and not based on our sales to such Distributors. Beginning in January 2014, we concluded that we had developed sufficient history such that we can reliably estimate returns and as a result, began to recognize revenue based on sales to our Distributors. Consequently, we recognized revenues of \$37.7 million based on sales to Distributors during the nine months ended September 30, 2014. Through September 30, 2014, product returns were de minimis.

*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, which through September 30, 2014 was sourced from Nisshin and Chemport.



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

*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

**Table of Contents**

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. 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.

*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 notes and interest incurred under our December 2012 financing arrangement with BioPharma Secured Debt Fund II Holdings Cayman LP, or BioPharma. Interest expense under our exchangeable notes 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.

**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. 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. 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. We sell Vascepa to Distributors. In accordance with GAAP, until we had the ability to reliably estimate returns of Vascepa from our Distributors, revenue was recognized based on the resale of Vascepa for the purposes of filling patient prescriptions, and not based on our sales to such Distributors. Beginning in January 2014, we concluded that we had developed sufficient history such that we can reliably estimate returns and as a result, began to recognize revenue based on sales to our Distributors. Consequently, we recognized revenues of \$37.7 million based on sales to Distributors during the nine months ended September 30, 2014. Through September 30, 2014, product returns were de minimis.

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 have recorded financial derivatives related to the change in control provision

**Table of Contents**

associated with our December 2012 debt financing and the change in control provision associated with our May 2014 exchangeable senior notes. During 2013, we recorded a derivative liability related to our forward foreign exchange contracts, which was extinguished prior to December 31, 2013. The fair value of these derivatives could fluctuate based on changes in the assumptions used in the valuation models.

*Inventory* 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 and in July 2014 the FDA approved our sNDA covering Slanmhor such that there are now four suppliers FDA-qualified to produce Vascepa API. 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. 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, 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. We state 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, we will reduce the carrying value of such inventory to market value. We expense inventory identified for use as marketing samples when they are packaged. The 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 or was purchased prior to the sNDA approval of our suppliers. Additionally, the determination of the classification of our inventory requires the use of estimates in order to determine the portion of inventories anticipated to be utilized within twelve months of the balance sheet date.

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

We provide reserves for potential payments of tax to various tax authorities or do 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.

We assess our ability to realize deferred tax assets at each reporting period. The realization of deferred tax assets depends on generating future taxable income during the periods in which the tax benefits are deductible or creditable. The Company has been historically profitable in the U.S. When making its assessment about the realization of its U.S. deferred tax assets at September 30, 2014, the Company considered all available evidence, placing particular weight on evidence that could be objectively verified. The evidence considered included the (i) historical profitability of the Company's U.S. operations, (ii) sources of future taxable income, giving weight to sources according to the extent to which they can be objectively verified and (iii) the risks to our business related to the commercialization and development of Vascepa. Based on its assessment, the Company concluded that the U.S. deferred tax assets are more likely than not to be realizable as of September 30, 2014. Changes in historical earnings performance and future earnings projections, among other factors, may cause us to adjust our valuation allowance on deferred tax assets, which would impact our income tax expense in the period in which we determine that these factors have changed. In the event sufficient taxable income is not generated in future periods, additional valuation allowances could be required relating to these U.S. deferred tax assets.

**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. The Company considered the following recent accounting pronouncements which were not yet adopted as of September 30, 2014:

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606). This amendment provides principles for recognizing revenue for the transfer of promised goods or services to customers with the consideration to which the entity expects to be entitled in exchange for those goods or services. This amendment will be effective for our fiscal year beginning January 1, 2017. Early adoption is not permitted. We are currently evaluating the accounting, transition and disclosure requirements of the standard and cannot currently estimate the financial statement impact of adoption.

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

In June 2014, the FASB issued guidance for accounting for share-based payments when the terms of an award provide that a performance target could be achieved after the requisite service period. The standard states that a performance target in a share-based payment that affects vesting and that could be achieved after the requisite service period should be accounted for as a performance

**Table of Contents**

condition. As such, the performance target should not be reflected in estimating the grant-date fair value of the award. We are required to adopt this standard in the first quarter of fiscal 2016 and early adoption is permitted. This standard will not have an impact on our condensed consolidated financial statements.

In August 2014, the FASB issued ASU No. 2014-15, Presentation of Financial Statements—Going Concern, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (Subtopic 205-40). ASU 2014-15 requires management to assess an entity's ability to continue as a going concern by incorporating and expanding upon certain principles that are currently in U.S. auditing standards. Specifically, the ASU (i) provides a definition of the term substantial doubt, (ii) requires an evaluation every reporting period including interim periods, (iii) provides principles for considering the mitigating effect of management's plans, (iv) requires certain disclosures when substantial doubt is alleviated as a result of consideration of management's plans, (v) requires an express statement and other disclosures when substantial doubt is not alleviated and (vi) requires an assessment for a period of one year after the date that the financial statements are issued (or available to be issued). This standard is effective for the fiscal years ending after December 15, 2016, and for annual periods and interim periods thereafter. Early application is permitted. We are currently evaluating the accounting, transition and disclosure requirements of the standard and cannot currently estimate the financial statement impact of adoption.

Unless otherwise discussed, we believe that the impact of other 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, 2014 and September 30, 2013***

*Revenue.* We recorded revenue of \$14.1 million and \$8.4 million during the three months ended September 30, 2014 and 2013, respectively, an increase of \$5.7 million or 68%. We commenced our full commercial launch of Vascepa in the United States for use in the MARINE indication in January, 2013. All of our revenue in the three months ended September 30, 2014 and 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 GAAP, until we had the ability to reliably estimate returns of Vascepa from our Distributors, revenue was recognized based on the resale of Vascepa for the purposes of filling patient prescriptions, and not based on our sales to such Distributors. Beginning in January 2014, we concluded that we had developed sufficient history such that we can reliably estimate returns and as a result, began to recognize revenue based on sales to our Distributors. Through September 30, 2014, product returns were de minimis. Timing of shipments to wholesalers, as used for revenue recognition, and timing of prescriptions as estimated by third party sources such as Symphony Health Solutions and IMS Health may differ from period to period.

During the quarters ended September 30, 2014 and 2013, our net product revenues included an adjustment for co-pay mitigation rebates provided by us to commercially insured patients. Patients not covered on tier 2 by their commercial insurance carrier pay a higher co-pay payment when purchasing Vascepa. Such rebates are intended to offset the cost differential for such patients. Our cost for these co-payment mitigation rebates was up to \$75 per prescription filled prior to February 20, 2014 and up to \$70 per prescription filled after February 20, 2014 to September 30, 2014. Commencing in March 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. The number of lives covered by these payors increased throughout 2013 and continued to increase in 2014. As of November 1, 2014, over 119 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 in the pharmaceutical industry, the majority of Vascepa sales are to major commercial wholesalers which then resell Vascepa to retail pharmacies. As of November 1, 2014, over 23,000 clinicians had written prescriptions for Vascepa. As of November 1, 2014, 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 50% 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 the resulting target base coverage and the addition of the promotional efforts of 250 sales representatives from Kowa Pharmaceuticals America which commenced in May 2014, we anticipate continued Vascepa revenue growth over time. We further anticipate that such revenue growth may be inconsistent from period to period.

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

*Cost of Goods Sold.* Cost of goods sold during the three months ended September 30, 2014 and 2013 was \$5.4 million and \$3.7 million, respectively, an increase of \$1.7 million or 46%, which was driven by the increase in revenues and partially offset by lower

**Table of Contents**

supply costs. These amounts include 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 API included in the calculation of the average cost of goods sold during the three months ended September 30, 2014 and 2013 was sourced from two API suppliers. The contracted cost of supply from our initial API supplier was higher than the contracted cost from our other API supplier. In the future, we anticipate making continued purchases from this initial supplier and to make additional lower unit cost purchases of Vascepa API from other API suppliers. We began purchasing lower unit cost API from Chemport, which was approved by the FDA in April 2013 to produce Vascepa, in the second quarter of 2013. During the three months ended September 30, 2014 and 2013, the cost basis of product sold that had a carrying value of zero was \$0.6 million and zero, respectively. Had such inventories been valued at acquisition cost, it would have resulted in a corresponding increase in cost of goods sold and a decrease in gross margin during such periods. As of September 30, 2014, we maintained no inventory with a carrying value of zero.

Our gross margin for the three months ended September 30, 2014 and 2013 was 62% and 56%, respectively. This improvement was primarily driven by lower unit cost API purchases. In addition, over time we expect continued lower average unit cost purchases of API. We also expect that API costs will be lower in the future due to advantages derived from the mix of our suppliers. The average cost may be variable from period to period depending upon the timing and quantity of API purchased from each supplier.

*Selling, General and Administrative Expense.* Selling, general and administrative expense for the three months ended September 30, 2014 and 2013 was \$19.3 million and \$28.3 million, respectively, a decrease of \$9.0 million, or 32%. Selling, general and administrative expenses for the three months ended September 30, 2014 and 2013 are summarized in the table below (in thousands):

	Three months Ended	
	September 30	
	2014	2013
Selling, general and administrative expenses, excluding non-cash expenses (1)	\$ 18,284	\$ 24,333
Non-cash stock-based compensation expense (2)	1,312	3,665
Non-cash warrant related compensation (income) expense (3)	(326)	276
	\$ 19,270	\$ 28,274

- (1) Selling, general and administrative expense, excluding non-cash compensation charges for stock compensation and warrants, for the three months ended September 30, 2014 and 2013 was \$18.3 million and \$24.3 million, respectively, a decrease of \$6.0 million, or 25%. The decrease was due primarily to cost decreases in 2014 for sales force staffing, marketing program spending and costs for other general and administrative support incurred in connection with the commercialization of Vascepa.
- (2) Stock-based compensation expense for the three months ended September 30, 2014 and 2013 was \$1.3 million and \$3.7 million, respectively, a decrease of \$2.4 million, or 65%, primarily due to a decrease in the fair value of new stock option and restricted stock awards granted to attract and retain qualified employees as a result of a decrease in our stock price.
- (3) Warrant-related compensation (income) expense for the three months ended September 30, 2014 and 2013 was income of \$0.3 million and expense of \$0.3 million, respectively. Warrant related compensation (income) expense for the periods ended September 30, 2014 and 2013 reflects a non-cash change in fair value of the warrant derivative liability associated with warrants issued in October 2009 to three of our former employees, net of warrants exercised. The change in the fair value of the warrants is due primarily to the change in our stock price during each period. We anticipate that the value of this warrant derivative liability may increase or decrease from period to period based upon changes in the price of our common stock. Such non-cash changes in valuation could be significant as the history of our stock price has been volatile. The gain or loss resulting from such non-cash changes in valuation could have a material impact on our reported net income or loss from period to period. In particular, if the price of our stock increases, the change in valuation of this warrant derivative liability will add to our history of operating losses.

We anticipate a reduction in the level of selling, general and administrative costs in 2014 as compared to 2013 as a result of the reduction in force announced in October 2013 and expected reductions in certain marketing program spend and other overhead costs. Such cost reductions



will be partially offset by the incremental selling costs associated with the Kowa Pharmaceuticals America co-promotion agreement.

**Table of Contents**

*Research and Development Expense.* Research and development expense for the three months ended September 30, 2014 and 2013 was \$14.5 million and \$16.8 million, respectively, a decrease of \$2.3 million, or 14%. Research and development expenses for the three months ended September 30, 2014 and 2013 are summarized in the table below (in thousands):

	<b>Three months Ended September 30,</b>	
	<b>2014</b>	<b>2013</b>
REDUCE-IT study (1)	\$ 11,753	\$ 9,126
Pre-approval commercial supply (2)		2,623
Regulatory filing fees and expenses (3)	385	976
Internal staffing, overhead and other (4)	1,709	3,506
<b>Research and development expense, excluding non-cash expense</b>	<b>13,847</b>	<b>16,231</b>
Non-cash stock-based compensation (5)	610	590
<b>Total research and development expense</b>	<b>\$ 14,457</b>	<b>\$ 16,821</b>

The decrease in research and development expenses for the quarter ended September 30, 2014, as compared to the prior year period, is primarily due to a decrease in expenses associated with pre-commercial inventory supply and a decrease in staffing and overhead costs, 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, the epidemiology of the patients enrolled in the study, and the length of time that the enrolled patients are followed. 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. We currently have over 7,100 patients enrolled in REDUCE-IT. We estimate that we will complete patient enrollment in this study within 2015. For the three months ended September 30, 2014 and 2013, we incurred expenses through our CRO in connection with this trial of approximately \$9.5 million and \$8.3 million, respectively. Inclusive of CTM costs, the combined CRO and CTM costs in the three months ended September 30, 2014 and 2013 for REDUCE-IT were approximately \$11.8 million and \$9.1 million, respectively. 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 costs incurred for this study in 2014 will continue at approximately the same levels as we have incurred in 2013 but may vary from quarter to quarter. 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.
- (2) 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. The amount of commercial supply that we receive from potential additional API suppliers prior to sNDA approval depends upon production schedules at such suppliers 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.
- (3) The regulatory filing fees in each of the three months ended September 30, 2014 and 2013 included annual FDA fees for maintaining manufacturing sites.
- (4) Internal staffing, overhead and other research and development expenses primarily relate to the costs of our personnel employed to manage 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. Other research

and development costs in 2013 also include costs related to testing of the relative bioavailability of AMR102 capsules, Vascepa capsules with a selected statin taken concomitantly. We have suspended additional development of AMR102 pending resolution of the ANCHOR sNDA with the FDA.

- (5) 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.

*Gain (Loss) on Change in Fair Value of Derivative Liabilities.* Gain (loss) on change in fair value of derivative liabilities for the three months ended September 30, 2014 and 2013 was a gain of \$4.5 million and a loss of \$1.4 million, respectively. Gain (loss) 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

---

**Table of Contents**

value of the derivative liability related to the change in control provision associated with the December 2012 BioPharma financing, (iii) the change in fair value of the derivative liability related to the change in control provision associated with the May 2014 exchangeable senior notes and (iv) an unrealized loss on foreign exchange contracts for the three months ended September 30, 2013.

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, 2014 was \$4.5 million and we recognized a \$4.1 million gain on change in fair value of derivative liability for the quarter ended September 30, 2014 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 quarter ended September 30, 2013 for these warrants. The decrease or increase in the fair value of the warrant derivative liability is due primarily to the decrease or increase in the price of our common stock on the date of valuation.

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, 2014, the fair value of the derivative was determined to be \$6.1 million, and at September 30, 2014, the fair value of the derivative was determined to be \$4.6 million. We recognized a \$1.5 million gain on change in fair value of derivative liability for the three months ended September 30, 2014. 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.

Our 2014 Notes contain a redemption feature whereby, upon occurrence of a change in control, we would be required to repurchase the notes. The fair value of the embedded derivative was calculated using a probability-weighted model incorporating management estimates of the probability of a change in control occurring, and by determining the fair value of the debt with and without the change in control provision included. The difference between the two was determined to be the fair value of the embedded derivative. At June 30, 2014, the fair value of the derivative was determined to be \$3.3 million and at September 30, 2014, the fair value of the derivative was determined to be \$4.4 million. We recognized a \$1.1 million loss on change in fair value of derivative liability for the three months ended September 30, 2014.

We periodically use foreign exchange forward contracts to hedge against changes in exchange rates for inventory purchases denominated in foreign currency. As of September 30, 2014, there were no such outstanding contracts. As of September 30, 2013 we held a 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.

**Table of Contents**

*Interest Expense, net.* Net interest expense for the three months ended September 30, 2014 and 2013 was \$4.9 million and \$8.4 million, respectively, a decrease of \$3.5 million, or 42%. Net interest expense for the three months ended September 30, 2014 and 2013 is summarized in the table below (in thousands):

	<b>Three months Ended September 30,</b>	
	<b>2014</b>	<b>2013</b>
<b>Exchangeable senior notes (1):</b>		
Amortization of debt discounts	\$ 1,425	\$ 3,859
Contractual coupon interest	1,313	1,313
<b>Total exchangeable senior notes interest expense</b>	<b>2,738</b>	<b>5,172</b>
<b>Long-term debt BioPharma financing (2):</b>		
Cash interest current	1,415	840
Cash interest deferred	282	1,819
Non-cash interest	453	632
<b>Total long-term debt interest expense</b>	<b>2,150</b>	<b>3,291</b>
<b>Total interest expense</b>	<b>4,888</b>	<b>8,463</b>
<b>Interest income (3)</b>	<b>(12)</b>	<b>(22)</b>
<b>Total interest expense, net</b>	<b>\$ 4,876</b>	<b>\$ 8,441</b>

- (1) Cash and non-cash interest expense related to the exchangeable senior notes for the three months ended September 30, 2014 and 2013 was \$2.7 million and \$5.2 million, respectively.
- (2) Cash and non-cash interest expense related to the BioPharma financing for three months ended September 30, 2014 and 2013 was \$2.2 million and \$3.3 million, respectively. These amounts reflect the assumption that our Vascepa revenue levels will not 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. To date, our revenues have been below the contractual threshold amount each quarter such that each payment reflects the calculated optional reduction amount as opposed to the contractual threshold payments for each quarterly period.
- (3) Interest income for the three months ended September 30, 2014 and 2013 was \$0.01 million and \$0.02 million, respectively. Interest income represents income earned on cash balances.

*Other (Expense) Income, net.* Other (expense) income, net for the three months ended September 30, 2014 and 2013 was expense of \$0.2 million and \$0.3 million, respectively. Other (expense) income, net primarily consists of losses and gains on foreign exchange transactions, including realized gains and losses on foreign exchange forward contracts. We periodically use foreign exchange forward contracts to hedge against changes in exchange rates for inventory purchases denominated in foreign currency.

*(Provision for) Benefit from Income Taxes.* (Provision for) benefit from income taxes for the three months ended September 30, 2014 and 2013 was a provision of \$0.4 million and a benefit of \$1.6 million, respectively. The current provision relates entirely to the United States subsidiary operations. We are profitable in the United States as a result of intercompany transactions between our United States subsidiary and our other subsidiaries.

**Comparison of Nine Months Ended September 30, 2014 and September 30, 2013**

*Revenue.* We recorded revenue of \$37.7 million and \$16.2 million during the nine months ended September 30, 2014 and 2013, respectively, an increase of \$21.5 million, or 133%. We commenced our full commercial launch of Vascepa in the United States for use in the MARINE indication in January 2013. All of our revenue in the nine months ended September 30, 2014 and 2013 was derived from product sales of Vascepa, net of allowances, discounts, incentives, rebates, chargebacks and returns.

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

We sell Vascepa to Distributors. In accordance with GAAP, until we had the ability to reliably estimate returns of Vascepa from our Distributors, revenue was recognized based on the resale of Vascepa for the purposes of filling patient prescriptions, and not based on our sales to such Distributors. Beginning in January 2014, we concluded that we had developed sufficient history such that we can reliably estimate returns and as a result, began to recognize revenue based on sales to our Distributors. Through September 30, 2014, product returns were de minimis. Timing of shipments to wholesalers, as used for revenue recognition, and timing of prescriptions as estimated by third party sources such as Symphony Health Solutions and IMS Health may differ from period to period.

**Table of Contents**

During the nine months ended September 30, 2014 and 2013, our net product revenues included an adjustment for co-pay mitigation rebates provided by us to commercially insured patients. Patients not covered on tier 2 by their commercial insurance carrier pay a higher co-pay payment when purchasing Vascepa. Such rebates are intended to offset the cost differential for such patients. Our cost for these co-payment mitigation rebates was up to \$75 per prescription filled prior to February 20, 2014 and up to \$70 per prescription filled after February 20, 2014 to September 30, 2014. Commencing in March 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. The number of lives covered by these payors increased throughout 2013 and continued to increase in 2014. As of November 1, 2014, over 119 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 in the pharmaceutical industry, the majority of Vascepa sales are to major commercial wholesalers which then resell Vascepa to retail pharmacies. As of November 1, 2014, over 23,000 clinicians had written prescriptions for Vascepa. As of November 1, 2014, 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 50% 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 the resulting target base coverage and the addition of the promotional efforts of 250 sales representatives from Kowa Pharmaceuticals America which commenced in May 2014, 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 nine months ended September 30, 2014 and 2013 was \$14.6 million and \$7.8 million, respectively, an increase of \$6.8 million or 87%, which was driven by the increase in revenues and partially offset by lower supply costs. These amounts include 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 API included in the calculation of the average cost of goods sold during 2013 and the nine months ended September 30, 2014 was sourced from two API suppliers. The contracted cost of supply from our initial API supplier was higher than the contracted cost from our other API supplier. 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 and to make additional lower unit cost purchases of Vascepa API from other API suppliers. We began purchasing lower unit cost API from Chemport, which was approved by the FDA in April 2013 to produce Vascepa, in the second quarter of 2013. During the nine months ended September 30, 2014 and 2013, the cost basis of product sold that had a carrying value of zero was \$0.6 million and \$4.0 million, respectively. Had such inventories been valued at acquisition cost, it would have resulted in a corresponding increase in cost of goods sold and a decrease in gross margin during such periods. As of September 30, 2014, we maintained no inventory with a carrying value of zero.

Our gross margin for the nine months ended September 30, 2014 and 2013 was 61% and 52%, respectively. This improvement was primarily driven by lower unit cost API purchases. In addition, over time we expect continued lower average unit cost purchases of API. We also expect that API costs will be lower in the future due to advantages derived from the mix of our suppliers. The average cost may be variable from period to period depending upon the timing and quantity of API purchased from each supplier.

*Selling, General and Administrative Expense.* Selling, general and administrative expense for the nine months ended September 30, 2014 and 2013 was \$60.9 million and \$101.5 million, respectively, a decrease of \$40.6 million, or 40%. Selling, general and administrative expenses for the nine months ended September 30, 2014 and 2013 are summarized in the table below (in thousands):

Nine months Ended	
September 30	
2014	2013

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

Selling, general and administrative expenses, excluding non-cash expenses (1)	\$ 57,108	\$ 90,664
Non-cash stock-based compensation expense (2)	4,344	12,017
Non-cash warrant related compensation income (3)	(503)	(1,179)
	\$ 60,949	\$ 101,502



**Table of Contents**

- (1) Selling, general and administrative expense, excluding non-cash compensation charges for stock compensation and warrants, for the nine months ended September 30, 2014 and 2013 was \$57.1 million and \$90.7 million, respectively, a decrease of \$33.6 million, or 37%. The decrease was due primarily to cost decreases in 2014 for sales force staffing, marketing program spending and costs for other general and administrative support incurred in connection with the commercialization of Vascepa. The nine months ended September 30, 2013 was the period in which we were commenced selling Vascepa and costs during this period included certain launch-related costs.
- (2) Stock-based compensation expense for the nine months ended September 30, 2014 and 2013 was \$4.3 million and \$12.0 million, respectively, a decrease of \$7.7 million, or 64%, primarily due to a decrease in the fair value of new stock option and restricted stock awards granted to attract and retain qualified employees as a result of a decrease in our stock price.
- (3) Warrant-related compensation income for the nine months ended September 30, 2014 and 2013 was \$0.5 million and \$1.2 million, respectively. Warrant related compensation income for the nine months ended September 30, 2014 and 2013 reflects a non-cash change in fair value of the warrant derivative liability associated with warrants issued in October 2009 to three of our former employees, net of warrants exercised. The decrease in the fair value of the warrants is due primarily to a decrease in our stock price during each period. We anticipate that the value of this warrant derivative liability may increase or decrease from period to period based upon changes in the price of our common stock. Such non-cash changes in valuation could be significant as the history of our stock price has been volatile. The gain or loss resulting from such non-cash changes in valuation could have a material impact on our reported net income or loss from period to period. In particular, if the price of our stock increases, the change in valuation of this warrant derivative liability will add to our history of operating losses.

We anticipate a reduction in the level of selling, general and administrative costs in 2014 as compared to 2013 as a result of the reduction in force announced in October 2013 and expected reductions in certain marketing program spend and other overhead costs. Such cost reductions will be partially offset by the incremental selling costs associated with the Kowa Pharmaceuticals America co-promotion agreement.

*Research and Development Expense.* Research and development expense for the nine months ended September 30, 2014 and 2013 was \$37.9 million and \$56.1 million, respectively, a decrease of \$18.2 million, or 32%. Research and development expenses for the nine months ended September 30, 2014 and 2013 are summarized in the table below (in thousands):

	<b>Nine months Ended September 30,</b>	
	<b>2014</b>	<b>2013</b>
REDUCE-IT study (1)	\$ 28,409	\$ 34,154
Pre-approval commercial supply (2)	373	5,783
Regulatory filing fees and expenses (3)	1,383	2,658
Internal staffing, overhead and other (4)	5,797	11,352
Research and development expense, excluding non-cash expense	35,962	53,947
Non-cash stock-based compensation (5)	1,929	2,201
<b>Total research and development expense</b>	<b>\$ 37,891</b>	<b>\$ 56,148</b>

The decrease in research and development expenses for the nine months ended September 30, 2014, as compared to the prior year period, is primarily due to a decrease in costs associated with the REDUCE-IT study, a decrease in expenses associated with pre-commercial inventory supply, and a decrease in staffing and overhead costs, 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, the epidemiology of the patients enrolled in the study, and the length of time that the enrolled patients are followed. 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. We currently have over

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

7,100 patients enrolled in REDUCE-IT. We estimate that we will complete patient enrollment in this study within 2015. For the nine months ended September 30, 2014 and 2013, we incurred expenses through our CRO in connection with this trial of approximately \$22.3 million and \$28.0 million, respectively. Inclusive of CTM costs,

**Table of Contents**

- the combined CRO and CTM costs in the nine months ended September 30, 2014 and 2013 for REDUCE-IT were approximately \$28.4 million and \$34.2 million, respectively. 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 costs incurred for this study in 2014 will continue at approximately the same levels as we have incurred in 2013 but may vary from quarter to quarter. 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.
- (2) 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. The amount of commercial supply that we receive from other potential API suppliers to their sNDA approval depends upon production schedules at such suppliers 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.
  - (3) The regulatory filing fees in each of the nine months ended September 30, 2014 and 2013 included annual FDA fees for maintaining manufacturing sites. In addition, during the nine months ended September 30, 2013, these fees included regulatory filings associated with the sNDA for the ANCHOR indication as well as costs associated with preparing for the October 16, 2013 FDA advisory committee meeting.
  - (4) 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. Other research and development costs in 2013 also include costs related to testing of the relative bioavailability of AMR102 capsules, Vascepa capsules with a selected statin taken concomitantly. We have suspended additional development of AMR102 pending resolution of the ANCHOR sNDA with the FDA.
  - (5) 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.

*Gain (Loss) on Change in Fair Value of Derivative Liabilities.* Gain (loss) on change in fair value of derivative liabilities for the nine months ended September 30, 2014 and 2013 was a gain of \$11.9 million and a gain of \$21.1 million, respectively. Gain (loss) 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, (iii) the change in fair value of the derivative liability related to the change in control provision associated with the May 2014 exchangeable senior notes and (iv) an unrealized loss on foreign exchange contracts for the nine months ended September 30, 2013.

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, 2013 was \$6.9 million and we recognized a \$6.3 million gain on change in fair value of derivative liability for the nine months ended September 30, 2014 for these warrants. 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 decrease or increase in the fair value of the warrant derivative liability is due primarily to the decrease or increase in the price of our common stock on the date of valuation.

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, 2013, the fair value of the derivative was determined to be \$11.1 million, and at September 30, 2014, the fair value of the derivative was determined to be \$4.6 million. We recognized a \$6.5 million gain on change in fair value of derivative liability for the nine months ended September 30, 2014. 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.



**Table of Contents**

Our 2014 Notes contain a redemption feature whereby, upon occurrence of a change in control (as defined), we would be required to repurchase the notes. The fair value of the embedded derivative was calculated using a probability-weighted model incorporating management estimates of the probability of a change in control occurring, and by determining the fair value of the debt with and without the change in control provision included. The difference between the two was determined to be the fair value of the embedded derivative. At September 30, 2014, the fair value of the derivative was determined to be \$4.4 million. We recognized a \$0.9 million loss on change in fair value of derivative liability for the nine months ended September 30, 2014.

We periodically use foreign exchange forward contracts to hedge against changes in exchange rates for inventory purchases denominated in foreign currency. As of September 30, 2014, there were no such outstanding contracts. As of September 30, 2013 we held a 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.

*Gain on Extinguishment of Debt.* On May 15, 2014, we entered into separate, privately negotiated exchange agreements with certain holders of our exchangeable senior notes pursuant to which we exchanged \$118.7 million in aggregate principal amount of existing exchangeable senior notes for \$118.7 million in aggregate principal amount of new 3.50% exchangeable senior notes due 2032. The key changes in the terms of the new notes included moving the first put date from January 2017 to January 2019, adding an issuer conversion option whereby we can opt to convert the notes into equity should the Daily VWAP (as defined in the Indenture) exceed \$2.86 for a certain number of days and reducing the conversion price (see Note 6). As a result of the exchange, we assessed the value of the notes immediately prior to the exchange and immediately after the exchange and determined that the exchange resulted in a substantial modification of the terms of the notes resulting in an extinguishment of the original notes. We subsequently recorded a gain on extinguishment of the original notes of \$38.0 million in the nine months ended September 30, 2014.

*Interest Expense, net.* Net interest expense for the nine months ended September 30, 2014 and 2013 was \$13.6 million and \$26.6 million, respectively, a decrease of \$13.0 million, or 49%. Net interest expense for the nine months ended September 30, 2014 and 2013 is summarized in the table below (in thousands):

	<b>Nine months Ended September 30,</b>	
	<b>2014</b>	<b>2013</b>
<b>Exchangeable senior notes (1):</b>		
Amortization of debt discounts	\$ 2,756	\$ 11,066
Contractual coupon interest	3,937	3,938
<b>Total exchangeable senior notes interest expense</b>	<b>6,693</b>	<b>15,004</b>
<b>Long-term debt BioPharma financing (2):</b>		
Cash interest current	3,772	840
Cash interest deferred	1,728	8,854
Non-cash interest	1,435	2,166
<b>Total long-term debt interest expense</b>	<b>6,935</b>	<b>11,860</b>
Other interest expense	1	
<b>Total interest expense</b>	<b>13,629</b>	<b>26,864</b>
Interest income (3)	(64)	(218)
<b>Total interest expense, net</b>	<b>\$ 13,565</b>	<b>\$ 26,646</b>

(1) Cash and non-cash interest expense related to the exchangeable senior notes for the nine months ended September 30, 2014 and 2013 was \$6.7 million and \$15.0 million, respectively.

(2)

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

Cash and non-cash interest expense related to the BioPharma financing for nine months ended September 30, 2014 and 2013 was \$6.9 million and \$11.9 million, respectively. These amounts reflect the assumption that our Vascepa revenue levels will not 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. To date, our revenues have been below the contractual threshold amount such that each payment reflects the calculated optional reduction amount as opposed to the contractual threshold payments for each quarterly period.

- (3) Interest income for the nine months ended September 30, 2014 and 2013 was \$0.06 million and \$0.2 million, respectively. Interest income represents income earned on cash balances.

*Other (Expense) Income, net.* Other (expense) income, net for the nine months ended September 30, 2014 and 2013 was income of \$4.0 million and expense of \$0.8 million, respectively. Other (expense) income, net in the nine months ended September 30, 2014

**Table of Contents**

primarily consists of \$4.1 million received in the second quarter of 2014 with respect to settlement agreements with one of our suppliers and one of our encapsulators that provided for the reimbursement of certain amounts previously paid by us. Other (expense) income, net for the nine months ended September 30, 2013 primarily consisted of losses and gains on foreign exchange transactions, including realized gains and losses on foreign exchange forward contracts. We periodically use foreign exchange forward contracts to hedge against changes in exchange rates for inventory purchases denominated in foreign currency.

*(Provision for) Benefit from Income Taxes.* (Provision for) benefit from income taxes for the nine months ended September 30, 2014 and 2013 was a provision of \$1.3 million and a benefit of \$4.8 million, respectively. The current provision relates entirely to the United States subsidiary operations. We are profitable in the United States as a result of intercompany transactions between our United States subsidiary and our other companies.

**Liquidity and Capital Resources**

Our sources of liquidity as of September 30, 2014 include cash and cash equivalents of \$135.4 million. Our projected uses of cash include commercialization of Vascepa for the MARINE indication, the continued funding of the REDUCE-IT cardiovascular outcomes study, working capital and other general corporate activities. Our cash flows from operating, investing and financing activities, as reflected in the consolidated statements of cash flows, are summarized in the following table (in millions):

	<b>Nine months Ended September 30,</b>	
	<b>2014</b>	<b>2013</b>
Cash (used in) provided by continuing operations:		
Operating activities	\$ (58.7)	\$ (157.2)
Investing activities		
Financing activities	2.6	122.9
Decrease in cash and cash equivalents	\$ (56.1)	\$ (34.3)

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. As of September 30, 2014, the net remaining amount to be repaid to BioPharma is \$145.8 million. To date, our revenues have been below the contractual threshold amount such that each payment made has reflected the calculated optional reduction amount as opposed to the contractual threshold payments for each quarterly period. The quarterly repayments through the third quarter of September 2014 represented interest only. 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. No additional interest expense or liability is incurred as a result of such deferred repayments. The agreement does not expire until \$150 million in aggregate has been repaid. We can prepay 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.

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, or the 2012 Notes. The proceeds we received from the January 2012 debt offering were approximately \$144.3 million, net of fees and transaction costs. On May 20, 2014, we entered into separate, privately negotiated exchange agreements with certain holders of the 2012 Notes pursuant to which Corsicanto exchanged \$118.7 million in aggregate principal amount of the 2012 Notes for \$118.7 million in aggregate principal amount of new 3.50% May 2014 Exchangeable Senior Notes due 2032, or the 2014 Notes, following which \$31.3 million in aggregate principal amount of the 2012 Notes remain outstanding with terms unchanged.

The 2012 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 2012 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,

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

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



**Table of Contents**

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.

The 2014 Notes were issued pursuant to an indenture dated May 20, 2014 by and among Corsicanto, us as grantor, and Wells Fargo Bank, National Association, as trustee. The notes are senior unsecured obligations of Corsicanto and are guaranteed by us. The 2014 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, 2014, and ending upon the Notes' maturity on January 15, 2032, unless earlier repurchased or redeemed by Corsicanto or exchanged by the holders. At any time after the issuance of the 2014 Notes and prior to the close of business on the second business day immediately preceding January 15, 2032, holders may exchange their 2014 Notes at their option. If prior to January 15, 2018, a make-whole fundamental change (as defined in the Indenture) occurs or we elect to redeem the 2014 Notes in connection with certain changes in tax law, in each case as described in the Indenture, and a holder elects to exchange its 2014 Notes in connection with such make-whole fundamental change or election, as the case may be, such holder may be entitled to an increase in the exchange rate as described in the Indenture. The exchange rate will initially be 384.6154 ADSs per \$1,000 principal amount of the 2014 Notes (equivalent to an initial exchange price of approximately \$2.60 per ADS, or the Exchange Price), subject to adjustment in certain circumstances. The exchange rate is subject to adjustment from time to time upon the occurrence of certain events, including, but not limited to, the payment of cash dividends.

As of September 30, 2014, we had cash and cash equivalents of \$135.4 million, a decrease of \$56.1 million from December 31, 2013. The decrease is primarily due to net cash used in operating activities in support of the continued commercialization of Vascepa less accounts receivable collections. Cash flows from financing activities in the nine months ended September 30, 2014 include a refund of \$3.2 million for UK stamp duty taxes paid in prior periods related to the issuance of common stock. We have incurred annual operating losses since our inception and, as a result, we had an accumulated deficit of \$950.6 million as of September 30, 2014. We believe that our cash and cash equivalents balance of \$135.4 million at September 30, 2014 will be sufficient to fund our projected operations for at least the next twelve months. We anticipate that net cash outflows in 2014 will be significantly lower than net cash outflows in 2013 as a result of a reduction in expenses associated with the commercialization of Vascepa, lower headcount and lower supply purchases.

**Contractual Obligations**

The following table summarizes our contractual obligations at September 30, 2014 and the effects such obligations are expected to have on our liquidity and cash flows in future periods (in millions):

**Payments Due by Period**

(in millions)

	Total	2014	2015 to 2016	2017 to 2018	After 2018
Purchase Obligations (1)	\$ 54.5	\$ 1.4	\$ 26.6	\$ 22.7	\$ 3.8
Operating Lease Obligations (2)	2.2	0.2	1.2	0.8	
Interest Payment Obligations Exchangeable Debt (3)	21.5		10.5	8.9	2.1
Total Contractual Cash Obligations	\$ 78.2	\$ 1.6	\$ 38.3	\$ 32.4	\$ 5.9

- (1) We have agreements with API suppliers which include minimum purchase levels to enable us to maintain certain exclusivity with each respective supplier and certain agreements require any shortfall in such purchase levels to be paid in cash. The amounts in the table above reflect amounts potentially payable to our suppliers based on our minimum purchase obligations. Each supplier is required to meet certain performance obligations and the agreements may be terminated by us in the event of non-performance.
- (2) Represents operating lease costs, primarily consisting of leases for facilities in Dublin, Ireland, Bedminster, NJ and Groton, CT.
- (3) Represents scheduled interest payments due under the terms of the 2012 Notes and 2014 Notes, assuming that the 2012 Notes remain outstanding through January 19, 2017 and that the 2014 Notes remain outstanding through January 19, 2019 and they 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.

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

On December 6, 2012 the Company entered into an agreement with BioPharma Secured Debt Fund II Holdings Cayman LP, or 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 million received at the closing of the agreement which occurred in December 2012. The Company has agreed to repay BioPharma up to \$150 million of future revenue and receivables. As of September 30, 2014, the net remaining amount to be repaid to BioPharma is \$145.8 million. To date, each payment made has reflected the calculated optional reduction amount as opposed to the contractual threshold payments for each quarterly period. These quarterly payments are subject to

**Table of Contents**

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 our election be reduced and with the reduction carried forward without interest for payment in a future period.

We do not enter into financial instruments for trading or speculative purposes. At September 30, 2014, we had no outstanding forward exchange contracts. At September 30, 2013, we held a forward exchange contract with a notional amount of \$4.5 million to hedge payments made in foreign currency for API supply and we recorded an unrealized loss of \$0.4 million for one outstanding foreign exchange contract.

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). In April 2014, we reached a settlement agreement with BASF under which we received a refund for material purchases of \$3.0 million. The Chemport supply agreement provides access to additional API supply that is incremental to supply from Nisshin, our other existing FDA-approved API supplier. The Chemport agreement includes minimum annual purchase levels enabling us to maintain supply exclusivity. The Chemport and Slanmhor agreements also include a provision that any shortfall in the minimum purchase commitments is payable in cash, and the maximum amounts payable pursuant to this provision are reflected in the table above. The API supply agreement with BASF terminated in February 2014.

The 2011 supply agreement with Chemport includes commitments for us to fund (i) certain development fees (ii) material purchases for initial raw materials, which amount will be credited against future API purchases and (iii) a raw material purchase commitment. During the nine months ended September 30, 2014, we made payments of \$3.3 million to Chemport. We have paid \$3.1 million to BASF related to development and supply commitments through September 30, 2014. We have paid \$6.2 million to Slanmhor related to development and supply provisions through September 30, 2014 and during the nine months ended September 30, 2014 and 2013, we made payments of \$0.4 million and \$6.1 million, respectively, related to stability and technical batches and advances on anticipated future API purchases.

Concurrent with our supply agreement with Chemport entered into in 2011 for the supply of API materials for Vascepa, we agreed to make a non-controlling minority share equity investment in the supplier of up to \$3.3 million. We invested \$1.7 million under this agreement in July 2011 and the remaining \$1.6 million during 2012. In September 2013, we entered into an equity sale and purchase agreement between this supplier and a third party in which we agreed to sell approximately \$1.3 million of our investment in the supplier to the third party at cost. This transaction closed in the first quarter of 2014. The carrying amount of \$2.0 million and \$3.3 million as of September 30, 2014 and December 31, 2013, respectively, is included in other long term assets and is accounted for under the cost method.

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 for the nine months ended September 30, 2014 and 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 \$12.2 million at September 30, 2014). Additionally, 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, 2014) for each of the two potential market approvals (i.e. £10 million maximum, or approximately \$16.2 million at September 30, 2014).

In addition to the obligations in the table above, we have recorded a liability of \$0.6 million for uncertain tax positions that have been recorded in long-term liabilities at September 30, 2014. 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.

**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 27, 2014.



## **Table of Contents**

### **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, 2014, 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, 2014, 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, 2014, 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**

We have been in the process of appealing the October 2013 rescission of the Special Protocol Assessment, or SPA, agreement related to our ANCHOR clinical trial within the FDA in accordance with FDA dispute resolution guidance. A 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. As a basis for this determination, the FDA communicated that, consistent with discussion at the related, public October 16, 2013 advisory committee meeting, it 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 agreement including documents outlining why we believe the SPA was wrongfully rescinded. On November 21, 2013, we received notification from the dispute resolution group of the Office of New Drugs at the FDA that it had not accepted for review, on procedural grounds, our appeal regarding the rescission of the SPA. We were also notified by the FDA that our request for a meeting at a high level within the FDA regarding the appeal was not granted and that we would first need to address the matter at the division level within the FDA. On December 19, 2013, the FDA notified us it did not expect to take action on our underlying sNDA on December 20, 2013 because our request to re-instate the ANCHOR SPA agreement remained under consideration with the FDA. The FDA also communicated to us that, as of December 19, 2013, it viewed our appeal of the ANCHOR SPA agreement rescission and the ANCHOR sNDA as separate administrative decisions worthy of separate consideration and that the FDA planned to complete its review of our request to re-instate the ANCHOR SPA agreement. The FDA provided no additional information on when it expects to complete its review of the ANCHOR sNDA.

On January 17, 2014, the Division of Metabolism and Endocrinology Products, or DMEP, within the FDA notified Amarin in connection with Amarin's request for reconsideration of the October 2013 decision to rescind the ANCHOR SPA agreement that the DMEP does not plan to re-instate the ANCHOR SPA agreement. We appealed the DMEP decision to the next level within the FDA, the Office of Drug Evaluation II, or ODE II, and were informed in late April 2014, that ODE II determined to uphold the DMEP rescission determination. We appealed the ODE II decision to the next level within the FDA, the Director of the Office of New Drugs, Dr. John Jenkins, in accordance with FDA dispute resolution guidance and our appeal was denied on September 11, 2014.

In September 2014, based on the FDA's repeated position in its appeal denials and its internal consultation with FDA officials at higher levels, we determined and informed the FDA that we did not intend to appeal the SPA rescission further.

On November 1, 2013, a purported investor of Amarin filed a putative class action lawsuit captioned *Steven Sklar v. Amarin Corporation plc et al.*, No. 13-cv-6954 (D.N.J. Nov. 1, 2013) in the U.S. District Court for the District of New Jersey. Substantially similar lawsuits, captioned *Bove v. Amarin Corporation plc*, Civ. No. 13-07882 (AT) (S.D.N.Y. Nov. 5, 2013), *Bentley v. Amarin Corporation plc*, Civ. No. 13-08283 (AT) (S.D.N.Y. Nov. 20, 2013) and *Siegel v. Amarin Corporation plc*, No. 3:13-cv-07210 (D.N.J. Nov. 27, 2013), were subsequently filed in the U.S. District Court for the District of New Jersey and U.S. District Court for the Southern District of New York. On December 9, 2013, the cases filed in the Southern District of New York were transferred to the District of New Jersey and all such cases are now consolidated as *In re Amarin Corporation plc, Securities Litigation*, No. 3:13-cv-06663 (D.N.J. Nov. 1, 2013). The plaintiffs assert claims under the Securities Exchange Act of 1934 and allege that Amarin and certain of its current and former officers and directors made misstatements and omissions regarding the FDA's willingness to approve Vascepa's ANCHOR indication and related contributing factors and the potential relevance of data from the ongoing REDUCE-IT trial to that approval. The lawsuit seeks unspecified monetary damages and attorneys fees and costs. We believe that we have valid defenses and we will vigorously defend against this class action suit, but cannot predict the outcome. We are unable to reasonably estimate the loss exposure, if any, associated with the claims. We have insurance coverage that is anticipated to cover any significant loss exposure that may arise from this action after payment by us of the associated deductible obligation under such insurance coverage.

On February 27, 2014, we commenced a lawsuit against the FDA in the U.S. District Court for the District of Columbia captioned *Amarin Pharmaceuticals Ireland Ltd. v. Food & Drug Administration, et al.*, Civ. A. No. 14-0324 (D.D.C.) that challenges FDA's denial of our request for five-year NCE exclusivity for Vascepa based on our reading of the relevant statute, our view of FDA's inconsistency with its past actions in

this area and the retroactive effect of what we believe is a new policy at FDA as it relates

## Table of Contents

to our situation. Our complaint requests that the court vacate FDA's decision, declare that Vascepa is entitled to the benefits of five-year statutory exclusivity, bar the FDA from accepting any ANDA or similar application for which Vascepa is the reference-listed drug until after the statutory exclusivity period and set aside what we contend are due to the denial of five-year exclusivity to Vascepa prematurely accepted pending ANDA applications. We intend to litigate the case vigorously, but we cannot predict the outcome of this lawsuit.

On March 4, 2014, we filed a lawsuit for patent infringement of U.S. Patent No. 8,663,662 in the U.S. District Court for the District of Delaware against AstraZeneca Pharmaceuticals LP and its subsidiary, Omthera Pharmaceuticals, Inc., captioned *Amarin Pharmaceuticals Ireland Limited v. Omthera Pharmaceuticals, Inc. et al.*, Civ. A. No. 1:14-cv-00279 (D.Del). On June 23, a second complaint was filed against AstraZeneca and Omthera, captioned *Amarin Pharmaceuticals Ireland Limited v. Omthera Pharmaceuticals, Inc. et al.*, Civ. A. No. 1:14-cv-00791 (D.Del). That second complaint replaced the first complaint, which was voluntarily dismissed on June 27, and was filed in order to expedite the progress of this litigation on the merits. The focus of the lawsuit is the commercial marketing of Epanova® (omega-3-carboxylic acids) capsules in the United States. Epanova was approved by the FDA in May 2014 with substantially the same indication as Vascepa and is expected to compete with Vascepa. We are seeking damages and injunctive relief in the litigation. We intend to litigate the case vigorously, but we cannot predict the outcome of this lawsuit.

In March, April, and May 2014, we received paragraph IV certification notices from six companies contending to varying degrees that certain of our patents are invalid, unenforceable and/or will not be infringed by the manufacture, use, sale or offer for sale of a generic form of Vascepa as described in those companies' abbreviated new drug applications, or ANDAs. We have commenced patent infringement lawsuits against each of these ANDA applicants. In each of the lawsuits, Amarin is seeking, among other remedies, an order enjoining the defendants from marketing generic versions of Vascepa before the last to expire of the asserted patents expires in 2030. In April 2014, Amarin filed lawsuits against Apotex, Inc. and Apotex Corporation, or collectively, Apotex, in the U.S. District Court for the District of New Jersey and the U.S. District Court for the Northern District of Illinois. The cases against Apotex are captioned *Amarin Pharma, Inc. et al. v. Apotex, Inc. et al.*, Civ. A. No. 14-2550 (D.N.J) and *Amarin Pharma, Inc. et al. v. Apotex, Inc. et al.*, Civ. A. No. 14-2958 (N.D. Ill.). In April 2014, Amarin also filed lawsuits against Roxane Laboratories, Inc., or Roxane, in the U.S. District Court for the District of New Jersey and the U.S. District Court for the Northern District of Ohio. The cases against Roxane are captioned *Amarin Pharma, Inc. et al. v. Roxane Laboratories, Inc.*, Civ. A. No. 14-2551 (D.N.J) and *Amarin Pharma, Inc. et al. v. Roxane Laboratories, Inc.*, Civ. A. No. 14-901 (N.D. Ohio). Amarin voluntarily dismissed the Northern District of Ohio case against Roxane on May 7, 2014. In April 2014, Amarin also filed a lawsuit against Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd., or collectively, Dr. Reddy's, in the U.S. District Court for the District of New Jersey. The case against Dr. Reddy's is captioned *Amarin Pharma, Inc. et al. v. Dr. Reddy's Laboratories, Inc. et al.*, Civ. A. No. 14-2760 (D.N.J.). In May 2014, Amarin also filed a lawsuit against Watson Laboratories, Inc. and Actavis plc, or Watson, in the U.S. District Court for the District of New Jersey. One of our directors, Patrick J. O'Sullivan, is also a director of Actavis plc. The case against Watson is captioned *Amarin Pharma, Inc. et al. v. Watson Laboratories, Inc. et al.*, Civ. A. No. 14-3259 (D.N.J). On July 17, 2014, Amarin agreed to dismiss Actavis plc but the lawsuit against Watson remains pending. In June 2014, Amarin also filed a case against Teva Pharmaceuticals USA, Inc., or Teva, in the U.S. District Court for the District of New Jersey. The case against Teva is captioned *Amarin Pharma, Inc. et al. v. Teva Pharmaceuticals USA, Inc.*, Civ. A. No. 14-3558 (D.N.J.). In June 2014, Amarin also filed a lawsuit against Andrx Labs, LLC, Andrx Corporation, and Actavis plc, or collectively, Andrx, in the U.S. District Court for the District of New Jersey. The case against Andrx is captioned *Amarin Pharma, Inc. et al. v. Andrx Labs, LLC et al.*, Civ. A. No. 14-3924 (D.N.J.). As a result of the 30-month stay associated with the filing of these lawsuits under the Hatch-Waxman Act, the FDA cannot grant final approval to any ANDA before September 2016, unless there is an earlier court decision holding that the subject patents are not infringed and/or are invalid. We intend to vigorously enforce our intellectual property rights relating to Vascepa, but we cannot predict the outcome of these lawsuits.

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.

### **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 for our fiscal year ended December 31, 2013.*





## Table of Contents

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

*\* Our ability to generate increased revenue over the next few years depends, in part, on our ability to expand marketing approval beyond the currently approved MARINE indication. Based on our communications with the FDA, we currently expect that final positive results from the REDUCE-IT outcomes study will be required for label expansion for Vascepa.*

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, which we refer to as the ANCHOR indication. On October 16, 2013 the FDA convened an advisory committee meeting to review the sNDA for the ANCHOR indication. At the meeting, the advisory committee voted 9 to 2 against recommending approval of Vascepa, based on the following question:

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?

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 placebo group were likely randomly distributed to all treatment groups. Thus, the 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 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 committee, 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. The FDA determined, consistent with discussion at the advisory committee meeting, 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.

The FDA did not meet the originally assigned Prescription Drug User Fee Act, or PDUFA, goal date of December 20, 2013 for the completion of its review of the ANCHOR sNDA because of the pendency of our request to re-instate the ANCHOR SPA agreement. Beginning in November 2013, we sought reconsideration and appealed the SPA rescission decision to three levels of increasing authority within the FDA and were denied each time, most recently in September 2014. Based on FDA's repeated position in its appeal denials and its internal consultation with FDA officials at higher levels, we informed the FDA that we did not intend to appeal the SPA rescission further. Given our determination to not appeal the SPA rescission further, we expect the FDA to take action on our pending ANCHOR sNDA in the near future.



---

## **Table of Contents**

Based on our communications with the FDA, we currently expect that final positive results from the REDUCE-IT outcomes study will be required for FDA approval of label expansion for Vascepa. Any delay in obtaining, or an inability to obtain, expansion of our marketing approval rights could prevent us from growing revenue at greater than our current pace and could therefore 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.

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

*Our current and planned commercialization efforts may not be successful in increasing sales of Vascepa.*

In 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. In October 2013, following an FDA advisory committee recommendation against approval for the ANCHOR indication, we implemented a plan to reduce our workforce and our team of sales professionals in half. In May 2014 we began co-promoting Vascepa in the United States with Kowa Pharmaceuticals America, Inc., or Kowa Pharmaceuticals America, under a co-promotion agreement we entered into in March 2014. Under the agreement, approximately 250 Kowa Pharmaceuticals America sales representatives devote a substantial portion of their time to promoting Vascepa with Amarin's approximately 130 sales representatives based on a plan designed to substantially increase both the number of sales targets reached and the frequency of sales calls on existing sales targets. However, the commercialization 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 and co-promoting a pharmaceutical product with a partner.

Factors related to building and managing a sales and marketing organization that can inhibit our efforts to successfully commercialize Vascepa 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 and regulatory events 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 twelve months ended December 31, 2013 and the results for quarterly periods for the foreseeable future, 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 competitive developments in the

---

## **Table of Contents**

market in which we operate, our interactions with FDA on potential label expansions with Vascepa, the October 2013 approximately 50% reduction in our sales force, and the March 2014 co-promotion Agreement with Kowa Pharmaceuticals America. 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 to date together with results over several future quarters, or longer, before making an assessment about potential future performance.

If we are not successful in our efforts to market and sell Vascepa, our anticipated revenues will be materially and negatively affected, and we may not obtain profitability, may need to cut back on research and development activities or need to raise additional funding that could result in substantial dilution.

***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 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;

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;

perception that we will continue to market and sell Vascepa in the MARINE indications and any future approved indications;

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.

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

A 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 agreement 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 trial is adequate to support use of the conducted study as the primary basis for approval with respect to effectiveness. A SPA agreement 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 agreement 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 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. Beginning in November 2013, we sought reconsideration and appealed the SPA rescission decision to three levels of increasing authority within the FDA and were denied each time, most recently in September 2014. Based on FDA's repeated position in its appeal denials and its internal consultation with FDA officials at higher levels, we informed the FDA that we did not intend to appeal the SPA rescission further.

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

**Table of Contents**

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

The biotechnology and pharmaceutical industries are highly competitive. There are many pharmaceutical companies, biotechnology companies, public and private universities and research organizations actively engaged in the research and development of products that may be similar to our products. It is probable that the number of companies seeking to develop products and therapies similar to our products will increase. Many of these and other existing or potential competitors have substantially greater financial, technical and human resources than we do and may be better equipped to develop, manufacture and market products. These companies may develop and introduce products and processes competitive with or superior to ours. In addition, other technologies or products may be developed that have an entirely different approach or means of accomplishing the intended purposes of our products, which might render our technology and products noncompetitive or obsolete.

Our 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. GlaxoSmithKline plc, which currently markets Lovaza<sup>®</sup>, a prescription-only omega-3 fatty acid indicated for patients with severe hypertriglyceridemia has been on the market since 2004. As described below, generic versions of Lovaza are now available in the United States. Other large companies with competitive products include AbbVie, Inc., which currently markets Tricor<sup>®</sup> and Trilipix<sup>®</sup> for the treatment of severe hypertriglyceridemia and mixed dyslipidemia and Niaspan<sup>®</sup>, which is primarily used to raise HDL-C, but is also used to lower triglycerides. Generic versions of Tricor, Trilipix, and Niaspan are also now available in the United States. In addition, in May 2014, Epanova<sup>®</sup> (omega-3-carboxylic acids) capsules, a free fatty acid form of omega-3 (comprised of 55% EPA and 20% DHA), was approved by the FDA for patients with severe hypertriglyceridemia. Epanova was developed by Omthera Pharmaceuticals, Inc., and is now owned by AstraZeneca Pharmaceuticals LP (AstraZeneca). We expect AstraZeneca will utilize its substantial commercial resources to market its product imminently. Also, in April 2014, Omtryg, another omega-3-acid fatty acid composition developed by Trygg Pharma AS, received FDA approval for severe hypertriglyceridemia. We are not aware of the commercialization plan for Omtryg. Each of these competitors, other than Trygg, has greater resources than we do, including financial, product development, marketing, personnel and other resources.

In April 2014, Teva Pharmaceuticals USA Inc., or Teva, launched a generic version of Lovaza after winning its patent litigation against Pronova BioPharma Norge AS, now owned by BASF, which owns such patents rights. In June 2014 and September 2014, Par Pharmaceutical Inc., or Par, and Apotex Inc., or Apotex, received FDA approval of their respective version of generic Lovaza. In March 2011, Pronova/BASF entered into an agreement with Apotex to settle its patent litigation in the United States related to Lovaza. Pursuant to the terms of the settlement agreement, we believe 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, the details of which are not known to us.

In addition, we are aware of other pharmaceutical companies that are developing products that, if approved and marketed, would compete with Vascepa. We understand that 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 Catabasis Pharmaceuticals, or Catabasis, Resolvix Pharmaceuticals, or Resolvix, and Sancilio & Company are also developing potential treatments for hypertriglyceridemia based on omega-3 fatty acids. To our knowledge, Catabasis initiated a Phase 2 clinical trial of its product in December 2013; Resolvix's compound remains in Phase 1 clinical testing; and Sancilio is preparing to commence Phase 3 clinical testing. 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 filed an Investigational New Drug Application with the FDA and to conduct a human study in the treatment of severe hypertriglyceridemia. Isis Pharmaceuticals 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 and in patients with moderate to severe high triglycerides. Finally, Madrigal Pharmaceuticals has completed Phase 1 clinical testing of MGL-3196 for the treatment of high triglycerides and various lipid parameters in patients.

***Generic company competitors are seeking approval of generic versions of Vascepa.***

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, permit the FDA to approve abbreviated new drug applications, or ANDAs, for generic versions of brand name drugs like Vascepa. We refer to the process of generic drug applications as the ANDA process. The ANDA process permits competitor companies to obtain marketing approval for a drug product with the same active ingredient, dosage form, strength, route of administration, and labeling as the approved brand name drug, but without having to conduct and submit clinical studies to establish the safety and efficacy of the proposed generic product. In place of such clinical studies, an ANDA applicant needs to submit data demonstrating that its product is bioequivalent to the brand name product, usually based on pharmacokinetic studies.



**Table of Contents**

The Hatch-Waxman Amendments require an applicant for a drug product that relies, in whole or in part, on the FDA's prior approval of Vascepa, to notify us of its application, a paragraph IV notice, if the applicant is seeking to market its product prior to the expiration of the patents that claim Vascepa. A bona fide paragraph IV notice may not be given under the Hatch-Waxman Amendments until after the generic company receives from the FDA an acknowledgement letter stating that its ANDA is sufficiently complete to permit a substantive review.

The paragraph IV notice is required to contain a detailed factual and legal statement explaining the basis for the applicant's opinion that the proposed product does not infringe our patents, that our patents are invalid, or both. After receipt of a valid notice, we would have the option of bringing a patent infringement suit in federal district court against any generic company seeking approval for its product within 45 days from the date of receipt of each notice. If such a suit is commenced within this 45 day period, we will be entitled to receive a 30 month stay on FDA's ability to give final approval to any of the proposed products that reference Vascepa that begins on the date we receive the paragraph IV notice. The stay may be shortened or lengthened if either party fails to cooperate in the litigation and it may be terminated if the court decides the case in less than 30 months. If the litigation is resolved in favor of the applicant before the expiration of the 30 month period, the stay will be immediately lifted and the FDA's review of the application may be completed. Such litigation is often time-consuming and costly, and may result in generic competition if such patents are not upheld or if the generic competitor is found not to infringe such patents.

We have received six paragraph IV notices notifying us of submitted ANDAs to Vascepa under the Hatch-Waxman Amendments. We are now engaged in costly litigation with the ANDA applicants to protect our patent rights. If an ANDA filer is ultimately successful in patent litigation against us, it meets the requirements for a generic version of Vascepa to the satisfaction of the FDA under its ANDA (after any applicable regulatory exclusivity period and 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. Such a market entry would likely 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 our stock price.

In addition to the six paragraph notices received to date, in February 2014, prior to the FDA's three-year exclusivity determination for Vascepa, we received a purported paragraph IV notice from a generic drug company with respect to an ANDA to Vascepa. The FDA confirmed with us after we received the notice and before the exclusivity determination was made that the FDA had not accepted for review any ANDA to Vascepa. The FDA has repeatedly taken the position that paragraph IV notices delivered to pioneer companies such as Amarin prior to the acceptance by the FDA for review of a submitted ANDA are not effective under the Hatch-Waxman Amendments. The generic company may challenge the FDA's position on whether the notice is valid in court in connection with patent litigation. Generic companies are thought to send such premature notices to seek to avail themselves of the 180-day generic exclusivity period for an approved product under an ANDA based on the generic's view that it would then have first-to-file status and to seek an early end to related patent litigation with the branded drug company and the associated 30-month stay. Because we and the FDA do not believe this purported paragraph IV notice is an effective notice under the Hatch-Waxman Amendments we do not plan to initiate patent litigation against the generic company that submitted the ANDA until within the 45-day period after we receive a valid paragraph IV notice from such applicant.

***Our suit against FDA challenging its denial of five-year, NCE exclusivity to Vascepa under the Hatch-Waxman Amendments may not achieve its intended goal to delay generic competition challenges to Vascepa.***

The timelines and conditions under the ANDA process that permit the start of patent litigation and allow the FDA to approve generic versions of brand name drugs like Vascepa differ based on whether a drug receives three-year, or five-year, new chemical entity (NCE) marketing exclusivity. The FDA typically makes a determination on marketing exclusivity in connection with an NDA approval of a drug for a new indication. We applied to the FDA for five-year, NCE marketing exclusivity for Vascepa in connection with the NDA for our MARINE indication, which NDA was approved by the FDA on July 26, 2012. On February 21, 2014, in connection with the July 26, 2012 approval of the MARINE indication, the FDA denied a grant of NCE marketing exclusivity to Vascepa and granted three-year marketing exclusivity. Such three-year exclusivity extends through July 25, 2015 and is expected to be supplemented by a 30-month stay that we believe will extend into September 2016, assuming the related Vascepa patent litigation is not resolved against us sooner.

NCE marketing exclusivity, not granted to Vascepa, precludes approval during the five-year exclusivity period of certain 505(b)(2) applications and ANDAs 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, the pioneer drug company 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

**Table of Contents**

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. Another drug sponsor could also gain a form of 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.

The three-year period of exclusivity granted to Vascepa under the Hatch-Waxman Amendments is 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 clinical trial was a new clinical investigation that was essential to the approval of our new drug application. We are entitled to three-year exclusivity even though FDA determined 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 precludes the FDA from approving a marketing application for an ANDA, 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. The FDA may accept and commence review of such applications during the three-year exclusivity period. Such three-year exclusivity grant does not prevent a company from challenging the validity of our patents at any time. In this case, Amarin would be, and has been, afforded the benefit of a 30-month stay against the launch of such a competitive product that extends from the period that Amarin receives notice of the patent challenge (the paragraph IV notice), assuming Amarin responds to the patent challenge with 45 days, and Amarin may also be afforded a judicial extension if applicable requirements are met. Currently, Amarin believes its 30-month stay extends until September 2016. 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.

On February 27, 2014, we commenced a lawsuit against the FDA that challenges FDA's denial of our request for five-year NCE exclusivity for Vascepa based on our reading of the relevant statute, our view of FDA's inconsistency with its past actions in this area and the retroactive effect of what we believe is a new policy at FDA as it relates to our situation. Our complaint requests that the court vacate FDA's decision, declare that Vascepa is entitled to the benefits of five-year statutory exclusivity, bar the FDA from accepting any ANDA or similar application for which Vascepa is the reference-listed drug until after the statutory exclusivity period and set aside what we contend are due to the denial of five-year exclusivity to Vascepa prematurely accepted pending ANDA applications.

We may not be successful in this lawsuit against the FDA. Further, a generic company could enter this litigation, complicating the ultimate determination. Even if we are successful at the federal district court level, the FDA may appeal and we may need to win on appeal before the FDA takes, or the court imposes on the FDA, the remedies we request in suit. In addition, we may not be able to stay the continuation of currently pending ANDA-related patent litigation. The legal process can be costly and time-consuming and even if we are successful the remedies available to us diminish in value over time as we approach the natural expiration of the benefits associated with five-year exclusivity.

***\*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 and tested safety of Vascepa as having a superior therapeutic profile to naturally occurring omega-3 fatty acids and dietary supplements. In addition, the FDA has not enforced what we view as illegal drug claims made by certain supplement manufacturers to the extent we believe appropriate under applicable law and regulations, for example, claims that such supplements reduce triglyceride levels. Also, for more than a decade now, the FDA has expressly permitted dietary supplement manufacturers that sell supplements containing the omega-3 fatty acids EPA and/or DHA to make the following qualified health claim directly to consumers: Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease. Under FDA's regulatory regime, we cannot make this claim. These factors enable dietary supplements to effectively compete with Vascepa. In addition, to the extent the net price of Vascepa after insurance and offered discounts 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.

---

**Table of Contents*****We may not be successful in our Vascepa co-promotion effort with Kowa Pharmaceuticals America.***

In March 2014, we entered into a co-promotion agreement with Kowa Pharmaceuticals America to co-promote Vascepa in the United States under which approximately 250 Kowa Pharmaceuticals America sales representatives devote a substantial portion of their time to promoting Vascepa with Amarin's approximately 130 sales representatives. Co-promotion under the agreement commenced in May 2014 based on a plan designed to substantially increase both the number of sales targets reached and the frequency of sales calls on existing sales targets. While our agreement provides for minimum performance criteria, we have little control over Kowa Pharmaceuticals America, and it may fail to devote the necessary resources and attention to promote Vascepa 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. Or, we may seek to terminate the agreement and search for another commercialization partner. 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. 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.

***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. We must also comply with requirements to collect and report adverse events and product complaints associated with our products. For example, in September 2014, we participated in a routine inspection from the FDA in which the FDA made observations on perceived deficiencies related to our processes for collection and processing of adverse events. We have responded to FDA with respect to these observations and continue to work with FDA to show that we have improved related systems. Our 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. We may also be



---

**Table of Contents**

held responsible for the non-compliance of our partners, such as Kowa Pharmaceuticals America. In addition, even if we 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 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, the rescission of the ANCHOR SPA agreement 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 regulations 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 are, in fact, 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.

***The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products. If we or Kowa Pharmaceuticals America are found to have improperly promoted off-label uses of Vascepa, 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. We may also be held responsible for the non-compliance of our co-promotion partner, Kowa Pharmaceuticals America. 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-



---

**Table of Contents**

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 and is being studied in REDUCE-IT at 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. Also, 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. In addition, JELIS was an open-label trial, which could influence patient and 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;

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

political instability affecting our clinical trial sites, such as the potential for political unrest affecting our REDUCE-IT clinical trial sites in the Ukraine and Russia.



---

## **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.

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.

---

**Table of Contents**

*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 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 October 2013 worldwide reduction in force, which included the termination of approximately 50% of the then-staffed sales force, has made this process more difficult. As our operations expand with the anticipated growth of our produce sales, 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**

*\* 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 Vascepa. 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 volumes of active pharmaceutical ingredient (drug substance) or encapsulated bulk product (drug product), it would have a material adverse effect on our ability to continue to commercialize Vascepa.

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 purchase and use commercial supply from Chemport in addition to Nisshin. We recently terminated our agreement with BASF due to its inability to meet the agreement requirements and may enter into a new development and supply agreement with BASF and may purchase API from BASF. 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 and Chemport currently supply all 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.

Expanding manufacturing capacity and qualifying such capacity is difficult and subject to numerous regulations and other operational challenges. The resources of our suppliers vary and are limited; costs associated with projected expansion and qualification can be significant. For example, Chemport, which was approved as one of our API suppliers 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 previously approved suppliers. If our third party manufacturing capacity is not expanded and compliant with application regulatory requirements, we may not be able to supply sufficient quantities of Vascepa to meet anticipated demand. We cannot assure you that we can contract with any future manufacturer on acceptable terms or that any such alternative supplier will not require capital investment from us in order for them to meet our requirements. Alternatively, our purchase of supply may exceed actual demand for Vascepa.



---

**Table of Contents**

We currently rely on Patheon (formerly Banner Pharmacaps) for the encapsulation of Vascepa. We have encapsulation agreements with two other commercial API encapsulators. These companies are working to qualify their processes and to prove that the Vascepa capsules they produce meet the same quality standards as the capsules produced by Patheon. 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 certain third-party Vascepa suppliers if we do not meet minimum purchase obligations due to lower than anticipated sales of Vascepa.***

Certain of 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, in certain cases, will be free to sell the active pharmaceutical ingredient of Vascepa to potential competitors of Vascepa. Similarly if we terminate certain of our supply agreements, such suppliers may be free to sell the active pharmaceutical ingredient of Vascepa to potential competitors of Vascepa. While we anticipate that intellectual property barriers and FDA regulatory exclusivity 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 have limited 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.***

Certain of 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. Certain of our agreements also include contractual minimum purchase commitments regardless of the rolling twelve-month forecasts. We have limited experience with the commercial sale of Vascepa, and as such expectations regarding expected demand may be wrong. We may not purchase sufficient quantities of Vascepa to meet actual demand or our purchase of supply may exceed actual demand. In either case, such event could have a material adverse effect on our financial results and financial condition.

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

The manufacture and packaging of pharmaceutical products, such as Vascepa, are regulated by the FDA and similar foreign regulatory bodies and must be conducted in accordance with the FDA's current good manufacturing practices, 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 our current and 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. 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.

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.



## **Table of Contents**

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.

### **Risks Related to our Intellectual Property**

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

Our success depends in part on our ability to obtain and maintain intellectual property protection for our drug candidates, technology and know-how, and to operate without infringing the proprietary rights of others. Our ability to successfully implement our business plan and to protect our products with our intellectual property 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.

Amarin has prosecuted, and is currently prosecuting, multiple patent applications to protect the intellectual property developed during the Vascepa cardiovascular program. As of the date of this report, we had 40 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 40 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,

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

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

1 additional patent related to the use of a pharmaceutical composition comprised of free fatty acids to treat the ANCHOR patient population with a term that expires in 2030, and

1 additional patent related to the use of a pharmaceutical composition comprised of free fatty acids to treat the MARINE patient population with a term that expires in 2030.

A Notice of Allowance is issued after the USPTO makes a determination that a patent can be granted from an application. A Notice of Allowance does not afford patent protection until the underlying patent is issued by the USPTO. No assurance can be given that 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. 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 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.



---

**Table of Contents**

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 may not prevent competitors from competing with Vascepa, even if we seek to enforce our patent rights.***

We plan to vigorously defend our rights under issued patents. For example, in March 2014, we filed a patent infringement suit against Omthera Pharmaceuticals, Inc., and its parent company, AstraZeneca Pharmaceuticals LP. The suit seeks injunctive relief and monetary damages for infringement of Amarin's U.S. Patent No. 8,663,662. The complaint alleges infringement of the patent arising from the expected launch of Epanova, a product that is expected to compete with Vascepa in the United States. The patent covers methods of lowering triglycerides by administering a pharmaceutical composition that includes amounts of EPA as free acid, and no more than about 30% DHA. Amarin intends to pursue this litigation vigorously and aggressively protect its intellectual property rights. However, patent litigation is a time-consuming and costly process. There can be no assurance that we will be successful in enforcing this patent or that it will not be successfully challenged and invalidated. Even if we are successful in enforcing this patent, the process could take years to reach conclusion.

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 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.



---

## **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**

*We and certain of our current and former executive officers have been named as defendants in four lawsuits that could result in substantial costs and divert management's attention.*

The market price of our ADSs declined significantly after the October 2013 decision by the FDA Advisory Committee to recommend against approval of Vascepa in the ANCHOR indication. We, and certain of our current and former executive officers and directors, have been named as defendants in four purported class action lawsuits initiated earlier this year that generally allege that we and certain of our current and former officers and directors violated Sections 10(b) and/or 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder by making allegedly false and/or misleading statements or material omissions concerning the ANCHOR sNDA and related FDA regulatory approval process in an effort to lead investors to believe that Vascepa would receive approval from the FDA in the ANCHOR indication. The complaints seek unspecified damages, interest, attorneys' fees, and other costs.

We intend to engage in a vigorous defense of the lawsuits, and we believe that we have meritorious defenses to these claims. However, we are unable to predict the outcome of these matters at this time. Moreover, any conclusion of these matters in a manner adverse to us could have a material adverse effect on our financial condition and business. For example, we could incur substantial costs not covered by our directors' and officers' liability insurance, suffer a significant adverse impact on our reputation and divert management's attention and resources from other priorities, including the execution of business plans and strategies that are important to our ability to grow our business, any of which could have a material adverse effect on our business. In addition, any of these matters could require payments that are not covered by, or exceed the limits of, our available directors' and officers' liability insurance, which could have a material adverse effect on our operating results or financial condition.

*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.

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

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.

---

**Table of Contents**

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.

***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, in October 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.

***We could be adversely affected by our exposure to customer concentration risk.***

A significant portion of our sales are to wholesalers in the pharmaceutical industry. Our top three customers accounted for 95% and 96% of gross product sales for the nine months ended September 30, 2014 and 2013, respectively and represented 96% and 98% of the gross accounts receivable balance as of September 30, 2014 and September 30, 2013, respectively. There can be no guarantee that we will be able to sustain our accounts receivable or gross sales levels from our key customers. If, for any reason, we were to lose, or experience a decrease in the amount of business with our largest customers, whether directly or through our distributor relationships, our financial condition and results of operations could be negatively affected.

## **Table of Contents**

### **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, 2013, 2012, and 2011, we reported losses of approximately \$166.2 million, \$179.2 million, and \$69.1 million, respectively, and we had an accumulated deficit at December 31, 2013 of \$913.9 million. For the nine months ended September 30, 2014 and 2013, we reported losses of approximately \$36.7 million and \$150.8 million, respectively, and we had an accumulated deficit at September 30, 2014 of \$950.6 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, costs related to the commercialization of Vascepa, 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. 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.

*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.

---

## **Table of Contents**

*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 with our new co-promotion partner, Kowa Pharmaceuticals America;

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, including recently initiated shareholder litigation, regulatory matters and tax matters; and

our regulatory dialogue on the REDUCE-IT study.

*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 \$135.4 million at September 30, 2014 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 new 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 with our new co-promotion partner, Kowa Pharmaceuticals America, and the cost and timing of securing commercial supply of Vascepa and the timing of entering into any new 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;

continued cost associated with litigation and other legal proceedings, including recently initiated shareholder litigation and patent litigation;

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.



---

## **Table of Contents**

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.

*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, 2014, there were warrants outstanding for the purchase of up to 8,087,388 ADSs each representing one of our ordinary shares, with a weighted average exercise price of \$1.50 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. In the event of physical settlement, the notes would initially be exchangeable into a total of 49,214,841 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. For example, in March 2014, we entered into a co-promotion agreement with Kowa Pharmaceuticals America related to the commercialization of Vascepa in the United States. The consummation and performance of any such future transactions or collaborations will involve risks, such as:

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

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

misjudgment with respect to the value;

higher than expected transaction costs; or

an inability to successfully consummate any such transaction or collaboration.

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

---

## **Table of Contents**

### **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, 2014 we had 174,610,451 common shares outstanding including 174,146,088 shares held as ADSs and 464,363 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:

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.***

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 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.

***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. We do not believe that we were classified as a PFIC in 2013. Our status as a PFIC is subject to change in future years.

---

## **Table of Contents**

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, certain licensings 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 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 consist of \$150.0 million in aggregate principal amount of 3.50% exchangeable senior notes due 2032, \$31.3 million of which relates to the January 2012 notes with provisions for the notes to be put to us on or after January 19, 2017 while the balance of \$118.7 million relates to the May 2014 notes with provision for the notes to be redeemed by the Company on or after January 19, 2018 or put to us by the holders on or after January 19, 2019.

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;

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

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.

**Table of Contents**

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

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

***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 change in control 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 change in control 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.

## **Table of Contents**

*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 depositary bank.

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

Under English law and our Articles of Association, certain matters require the approval of 75% of the shareholders who vote (in person or by proxy) on the relevant resolution (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.*



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

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.

**Table of Contents**

*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.

**Item 6. Exhibits**

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

Exhibit	
Number	Description
10.1	Form of Warrant Amendment (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed October 16, 2014, File No. 000-21392)
31.1	Certification of Chief Executive Officer (Principal Executive Officer) pursuant to Section 302 of Sarbanes-Oxley Act of 2002
31.2	Certification of Controller (Principal Financial Officer) pursuant to Section 302 of Sarbanes-Oxley Act of 2002
32.1	Certification of Chief Executive Officer (Principal Executive Officer) and Controller (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 and Chief Executive Officer

(Principal Executive Officer)

(On behalf of the Registrant)

Date: November 6, 2014