AMARIN CORP PLC\UK
Form 10-Q
November 04, 2015
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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, 2015

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	**Not applicable**
(State or Other Jurisdiction of	**(I.R.S. Employer**
Incorporation or Organization)	**Identification No.)**

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

182,530,173 shares held as American Depository Shares (ADSs), each representing one Ordinary Share, 50 pence par value per share, and 956,654 ordinary shares, were outstanding as of November 1, 2015.

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PART I

AMARIN CORPORATION PLC

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited, in thousands, except share amounts)

	September 30, 2015	December 31, 2014
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 118,976	$ 119,539
Restricted cash	600	600
Accounts receivable, net	11,239	7,842
Inventory	19,704	13,733
Deferred tax assets	934	934
Prepaid and other current assets	4,689	2,633
Total current assets	156,142	145,281
Property, plant and equipment, net	266	381
Deferred tax assets	14,138	12,556
Other non-current assets	2,297	2,826
Intangible asset, net	9,579	10,063
TOTAL ASSETS	$ 182,422	$ 171,107
LIABILITIES AND STOCKHOLDERS DEFICIT		
Current Liabilities:		
Accounts payable	$ 17,899	$ 8,525
Current portion of long-term debt	13,995	15,394
Deferred revenue, current	923	
Accrued expenses and other current liabilities	22,503	16,387
Total current liabilities	55,320	40,306
Long-Term Liabilities:		
Exchangeable senior notes, net of discount	126,108	121,846
Long-term debt	91,009	89,617
Long-term debt derivative liabilities	6,930	7,400
Deferred revenue, long-term	13,538	
Other long-term liabilities	608	386

Total liabilities	293,513	259,555
Commitments and contingencies (Note 7)		
Stockholders Deficit:		
Series A Convertible Preferred Stock, £0.05 par, unlimited authorized; 328,184,640 issued and outstanding as of September 30, 2015 (equivalent to 32,818,464 ordinary shares upon future consolidation and redesignation at a 10:1 ratio); zero shares issued and outstanding as of December 31, 2014	24,364	
Common stock, £0.50 par, unlimited authorized; 183,480,577 issued, 183,328,506 outstanding as of September 30, 2015; 174,610,451 issued, 174,590,372 outstanding as of December 31, 2014	149,906	143,113
Additional paid-in capital	812,409	738,890
Treasury stock; 152,071 shares as of September 30, 2015; 20,079 shares as of December 31, 2014	(368)	(217)
Accumulated deficit	(1,097,402)	(970,234)
Total stockholders deficit	(111,091)	(88,448)
TOTAL LIABILITIES AND STOCKHOLDERS DEFICIT	$ 182,422	$ 171,107

See notes to condensed consolidated financial statements.

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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,	
	2015	2014	2015	2014
Product revenue, net	$ 21,320	$ 14,149	$ 54,585	$ 37,722
Licensing revenue	163		538	
Total revenue, net	21,483	14,149	55,123	37,722
Less: Cost of goods sold	7,478	5,366	19,486	14,637
Gross margin	14,005	8,783	35,637	23,085
Operating expenses:				
Selling, general and administrative	26,727	19,270	77,522	60,949
Research and development	13,092	14,457	37,715	37,891
Total operating expenses	39,819	33,727	115,237	98,840
Operating loss	(25,814)	(24,944)	(79,600)	(75,755)
(Loss) gain on change in fair value of derivative liabilities	(230)	4,466	(366)	11,870
Gain on extinguishment of debt				38,034
Interest expense, net	(5,061)	(4,876)	(14,753)	(13,565)
Other (expense) income, net	(102)	(247)	(135)	3,994
Loss from operations before taxes	(31,207)	(25,601)	(94,854)	(35,422)
Benefit from (provision for) income taxes	532	(449)	1,541	(1,285)
Net loss	(30,675)	(26,050)	(93,313)	(36,707)
Preferred stock purchase option			(868)	
Preferred stock beneficial conversion features	(1,646)		(32,987)	
Net loss applicable to common shareholders	$ (32,321)	$ (26,050)	$ (127,168)	$ (36,707)
Loss per share:				
Basic	$ (0.18)	$ (0.15)	$ (0.71)	$ (0.21)
Diluted	$ (0.18)	$ (0.17)	$ (0.71)	$ (0.25)

Weighted average shares:				
Basic	183,245	174,502	179,780	173,426
Diluted	183,245	175,141	179,780	174,305

See notes to condensed consolidated financial statements.

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AMARIN CORPORATION PLC

CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS DEFICIT

(Unaudited, in thousands, except share amounts)

	Preferred Shares	Common Shares	Treasury Shares	Preferred Stock	Common Stock	Additional Paid-in Capital	Treasury Stock	Accumulated Deficit	Total
December 31, 2014		**174,610,451**	**(20,079)**	**$**	**$ 143,113**	**$ 738,890**	**$ (217)**	**$ (970,234)**	**$ (88,448)**
Issuance of Series A Convertible Preferred Stock, net	391,017,970			29,168		28,685			57,853
Conversion of Series A Convertible Preferred Stock, net	(62,833,330)	6,283,333		(4,804)	4,804	(187)			(187)
Preferred stock purchase option						1,814		(868)	946
Preferred stock beneficial conversion features						32,987		(32,987)	
Exercise of stock options		18,020			13	18			31
Exercise of warrants		1,844,585			1,429	1,284			2,713
Vesting of restricted stock units		724,188	(131,992)		547	(547)	(151)		(151)
Tax provision on stock-based compensation						(707)			(707)
Stock-based compensation						10,172			10,172
Loss for the period								(93,313)	(93,313)
September 30, 2015	**328,184,640**	**183,480,577**	**(152,071)**	**$ 24,364**	**$ 149,906**	**$ 812,409**	**$ (368)**	**$ (1,097,402)**	**$ (111,091)**

See notes to condensed consolidated financial statements.

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AMARIN CORPORATION PLC

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited, in thousands)

	Nine Months Ended September 30,	
	2015	2014
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (93,313)	$ (36,707)
Adjustments to reconcile loss to net cash used in operating activities:		
Depreciation and amortization	125	155
Stock-based compensation	10,177	6,272
Stock-based compensation warrants	(9)	(503)
Excess tax provision on (benefit from) stock-based awards	707	(1)
Amortization of debt discount and debt issuance costs	5,654	4,039
Amortization of intangible asset	484	484
Loss (gain) on changes in fair value of derivative liabilities	366	(11,870)
Gain on extinguishment of debt		(38,034)
Deferred income taxes	(1,582)	82
Changes in assets and liabilities:		
Restricted cash		400
Accounts receivable	(3,397)	(3,022)
Inventories	(5,971)	14,805
Prepaid and other current assets	(2,056)	(1,371)
Other non-current assets	529	2,017
Accrued interest payable	(1,399)	816
Deferred revenue	14,461	(1,703)
Accounts payable and other current liabilities	14,902	5,456
Other non-current liabilities	222	
Net cash used in operating activities	(60,100)	(58,685)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of equipment	(10)	
Net cash used in investing activities	(10)	
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of preferred stock, net of transaction costs	57,666	
Proceeds from exercise of stock options, net of transaction costs	31	307
Proceeds from exercise of warrants, net of transaction costs	2,713	1,651
Refund of equity issuance costs		3,191
Debt issuance costs		(2,480)
Excess tax (provision on) benefit from stock-based awards	(707)	1
Acquisition of treasury stock	(151)	

Payments under capital leases		(5)		(64)
Net cash provided by financing activities		59,547		2,606
NET DECREASE IN CASH AND CASH EQUIVALENTS		(563)		(56,079)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD		119,539		191,514
CASH AND CASH EQUIVALENTS, END OF PERIOD	$	118,976	$	135,435
Supplemental disclosure of cash flow information:				
Cash paid during the year for:				
Interest	$	10,225	$	8,622
Income taxes	$	526	$	581
Non-cash transactions:				
Transfer of preferred stock purchase option derivative liability to equity	$	868	$	
Conversion of Series A Convertible Preferred Stock into common stock	$	4,804	$	
Accretion of preferred stock beneficial conversion features	$	32,987	$	
Reacquisition of conversion option in convertible notes	$		$	10,100

See notes to condensed consolidated financial statements.

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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 ³500 mg/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 May 2014, Kowa Pharmaceuticals America, Inc. commenced co-promotion of Vascepa in accordance with a co-promotion agreement with the Company. Kowa Pharmaceuticals America, Inc. co-promotes Vascepa through its approximately 250 sales representatives who now devote a substantial portion of their time to promoting Vascepa in conjunction with the promotion of Kowa Pharmaceutical America, Inc. 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 FDA approval of 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 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, 2014, or the 2014 Form 10-K, filed with the SEC. The balance sheet amounts as of December 31, 2014 in this report were derived from the Company s audited 2014 consolidated financial statements included in the 2014 Form 10-K.

The condensed consolidated financial statements reflect all adjustments of a normal and recurring nature 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 the Company s condensed consolidated financial statements in conformity with U.S. Generally Accepted Accounting Principles (GAAP) requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities as of 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, 2015 and 2014, are not necessarily indicative of the results for the entire fiscal year or any future period.

The accompanying condensed 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 condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

As of September 30, 2015, the Company had cash and cash equivalents of $119.0 million. The Company s condensed consolidated balance sheets also include derivative liabilities as well as long-term debt and exchangeable senior notes. 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

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these dates except upon the occurrence of certain contingent events. The 2012 Notes are exchangeable under certain circumstances into cash, American Depository 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 long-term debt and exchangeable senior notes do not represent 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

Principles of Consolidation

The condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates

Accounting estimates are based on historical experience and other factors that are considered reasonable under the circumstances. Estimates are used in determining such items as provisions for sales returns, rebates and incentives, chargebacks, and other sales allowances, depreciable/amortizable lives, asset impairments, valuation allowance on deferred taxes, probabilities of achievement of performance conditions for certain equity awards, amounts recorded for licensing revenue, contingencies and accruals, and valuations of derivative and long-term debt instruments. Because of the uncertainties inherent in such estimates, actual results may differ from these estimates. Management periodically evaluates estimates used in the preparation of the condensed consolidated financial statements for continued reasonableness.

Use of Forecasted Financial Information in Accounting Estimates

The use of forecasted financial information is inherent in many of the Company s accounting estimates, including but not limited to, determining the estimated fair values of derivatives, debt instruments and intangible assets, and evaluating the need for valuation allowances for deferred tax assets. Such forecasted financial information is comprised of numerous assumptions regarding the Company s future revenues, cash flows, and operational results. Management believes that its financial forecasts are reasonable and appropriate based upon current facts and circumstances. Because of the inherent nature of forecasts, however, actual results may differ from these forecasts. Management regularly reviews the information related to these forecasts and adjusts the carrying amounts of the applicable assets prospectively, if and when actual results differ from previous 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. As of 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

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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 judgment and experience, the Company expects its Distributors to earn these discounts and fees, and deducts the full amount of these discounts and fees from its gross product revenues and accounts receivable at the time such revenues are recognized.

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

Product Returns: The Company s Distributors have the right to return unopened unprescribed 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, 2015, 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.

The following table summarizes activity in each of the net product revenue allowance and reserve categories described above for the nine months ended September 30, 2015 (in thousands):

	Trade Allowances	Rebates, Chargebacks and Discounts	Product Returns	Other Incentives	Total
Balance as of December 31, 2014	**$ 2,207**	**$ 3,610**	**$ 481**	**$ 792**	**$ 7,090**
Provision related to current period sales	10,104	21,633	231	5,976	37,944
Provision related to prior period sales	(174)	(70)			(244)
Credits/payments made for current period sales	(6,729)	(14,194)		(4,220)	(25,143)
Credits/payments made for prior period sales	(2,043)	(3,522)	(26)	(792)	(6,383)
Balance as of September 30, 2015	$ 3,365	$ 7,457	$ 686	$ 1,756	$ 13,264

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Such net product revenue allowances and reserves are included within accrued expenses and other current liabilities within the condensed consolidated balance sheets, with the exception of trade allowances and chargebacks, which are included within accounts receivable, net as discussed below.

Multiple-Element Arrangements and Licensing Revenue

When evaluating multiple-element arrangements, the Company identifies the deliverables included within the agreement and evaluates which deliverables represent separate units of accounting based on whether the delivered element has stand-alone value to the customer or if the arrangement includes a general right of return for delivered items.

The consideration received is allocated between each of the separable elements in the arrangement using the relative selling price method. The selling price used for each separable element will be based on vendor specific objective evidence (VSOE) if available, third party evidence if VSOE is not available, or estimated selling price if neither VSOE nor third party evidence is available. Revenue is then recognized as each of the separable elements to which the revenue has been allocated is delivered.

The Company may receive up-front, non-refundable payments when licensing its intellectual property in conjunction with research, development and commercialization agreements. In determining the units of accounting, management evaluates whether the license has stand-alone value from the undelivered elements to the collaborative partner based on the consideration of the relevant facts and circumstances for each arrangement. Factors considered in this determination include the stage of development of the license delivered, research and development capabilities of the partner and the ability of partners to develop and commercialize Vascepa independent of the Company.

When management believes the license to its intellectual property does not have stand-alone value from the other deliverables to be provided in the arrangement, the Company generally recognizes revenue attributable to the license over the Company s contractual or estimated performance period. Any unrecognized portion of license revenue is classified within deferred revenue in the accompanying condensed consolidated balance sheets. When management believes the license to its intellectual property has stand-alone value, the Company recognizes revenue attributed to the license upon delivery. The periods over which revenue is recognized is subject to estimates by management and may change over the course of the agreement. Such a change could have a material impact on the amount of revenue the Company records in future periods.

Milestones

Contingent consideration from activities that is earned upon the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved. At the inception of each arrangement that includes milestone payments, the Company evaluates whether each milestone is substantive. This evaluation includes an assessment of whether: (a) the consideration is commensurate with either (1) the entity s performance to achieve the milestone, or (2) the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity s performance to achieve the milestone, (b) the consideration relates solely to past performance and (c) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. The Company evaluates factors such as the scientific, clinical, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement in making this assessment.

Distribution Costs

The Company records distribution costs related to shipping product to its customers, primarily through the use of common carriers or external distribution services, in cost of goods sold.

Cash and Cash Equivalents

Cash and cash equivalents consist of cash, deposits with banks and short-term highly liquid money market 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, net

Accounts receivable, net, 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.

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The following table summarizes the impact of accounts receivable reserves on the gross trade accounts receivable balances as of September 30, 2015 and December 31, 2014 (in thousands):

	September 30, 2015	December 31, 2014
Gross trade accounts receivable	$ 14,721	$ 10,215
Trade allowances	(3,365)	(2,207)
Chargebacks	(117)	(166)
Accounts receivable, net	$ 11,239	$ 7,842

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 active pharmaceutical ingredient, or 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.

Property, Plant and Equipment

The Company 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:

Asset Classification	Useful Lives
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. See Note 7 Commitments and Contingencies for further information regarding other obligations related to the acquisition of Laxdale Limited.

Beneficial Conversion Features

The Company issued Series A preference shares in a private placement transaction executed in two tranches that each contain a conversion feature whereby such shares are convertible into ordinary shares at a fixed rate. The conversion price on the date of issuance was less than the market price of the Company s ordinary shares. It was determined that these discounts represent contingent beneficial conversion features, which were valued based on the difference between the conversion price and the market price of the

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ordinary shares on the date of issuance, which is the commitment date. These features are analogous to preference dividends and were each recorded as a non-cash return to preferred shareholders through accumulated deficit upon the earliest possible date of conversion, which occurred in the three months ended June 30, 2015 upon effectiveness of the related resale Registration Statement on Form S-3 and in the three months ended September 30, 2015 upon shareholder approval received at the Company s Annual General Meeting of Shareholders. See Note 8 Equity for further discussion.

Costs for Patent Litigation and Legal Proceedings

Costs for patent litigation or other legal proceedings are expensed as incurred and included in selling, general and administrative expenses.

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 those incurred as a result of the commercialization of Vascepa in the United States as well as co-promotion fees payable to Kowa Pharmaceuticals America, Inc.

Income Taxes

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

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

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 features are valued using probability-weighted models 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. 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

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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 the warrant derivative liability, for diluted net loss per share purposes, the impact of such gains is reversed and the treasury stock method is used to determine diluted net loss per share.

The Company s preferred stock is entitled to receive dividends on an as-if-converted basis in the same form as dividends actually paid on common shares. Accordingly, the preferred stock is considered a participating security and the Company is required to apply the two-class method to consider the impact of the preferred stock on the calculation of basic and diluted earnings per share. The Company is currently in a net loss position and is therefore not required to present the two-class method, however, in the event the Company is in a net income position, the two-class method must be applied by allocating all earnings during the period to common shares and preferred stock based on their contractual entitlements assuming all earnings were distributed.

The calculation of net loss and the number of shares used to compute basic and diluted net loss per share for the three and nine months ended September 30, 2015 and 2014 are as follows:

	Three months ended		Nine months ended	
In thousands	**September 30, 2015**	**September 30, 2014**	**September 30, 2015**	**September 30, 2014**
Net loss	$ (30,675)	$ (26,050)	$ (93,313)	$ (36,707)
Preferred stock purchase option (see Note 8)			(868)	
Preferred stock beneficial conversion features (see Note 8)	(1,646)		(32,987)	
Net loss applicable to common shareholders basic	(32,321)	(26,050)	(127,168)	(36,707)
Gain on warrant derivative liability		(4,392)	(119)	(6,773)
Net loss diluted	(32,321)	(30,442)	(127,287)	(43,480)
Net loss per share basic	(0.18)	(0.15)	(0.71)	(0.21)
Weighted average shares outstanding basic	183,245	174,502	179,780	173,426
Effect of dilutive warrants		639		879
Weighted average shares outstanding diluted	183,245	175,141	179,780	174,305
Net loss per share diluted	$ (0.18)	$ (0.17)	$ (0.71)	$ (0.25)

For the three and nine months ended September 30, 2015 and 2014, the following potentially dilutive securities were not included in the computation of net loss per share because the effect would be anti-dilutive:

	Three months ended	Nine months ended
In thousands		

	September 30, 2015	September 30, 2014	September 30, 2015	September 30, 2014
Stock options	17,627	11,246	17,627	11,246
Restricted stock and restricted stock units	11,001	2,262	11,001	2,262
Exchangeable senior notes (if converted)	49,215	49,215	49,215	49,215
Preferred stock (if converted)	32,818		32,818	

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 is 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.

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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 expense over the requisite service period. For awards with performance conditions, if the achievement of the performance conditions is deemed probable, the Company recognizes compensation expense based on the fair value of the award over the estimated service period. The Company reassesses the probability of achievement of the performance conditions for such awards each reporting 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% of gross product sales for each of the nine months ended September 30, 2015 and 2014, and represented 95% and 96% of the gross accounts receivable balance as of September 30, 2015 and 2014, respectively. The Company has not experienced any write-offs of its accounts receivable.

Concentration of Suppliers

The Company has contractual freedom to source the API for Vascepa and has entered into supply agreements with multiple suppliers. The Company s supply of product for commercial sale and clinical trials is dependent upon relationships with third party manufacturers and key suppliers, in particular three suppliers of API for Vascepa.

The Company cannot provide assurance that its efforts to procure uninterrupted supply of Vascepa API to meet market demand will continue to be successful or that it will be able to renew current API supply agreements on favorable terms or at all. Significant alteration to or termination of the Company s current API supply chain or its failure to enter into new and similar agreements, if needed, could have a material adverse effect on its business, condition (financial and other), prospects or results of operations.

The Company currently has manufacturing agreements with three FDA-approved commercial API encapsulators for Vascepa manufacturing. Each of these companies has qualified its manufacturing processes and is capable of manufacturing Vascepa. There can be no guarantee that these or other suppliers with which the Company may contract in the future to encapsulate API will continue to be qualified to manufacture the product to its specifications or that these and any future suppliers will have the manufacturing capacity to meet anticipated demand for Vascepa.

Foreign Currency

All subsidiaries use the U.S. dollar as the functional currency. Monetary assets and liabilities denominated in a foreign currency are remeasured into U.S. dollars at period-end exchange rates. Gains and losses from the remeasurement are included in other (expense) income, net in the condensed consolidated statements of operations. For transactions settled during the applicable period, gains and losses are included in other (expense) income, net in the condensed consolidated statements of operations. Certain supply contracts are denominated in currencies other than the U.S. dollar.

Debt Issuance Costs

Debt issuance costs are initially recorded as a deferred cost 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 condensed consolidated statements of operations.

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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 tables present information about the Company s assets and liabilities as of September 30, 2015 and December 31, 2014 that are measured at fair value on a recurring basis and indicate the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value:

	September 30, 2015			
In thousands	**Total**	**Level 1**	**Level 2**	**Level 3**
Asset:				
Cash equivalents money markets	$ 15,179	$ 15,179	$	$
Liabilities:				
Long-term debt derivative liabilities	$ 6,930	$	$	$ 6,930

	December 31, 2014			
In thousands	**Total**	**Level 1**	**Level 2**	**Level 3**
Asset:				
Cash equivalents money markets	$ 65,156	$ 65,156	$	$
Liabilities:				
Warrant derivative liability	$ 119	$	$	$ 119
Long-term debt derivative liabilities	$ 7,400	$	$	$ 7,400

The carrying amounts of cash, cash equivalents, accounts payable and accrued liabilities approximate fair value because of their short-term nature. The carrying amounts and the estimated fair values of debt instruments as of September 30, 2015 and December 31, 2014 are as follows:

In thousands	September 30, 2015 Carrying Value	September 30, 2015 Estimated Fair Value	December 31, 2014 Carrying Value	December 31, 2014 Estimated Fair Value
Long-term debt December 2012 financing	$ 91,009	$ 89,400	$ 89,617	$ 81,000
2012 Notes	31,266	27,627	31,266	25,689
2014 Notes	94,842	109,608	90,580	75,533

The estimated fair value of the long-term debt pursuant to the December 2012 financing is calculated utilizing the same Level 3 inputs utilized in valuing the related derivative liability (see Long-Term Debt Redemption Features below). The estimated fair value of the 2012 Notes and 2014 Notes is calculated based on Level 1 quoted bond prices. The carrying value of the 2012 Notes as of September 30, 2015 and December 31, 2014 does not include a debt discount, as it had been fully amortized as non-cash interest expense over the expected term of the 2012 Notes. The carrying value of the 2014 Notes as of September 30, 2015 and December 31, 2014 includes a debt discount of $23.9 million and $28.2 million, respectively, 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, 2014 to September 30, 2015 is largely related to changes in the quoted bond prices.

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Derivative Liabilities

Warrant Derivative Liability

The Company s warrant derivative liability is carried at fair value and is classified as Level 3 in the fair value hierarchy due to the use of significant unobservable inputs. Effective October 16, 2014, the Company entered into a series of warrant amendment agreements in order to extend the expiration date of certain outstanding warrants from its previously scheduled expiration date of October 16, 2014 to the close of business on February 27, 2015. Of the 8,087,388 warrants outstanding as of December 31, 2014, 1,844,585 warrants were exercised and the remaining 6,242,803 warrants expired on February 27, 2015. As such, no warrants were outstanding as of September 30, 2015 and the related derivative liability was extinguished.

As of December 31, 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 0.04%, (ii) remaining term of 0.16 years, (iii) no dividend yield, (iv) volatility of 79%, and (v) the stock price on the date of measurement. As there were no warrants outstanding as of September 30, 2015, the warrant derivative liability was extinguished. The $0.1 million decrease in the fair value of the warrants during the nine months ended September 30, 2015 was recognized as a $0.1 million gain on change in fair value of derivative liability.

Long-Term Debt Redemption Features

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 repay $150 million, less any previously repaid amount. 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 of future revenues and for a 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. As of September 30, 2015, the fair value of the derivative was determined to be $5.1 million, and the debt was valued by comparing debt issues of similar companies with (i) remaining terms of between 2.3 and 5.4 years, (ii) coupon rates of between 8.9% and 12.5% and (iii) market yields of between 10.5% and 18.8%. The Company recognized a $0.3 million loss on change in fair value of derivative liability for the nine months ended September 30, 2015. As of December 31, 2014, the fair value of the derivative was determined to be $4.8 million, and the debt was valued by comparing debt issues of similar companies with (i) remaining terms of between 2.3 and 3.6 years, (ii) coupon rates of between 9.8% and 10.8% and (iii) market yields of between 10.0% and 16.8%.

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. As of September 30, 2015, the fair value of the derivative was determined to be $1.8 million, and the debt was valued by using (i) the estimated remaining term of the notes, (ii) a bond yield of 22.9%, (iii) a risk-free interest rate of 2.7% and (iv) volatility of 83.0%. The Company recognized a $0.8 million gain on change in fair value of derivative liability for the nine months ended September 30, 2015. As of December 31, 2014, the fair value of the

derivative was determined to be $2.6 million, and the debt was valued by using (i) the estimated remaining term of the notes, (ii) a bond yield of 24.8%, (iii) a risk-free interest rate of 2.7% and (iv) volatility of 82.0%.

Preferred Stock Purchase Option Derivative Liability

Pursuant to a pre-existing contractual right to participate in certain private placement transactions effected by the Company in connection with the subscription agreement executed on March 5, 2015, the Company determined that such right represented a derivative liability (see Note 8). This preferred stock purchase option derivative liability was carried at fair value and classified as Level 3 in the fair value hierarchy due to the use of significant unobservable inputs. The fair value of this liability was calculated using a Black-Scholes model and was determined to be $0.9 million at inception. On March 30, 2015, this right was exercised and the liability was marked to fair value through such date. The liability was then reclassified to permanent equity on such date.

Any changes in the assumptions used to value the derivative liabilities, including the probability of a change in control, could result in a material change to the carrying value of such liabilities.

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The change in the fair value of derivative liabilities for the nine months ended September 30, 2015 and 2014 is as follows (in thousands):

	October 2009 Warrants	Long-Term Debt Derivative Liabilities	Preferred Stock Purchase Option	Totals
Balance as of December 31, 2014	**$ 119**	**$ 7,400**	**$**	**$ 7,519**
Record derivative liability			868	868
(Gain) loss on change in fair value of derivative liabilities	(110)	(470)	946	366
Compensation income for change in fair value of warrants issued to former employees	(9)			(9)
Transfer derivative liability to equity			(1,814)	(1,814)
Balance as of September 30, 2015	**$**	**$ 6,930**	**$**	**$ 6,930**

	October 2009 Warrants	Long-Term Debt Derivative Liabilities	Preferred Stock Purchase Option	Totals
Balance as of December 31, 2013	**$ 6,894**	**$ 11,100**	**$**	**$ 17,994**
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)
Balance as of September 30, 2014	**$ 121**	**$ 9,000**	**$**	**$ 9,121**

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, 2015:

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, and is effective for annual periods beginning after December 15, 2016 (the original effective date). In April 2015, the FASB issued a proposal, which was subsequently adopted in July 2015, to defer the original effective date of this standard by one year, such that the amendment is effective for the Company s fiscal year beginning January 1, 2018. Early adoption is permitted, but not before the original effective date. 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 is not expected to have an impact on the Company s condensed consolidated financial statements.

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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 fiscal years ending after December 15, 2016, and for annual 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.

In April 2015, the FASB issued ASU No. 2015-03, *Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs*. The amendments in this ASU require that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The Company is required to adopt this standard in the first quarter of fiscal 2016 on a retrospective basis. The implementation of this standard will result in the reclassification of certain debt issuance costs from other assets to a reduction in the carrying amount of the related debt liability within the condensed consolidated balance sheets.

In July 2015, the FASB issued Accounting Standards Update (ASU) No, 2015-11, *Inventory (Topic 330): Simplifying the Measurement of Inventory*. The amendments in this ASU require that in-scope inventory should be measured at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The amendments do not apply to inventory that is measured using last-in, first-out (LIFO) or the retail inventory method but applies to all other inventory, which include inventory that is measured using first-in, first-out (FIFO) or average cost. This standard is effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. 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 condensed consolidated financial position, results of operations, and cash flows, or do not apply to the Company s operations.

(3) Intangible Assets

Intangible assets consist of the historical acquisition cost of certain technology rights for Vascepa and have an estimated remaining useful life of 14.8 years. The carrying value as of September 30, 2015 and December 31, 2014 is as follows (in thousands):

	September 30, 2015	December 31, 2014
Technology rights	$ 11,624	$ 11,624
Accumulated amortization	(2,045)	(1,561)

	$	9,579	$	10,063

(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 as of September 30, 2015 and December 31, 2014 consist of the following (in thousands):

		September 30, 2015		December 31, 2014
Raw materials	$	3,741	$	5,225
Work in process		3,542		4,757
Finished goods		12,421		3,751
Total inventory	$	19,704	$	13,733

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(5) Warrants and Warrant Derivative Liability

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 a purchase price of $1.00 and (ii) a warrant with a five year term to purchase 0.5 of an ADS at an exercise price of $1.50 per ADS. In consideration for the conversion of $3.6 million of convertible bridge notes, Amarin issued 4.0 million units, each unit consisting of (i) one ADS (representing one ordinary share) at a purchase price of $0.90 and (ii) a warrant with a five year term to purchase 0.5 of an ADS at an exercise price of $1.50 per ADS. The total number of warrants issued in conjunction with the financing was 35.2 million.

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.

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.

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. Of the 8,087,388 warrants outstanding as of December 31, 2014, 1,844,585 warrants were exercised, resulting in net proceeds to the Company of $2.7 million, and the remaining 6,242,803 warrants expired on February 27, 2015. As such, no warrants were outstanding as of September 30, 2015.

July 2009 Warrants

The Company issued several warrants in July 2009. As of September 30, 2015 and December 31, 2014, there were no July 2009 warrants outstanding. During the year ended December 31, 2014, 1,684,888 of the July 2009 warrants were exercised, resulting in proceeds to the Company of $1.7 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. Under these terms, the Company continues to own all Vascepa intellectual property rights, however, such rights, as described below, could be used by BioPharma as collateral for repayment of the remaining unpaid balance under this agreement if the Company defaults on making required payments under the agreement. In the agreement, the Company agreed to repay BioPharma up to $150 million with such repayment based on a portion of revenues and receivables generated from Vascepa after the date of the agreement.

As of September 30, 2015, the remaining amount to be repaid to BioPharma is $139.4 million. During the three and nine months ended September 30, 2015, the Company made repayments under the agreement of $1.8 million and $5.0 million, respectively, to BioPharma and an additional $2.1 million is scheduled to be paid in November 2015. These payments 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.

The maximum quarterly amounts which could be due for payment, except upon a change of control and subject each quarter to the threshold limitation, is in accordance with the following schedule: $10.0 million in the first quarter of 2016, $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

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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. Except in the event of the Company s default, there is no compounding of interest and no scheduled cliff payment due under this agreement. Rather, payment is intended, subject to the threshold limitation, until $150 million in aggregate has been repaid, including payments made previously. 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 maximum quarterly 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. 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, prospectively.

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 and any changes in the assumptions used in measuring the fair value of the derivative liability could result in a material increase or decrease in its carrying value. The Company recognized a loss on change in fair value of derivative liability of $0.3 million and a gain on change in fair value of derivative liability of $6.5 million during the nine months ended September 30, 2015 and 2014, respectively.

During the nine months ended September 30, 2015, the Company recorded $4.9 million and $1.4 million of cash and non-cash interest expense, respectively, in connection with the BioPharma debt. 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. 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).

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 and 2014 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 (equivalent to an initial exchange price of approximately $8.8125 per ADS), subject to adjustment in certain circumstances, including adjustment if the Company pays cash dividends. 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). Based on the closing price of the Company s stock as of September 30, 2015, the principal amount of the 2012 Notes would exceed the value of the shares if converted on that date by $24.4 million.

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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 Securities Exchange Act of 1934 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 was 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, 2015 and December 31, 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, 2015 and December 31, 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

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).

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 initial exchange rate is 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

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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. Based on the closing price of the Company s stock as of September 30, 2015, the principal amount of the 2014 Notes would exceed the value of the shares if converted on that date by $30.6 million.

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 nine months ended September 30, 2015, the Company recognized a $0.8 million gain on the

change in fair value of the redemption feature. The fair value of this derivative liability is remeasured at each reporting period, with changes in fair value recognized in the statement of operations and any changes in the assumptions used in measuring the fair value of the derivative liability could result in a material increase or decrease in its carrying value.

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, 2015 and December 31, 2014, the carrying value of the 2014 Notes, net of the unamortized debt discount, was $94.8 million and $90.6 million, respectively. During the nine months ended September 30, 2015, the Company recognized aggregate interest expense of $8.5 million related to the Notes, of which $4.6 million represents amortization of the debt discount and $3.9 million represents contractual coupon interest. During the nine months ended September 30, 2014, the Company recognized aggregate interest expense of $6.7 million related to the Notes, of which $2.8 million represents non-cash interest and $3.9 million represents contractual coupon interest.

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As of September 30, 2015 and December 31, 2014, the Company had accrued interest on the Notes of $1.1 million and $2.4 million, respectively, which is included in other current liabilities. The Company made the contractual interest payments due on the Notes during the nine months ended September 30, 2015 and 2014 of $5.3 million.

(7) Commitments and Contingencies

Litigation

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 its business. Item 3. Legal Proceedings of the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2014 includes a discussion of the Company s current legal proceedings. There have been no material changes to those disclosures as of the date of this filing other than as set forth below.

On May 7, 2015, the Company and a group of independent physicians filed a federal lawsuit to permit the Company to share truthful and non-misleading information, including, but not limited to, the ANCHOR trial clinical data, with healthcare professionals in the United States about certain uses of Vascepa not included with approved FDA labeling of Vascepa and thus not permitted under the FDA s interpretation of applicable law. The lawsuit, captioned *Amarin Pharma, Inc., et al. v. Food & Drug Administration, et al.* (1:15-cv-03588-PAE), was filed in the United States District Court for the Southern District of New York and seeks a judicial declaration based on several legal theories. On August 7, 2015, the Court granted the Company s request for preliminary relief in this litigation through a declaratory judgment that confirmed the Company may engage in truthful and non-misleading speech with healthcare professionals promoting the off-label use of Vascepa, i.e., to treat patients with persistently high triglycerides, and such speech may not form the basis of a misbranding action under the Federal Food and Drug Cosmetic Act. FDA did not appeal the Court s preliminary ruling prior to the October 6, 2015 deadline for appeal. The underlying litigation has been stayed for settlement discussion and the parties are working toward settlement. The Company cannot predict the outcome of settlement negotiations or this litigation.

On May 28, 2015, the U.S. District Court for the District of Columbia granted the Company s motion for summary judgment in the Company s lawsuit against the FDA, captioned *Amarin Pharmaceuticals Ireland Ltd. v. Food & Drug Administration, et al.*, Civ. A. No. 14-0324 (D.D.C.). This lawsuit sought an order requiring FDA to recognize five-year, New Chemical Entity (NCE) marketing exclusivity for Vascepa. The decision vacated the FDA s denial of the Company s claim for such exclusivity and remanded to the FDA for proceedings consistent with the decision. On July 22, 2015, Watson Laboratories Inc., the purported first Vascepa ANDA filer, sought to intervene and appeal the Court s decision. The Company intends to continue to litigate the case vigorously, but cannot predict the outcome of this litigation. FDA did not appeal the Court s decision prior to the July 28, 2015 deadline for appeal.

Based on the May 28, 2015 U.S. District Court for the District of Columbia order granting the Company s motion for summary judgment in the NCE litigation, on June 26, 2015, the parties to the related Vascepa patent litigation that followed acceptance by FDA of abbreviated new drug applications, or ANDAs, to Vascepa agreed to a full stay of proceeding in that patent litigation. Based on subsequent FDA notification to the ANDA filers that FDA had changed the status of their ANDAs to submitted, but no longer accepted, the Company believes the statutory basis for the patent litigation (accepted ANDAs) no longer exists. Thus, on July 24, 2015, the Company moved to dismiss the pending patent infringement lawsuits against each of the Vascepa ANDA applicants. The Company cannot predict the outcome of this motion to dismiss or litigation. If the motion to dismiss is granted, the Company plans to defend the exclusivity of Vascepa through patent litigation after notification that FDA has accepted an ANDA application related to Vascepa which, assuming NCE exclusivity, the Company would expect no sooner than late July 2016.

On June 29, 2015, the U.S. District Court for the District of New Jersey granted the Company s motion to dismiss the putative consolidated class action lawsuit captioned *In re Amarin Corporation plc, Securities Litigation,* No. 3:13-cv-06663 (D.N.J. Nov. 1, 2013). The class action was dismissed without prejudice with leave for plaintiffs to file an amended complaint. The lawsuit sought unspecified monetary damages and attorneys fees and costs alleging 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 potential approval. On July 29, 2015, plaintiffs filed an amended complaint alleging facts similar to those in the original complaint. Like the first complaint, the amended complaint seeks unspecified monetary damages and attorneys fees and costs. The Company believes it has valid defenses and will continue to vigorously defend against this lawsuit, but cannot predict the outcome. The Company has insurance coverage that is anticipated to cover any significant loss exposure that may arise from this action.

Milestone and Supply Purchase Obligations

The Company entered into several product development agreements with, subject to performance obligations, certain milestone and supply purchase obligations.

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The Company entered into long-term supply agreements with multiple FDA-approved API suppliers and encapsulators. Certain supply agreements require annual minimum volume commitments by the Company and certain volume shortfalls may require payments for such shortfalls. The Company continues to meet its contractual volume obligations.

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 shareholders of Laxdale (at the sole option of each of the sellers) of £7.5 million (approximately $11.4 million as of September 30, 2015). Also under the Laxdale agreement, upon receipt of a marketing approval in the United States or Europe for a further indication of Vascepa (or further indication of any other product using Amarin Neuroscience intellectual property), the Company must make an aggregate stock or cash payment (at the sole option of each of the sellers) of £5 million (approximately $7.6 million as of September 30, 2015) for each of the two potential market approvals (i.e., £10 million maximum, or approximately $15.2 million as of September 30, 2015).

The Company has no provision for any of the obligations above since the amounts are either not probable or able to be estimated as of September 30, 2015.

(8) Equity

Warrants

During the nine months ended September 30, 2015, the Company issued 1,844,585 shares upon the exercise of warrants, resulting in gross and net proceeds of $2.8 million and $2.7 million, respectively. During the nine months ended September 30, 2014, the Company issued 1,684,888 shares upon the exercise of warrants, resulting in gross and net proceeds of $1.7 million.

Incentive Equity Awards

As of September 30, 2015, there were an aggregate of 17,626,803 stock options and 11,001,361 restricted stock units (RSUs) outstanding, representing approximately 7% and 4%, respectively, of outstanding shares (including common and preferred shares) on a fully diluted basis.

During the nine months ended September 30, 2015 and 2014, the Company issued 18,020 and 234,500 shares, respectively, as a result of the exercise of stock options, resulting in gross and net proceeds of $31 thousand and $0.3 million, respectively, for each period.

On July 6, 2015, the Company granted a total of 1,455,000 RSUs and 5,470,000 stock options to employees under the Amarin Corporation plc Stock Incentive Plan (the 2011 Plan). The RSUs granted vest over a four year period. Of the total stock options granted, 3,670,000 stock options vest over a four year period while the remaining 1,800,000 stock options vest upon the achievement of certain performance conditions. During the nine months ended September 30, 2015, the Company issued 84,688 common shares related to the vesting of these RSUs, of which 17,734 shares were retained as treasury shares as settlement of employee tax obligations.

Also on July 6, 2015, the Company granted a total of 413,500 RSUs and 288,657 stock options to members of the Company s Board of Directors under the 2011 Plan. Of the total awards granted, 283,500 RSUs and 121,506 stock options vest in equal installments over a three year period upon the earlier of the one-year anniversary of the grant

date or the Company s annual general meeting of shareholders in such anniversary year, while the remaining 130,000 RSUs and 167,151 stock options vest in full upon the earlier of the one-year anniversary of the grant date or the Company s annual general meeting of shareholders in such anniversary year. Upon termination of service to the Company or upon a change of control, 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.

On January 29, 2015, the Company granted a total of 2,564,251 RSUs and 1,622,500 stock options to employees under the 2011 Plan. The RSUs vest annually over a three year period and the stock options vest over a four year period. Also on January 29, 2015, the Company granted 5,455,500 RSUs to employees under the 2011 Plan that vest upon the achievement of certain performance conditions. The issuance of these performance RSUs was contingent upon shareholder approval to increase the aggregate number of shares authorized for issuance under the 2011 Plan, which was obtained at the Company s Annual General Meeting of Shareholders held on July 6, 2015.

On March 11, 2014, the Company granted a total of 173,348 RSUs and 205,890 stock options to members of the Company s Board of Directors under the 2011 Plan. Upon termination of service to the Company or upon a change of control, 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 RSUs vest in equal installments over a three year period 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 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.

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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. During the nine months ended September 30, 2015, the Company issued 639,500 common shares related to the vesting of these RSUs, of which 114,258 shares were retained as treasury shares as settlement of employee tax obligations.

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.

Preferred Stock

On March 5, 2015, the Company entered into a subscription agreement with four institutional investors (the Purchasers), including both existing and new investors, for the private placement of 352,150,790 restricted American Depositary Shares, each representing one (1) share of Amarin s Series A Convertible Preference Shares, par value £0.05 per share, in the capital of the Company (Series A Preference Shares), resulting in gross proceeds to the Company of $52.8 million. The closing of the private placement occurred on March 30, 2015.

For each restricted American Depositary Share, the Purchasers paid a negotiated price of $0.15 (equating to $1.50 on an as-converted to ordinary share basis), resulting in $52.8 million in aggregate gross proceeds to the Company, before deducting estimated offering expenses of approximately $0.7 million. The net proceeds are reflected as preferred stock in the accompanying condensed consolidated balance sheets.

Each ten (10) Series A Preference Shares may be consolidated and redesignated as one (1) ordinary share, par value £0.50 per share, in the capital of the Company, each ordinary share to be represented by American Depositary Shares (ADSs), provided that consolidation will be prohibited if, as a result, the holder of such Series A Preference Shares and its affiliates would beneficially own more than 4.99% of the total number of Amarin ordinary shares or ADSs outstanding following such redesignation (the Beneficial Ownership Limitation). By written notice to the Company, a holder may from time to time increase or decrease the Beneficial Ownership Limitation to any other percentage not in excess of 19.9% specified in such notice; provided that any such increase will not be effective until the sixty-first (61st) day after such notice is delivered to the Company. This consolidation and redesignation may be effected by a holder of Series A Preference Shares following the first to occur of the resale of the ADSs representing the ordinary shares being registered for resale under the Securities Act pursuant to an effective registration statement, following any sale of the ADSs representing the ordinary shares pursuant to Rule 144 under the Securities Act, or if such ADSs representing the ordinary shares are eligible for sale under Rule 144, following the expiration of the one-year holding requirement under Rule 144. During the nine months ended September 30, 2015, at the request of the holders, a portion of the Series A Preference Shares were consolidated and redesignated, resulting in the issuance of 6,283,333 ADSs such that a maximum of 32,818,464 ordinary shares remain issuable upon future consolidation and redesignation of the remaining Series A Preference Shares, inclusive of the shares issued in July 2015 as discussed below, subject to certain adjustments for dilutive events.

Except as otherwise provided in the Series A Preference Share Terms or as required by applicable law, the Series A Preference Shares have no voting rights. However, as long as any Series A Preference Shares are outstanding, the Company cannot, without the approval of the holders of seventy-five percent (75%) of the then outstanding Series A Preference Shares, alter or change adversely the powers, preferences or rights attaching to the Series A Preference Shares or enter into any agreement with respect to the foregoing.

Holders of the Series A Preference Shares are entitled to receive, and the Company is required to pay, dividends (other than dividends in the form of ordinary shares) on the Series A Preference Shares equal (on an as-if-converted-to-ordinary-shares basis) to and in the same form as dividends (other than dividends in the form of ordinary shares) actually paid on ordinary shares when, as and if such dividends (other than dividends in the form of ordinary shares) are paid on the ordinary shares.

The restricted American Depositary Shares and Series A Preference Shares have not been registered under the Securities Act of 1933, as amended (the Securities Act), or state securities laws and may not be offered or sold in the United States absent registration with the Securities and Exchange Commission (SEC) or an applicable exemption from registration requirements. The Company filed a registration statement with the SEC covering the resale of the restricted American Depositary Shares and the ADSs representing ordinary shares created by the consolidation and redesignation of the Series A Preference Shares (the Registrable Securities) on April 9, 2015. In addition, the Company agreed to use its commercially reasonable best efforts to effect and to keep the registration, and any qualification, exemption or compliance under state securities laws which the Company determines to obtain, continuously effective, and to keep the Registration Statement free of any material misstatements or omissions, until the earlier of (a) March 11, 2017 or (b) the date on which all Registrable Securities held by Purchasers may be sold or transferred in compliance with Rule 144 under the Securities Act, without any volume or manner of sale restrictions.

The Series A Preference Shares contain a contingent beneficial conversion feature (BCF) because they contain a conversion feature at a fixed rate that was in-the-money when issued. The BCF was recorded in the three months ended June 30, 2015 as a result of the related Form S-3 Registration Statement being declared effective, which represents the resolution of the contingency to convert the Series A Preference Shares. The BCF was recognized in stockholders deficit and was measured by allocating a portion of the

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proceeds equal to the intrinsic value of that feature to additional paid-in capital. The effective purchase price of the ordinary shares into which the preferred shares are convertible was $1.50, which was used to compute the intrinsic value. The intrinsic value was calculated as the difference between the effective purchase price of the ordinary shares and the market value ($2.39 per share) on the date the preferred shares were issued, multiplied by the number of shares into which the preferred shares are convertible. The BCF resulting from the issuance of the Series A Preference Shares was determined to be $31.3 million. The BCF was recorded as a non-cash dividend to preferred shareholders through accumulated deficit, and is therefore reflected as an adjustment to net loss applicable to common shareholders for earnings per common share purposes in accordance with GAAP.

On March 30, 2015, in connection with the closing of the private placement, and pursuant to a pre-existing contractual right to participate in certain private placement transactions effected by the Company, the Company entered into a separate subscription agreement with an existing investor, Sofinnova Venture Partners VII L.P. (Sofinnova), for the purchase of an additional $5.8 million of restricted American Depositary Shares, each representing one (1) share of the Company s Series A Preference Shares, at the same price per share and otherwise on substantially the same terms as the initial private placement (the Second Private Placement). In accordance with applicable marketplace rules of the NASDAQ Stock Market, the consummation of the Second Private Placement was conditioned upon approval by the Company s shareholders at a future meeting of the Company s shareholders. Such approval was received at the Company s Annual General Meeting of Shareholders on July 6, 2015 and as a result, the closing of the Second Private Placement occurred on July 10, 2015. The Company issued 38,867,180 restricted ADSs, each representing one Series A Preference Share, which may be consolidated and redesignated from time to time up to a maximum of 3,886,718 ordinary shares, each ordinary share to be represented by one ADS. For each restricted ADS, Sofinnova paid a negotiated price of $0.15 (equating to $1.50 on an as converted to ordinary share basis) resulting in gross proceeds to the Company of $5.8 million. Dr. James Healy, a member of the Company s Board, is a managing member of Sofinnova Management VII, L.L.C., the general partner of Sofinnova.

The existence of this preferred stock purchase option was determined to be a derivative liability effective March 5, 2015, the date in which the private placement was initially subscribed. The fair value of this liability was calculated using a Black-Scholes model and was determined to be $0.9 million at inception and was charged to accumulated deficit as a deemed non-cash dividend to Sofinnova. The liability was then marked to fair value as of March 30, 2015, the date on which the Company executed a subscription agreement with Sofinnova, resulting in a charge of $0.9 million through (loss) gain on change in fair value of derivatives. The liability of $1.8 million was reclassified to permanent equity (additional paid-in capital) on such date. Subsequent to approval of the Second Private Placement, the Company recorded the remaining value of the BCF related to this share issuance as a non-cash dividend to preferred shareholders through accumulated deficit. The value of the BCF was determined on the same basis as the first private placement and amounted to $3.4 million less $1.8 million previously recorded for the preferred stock purchase option for a net non-cash charge of $1.6 million.

(9) Co-Promotion Agreement

On March 31, 2014, the Company entered into a Co-Promotion Agreement (the Agreement) with Kowa Pharmaceuticals America, Inc. related to the commercialization of Vascepa® (icosapent ethyl) capsules in the United States. Under the terms of the Agreement, Amarin granted to Kowa Pharmaceuticals America, Inc. 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, Inc. 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, and the use of a negotiated number of minimum sales representatives from each party, including no less than 250 Kowa Pharmaceuticals America, Inc. sales representatives. Kowa Pharmaceuticals America, Inc. 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.

In exchange for Kowa Pharmaceuticals America, Inc. s co-promotional services, Kowa Pharmaceuticals America, Inc. is entitled to a quarterly co-promotion fee based on a percentage of Vascepa gross margin that increases during the Agreement s term, from the high single digits in 2014 to the low twenty percent level 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 certain circumstances, upon the earlier of the expiration or termination of the Agreement in accordance with its terms, Kowa Pharmaceuticals America, Inc. may be eligible for a co-promotion tail fee equal to declining fractions of the co-promote fee in effect prior to such expiration or termination for periods ranging from one to three years following such expiration or termination.

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As of September 30, 2015 and December 31, 2014, the Company had a net payable of $0.4 million and a net receivable of $0.6 million, respectively, from Kowa Pharmaceuticals America, Inc. representing co-promotion fees payable to Kowa Pharmaceuticals America, Inc. net of reimbursable amounts incurred for samples and other marketing expenses.

(10) Development, Commercialization and Supply Agreement

On February 26, 2015, the Company entered into a Development, Commercialization and Supply Agreement (the DCS Agreement) with Eddingpharm (Asia) Macao Commercial Offshore Limited (Eddingpharm) related to the development and commercialization of Vascepa in Mainland China, Hong Kong, Macau and Taiwan (the China Territory). Under the terms of the DCS Agreement, the Company granted to Eddingpharm an exclusive (including as to the Company) license with right to sublicense to develop and commercialize Vascepa in the China Territory for uses that are currently commercialized and under development by the Company based on the Company s MARINE, ANCHOR and ongoing REDUCE-IT clinical trials of Vascepa.

Under the DCS Agreement, Eddingpharm will be solely responsible for development and commercialization activities in the China Territory and associated expenses. The Company will provide development assistance and be responsible for supplying finished and later bulk drug product at defined prices under negotiated supply terms. The Company will retain all Vascepa manufacturing rights. Eddingpharm has agreed to certain restrictions regarding the commercialization of competitive products globally and the Company has agreed to certain restrictions regarding the commercialization of competitive products in the China Territory.

The Company and Eddingpharm agreed to form a joint development committee to oversee regulatory and development activities for Vascepa in the China Territory in accordance with a negotiated development plan and to form a separate joint commercialization committee to oversee Vascepa commercialization activities in the China Territory. Development costs will be paid by Eddingpharm to the extent such costs are incurred in connection with the negotiated development plan or otherwise incurred by Eddingpharm. Eddingpharm will be responsible for preparing and filing regulatory applications in all countries of the China Territory at Eddingpharm s cost with the Company s assistance. The DCS Agreement also contains customary provisions regarding indemnification, packaging, record keeping, audit rights, reporting obligations, and representations and warranties that are customary for an arrangement of this type.

The term of the DCS Agreement expires, on a product-by-product basis, upon the later of (i) the date on which such product is no longer covered by a valid claim under a licensed patent in the China Territory, or (ii) the twelfth (12th) anniversary of the first commercial sale of such product in Mainland China. The DCS Agreement may be terminated by either party in the event of a bankruptcy of the other party and for material breach, subject to customary cure periods. In addition, at any time following the third anniversary of the first commercial sale of a product in Mainland China, Eddingpharm has the right to terminate the DCS Agreement for convenience with twelve months prior notice. Neither party may assign or transfer the DCS Agreement without the prior consent of the other party, provided that the Company may assign the DCS Agreement in the event of a change of control transaction.

Upon closing of the DCS Agreement, the Company received a non-refundable $15.0 million up-front payment, which it will recognize as revenue over the estimated period in which the Company is required to provide initial and on-going regulatory and development support and clinical supply for obtaining regulatory approvals in the China Territory and through the estimated period in which the Company is required to provide commercial supply, which is currently estimated to be a period of approximately 16 years. Consequently, the Company recognized $0.5 million of the up-front payment as licensing revenue during the nine months ended September 30, 2015 and recorded $14.5

million as deferred revenue as of September 30, 2015. In addition to the non-refundable, up-front payment, the Company is entitled to receive development, regulatory and sales-based milestone payments of up to an additional $154.0 million as well as tiered double-digit percentage royalties on net sales of Vascepa in the China Territory escalating to the high teens. Revenues relating to these milestone payments and royalties will be recognized upon satisfaction of the applicable performance obligations or over the period in which such performance obligations are completed, as applicable.

(11) Subsequent Events

The Company has evaluated subsequent events from September 30, 2015 through the date of the issuance of these condensed consolidated financial statements.

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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, 2014 and below under Part II, Item IA, 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 ³500 mg/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. In August 2015, we also began marketing Vascepa in the United States for the treatment of patients with high (TG ³200 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 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. under which approximately 250 Kowa Pharmaceuticals America, Inc. sales representatives began to devote a substantial portion of their time to promoting Vascepa starting in May 2014.

In February 2015, we announced an exclusive agreement with Eddingpharm (Asia) Macao Commercial Offshore Limited, or Eddingpharm, to develop and commercialize Vascepa capsules in Mainland China, Hong Kong, Macau and Taiwan (the China Territory). We are also assessing other partnership opportunities for licensing Vascepa in other territories outside of the United States.

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 70 million adults in the United States have elevated triglyceride levels (TG ≥150 mg/dL), approximately 40 million adults in the United States have high triglyceride

levels (TG ≥200 mg/dL), and approximately 4.0 million people in the United States have severely high triglyceride levels (TG ≥500 mg/dL), commonly known as very high triglyceride levels. Many patients with high triglycerides also have other lipid level abnormalities such as high cholesterol. The patient condition of having more than one lipid level abnormality is referred to as mixed dyslipidemia. According to *The American Heart Association Scientific Statement on Triglycerides and Cardiovascular Disease* (2011), triglycerides provide important information as a marker associated with the risk for heart disease and stroke, especially when an individual also has low high-density lipoprotein 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.

We are currently focused on completing the ongoing REDUCE-IT (Reduction of Cardiovascular Events with EPA Intervention Trial) cardiovascular outcomes study of Vascepa, which we started in December 2011. 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 indicated uses for Vascepa. In REDUCE-IT, cardiovascular event rates for patients on stable statin therapy plus

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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 and published in 2018. An interim review of the efficacy and safety 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 and it is our expectation that the trial will run to completion. The DMC has been more frequently examining interim reviews of the safety data from the study. Following each of these reviews, the DMC has communicated to us that we should continue the study as planned. We remain blinded to all data from the study. Over 97% of the 8,000 patients targeted for enrollment in the REDUCE-IT study have been enrolled.

The potential efficacy and safety of Vascepa (known in its development stage as AMR 101) has been 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 also developed Vascepa for FDA approval for the treatment of patients with high (TG ³200 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.

On October 16, 2013, the FDA convened an advisory committee to review our supplemental new drug application, or sNDA, seeking marketing approval of Vascepa for use in the ANCHOR indication. 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 would improve cardiovascular outcomes or whether approval of the ANCHOR indication should wait for successful completion of the REDUCE-IT study. The advisory committee voted 9 to 2 against recommending approval of the ANCHOR indication based on information presented at the meeting.

The ANCHOR clinical study was conducted under a special protocol assessment, or SPA, agreement 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. On April 27, 2015, following three attempts by us to appeal the SPA agreement rescission decision by the FDA, we received a Complete Response Letter, or CRL, from the FDA regarding our ANCHOR sNDA. In the CRL, the FDA acknowledged that Vascepa yielded a treatment difference showing reduced triglyceride levels compared to placebo in patients treated in the ANCHOR study. The FDA concluded that, for regulatory approval purposes, there are insufficient data at this time to support a drug-induced change in serum triglycerides as a surrogate for reducing cardiovascular risk in the ANCHOR population. The FDA views the ANCHOR indication as ostensibly and impliedly an indication to reduce cardiovascular risk. The FDA did not determine that the drug-induced effects of Vascepa, which go beyond triglyceride-lowering, would not actually reduce cardiovascular risk in this population. We had proposed to the FDA multiple alternative indications, data

presentations, disclaimers and other regulatory pathways to approval under the ANCHOR sNDA, but the FDA determined not to approve label expansion reflecting the ANCHOR clinical trial efficacy data at this time. Safety data from the ANCHOR study remain in the currently approved label for Vascepa. Vascepa remains FDA approved for use as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia, and current Vascepa labeling remains unchanged. The CRL has no effect on the SPA agreement for the REDUCE-IT study or the anticipated timing for results from the REDUCE-IT study. Based on our communications with the FDA, we expect that final positive results from the REDUCE-IT outcomes study will be required for label expansion for Vascepa.

On May 7, 2015, we and a group of independent physicians filed a lawsuit in federal court to permit us to promote to healthcare professionals the use of Vascepa in patients with mixed dyslipidemia so long as the promotion is truthful and non-misleading. This use reflects recognized medical practice but is not covered by current FDA-approved labeling for the drug and is thus considered by FDA to be illegal off-label promotion. On August 7, 2015, we were granted preliminary relief in the form of a declaratory judgment in this lawsuit. The court declaration permits us to promote to healthcare professionals the FDA-reviewed and agreed effects of Vascepa demonstrated in the ANCHOR clinical trial and presentation of the current state of scientific research related to the potential of Vascepa to reduce the risk of cardiovascular disease including through use of peer-reviewed scientific publications of available data. The FDA did not appeal the court s ruling prior to the October 6, 2015 deadline. The underlying litigation has been stayed for settlement discussion and the parties are working toward settlement.

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Commercialization United States

We commenced the commercial launch of Vascepa in the United States in January 2013. We commenced sales and shipments of Vascepa at that time to our network of U.S.-based wholesalers. We now market Vascepa in the United States through our sales force of approximately 150 sales professionals and their managers. Commencing in May 2014, in addition to promotion by our sales representatives, approximately 250 Kowa Pharmaceuticals America, Inc. sales representatives began promoting Vascepa. We also employ various marketing personnel to support our commercialization of Vascepa.

Under our co-promotion agreement with Kowa Pharmaceuticals America, Inc., 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, Inc. sales representatives and the achievement of minimal levels of Vascepa revenue in 2015 and beyond. Kowa Pharmaceuticals America, Inc. 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, Inc. s co-promotional services, Kowa Pharmaceuticals America, Inc. 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, Inc. is scheduled to increase from the high single digits in 2014, to fifteen percent (15%) in 2015, and to the low twenty percent levels in 2018, subject to certain adjustments. The term of this co-promotion agreement expires on December 31, 2018.

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, 2015 was approximately 199,000 compared to 176,000, 154,000, and 132,000 in the three months ended June 30, 2015, March 31, 2015, and September 30, 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, 2015 was approximately 176,000 compared to 157,000, 137,000, and 113,000 in the three months ended June 30, 2015, March 31, 2015, and September 30, 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 third party resources and may be subject to adjustment and may overstate or understate actual prescriptions. Timing of shipments to wholesalers, as used for revenue recognition purposes, 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. While we expect to be able to grow Vascepa revenues over time, no such guidance should be inferred from the operating metrics described above. We also anticipate that such sales growth may be inconsistent from period to period. We believe that investors should view the above-referenced operating metrics with caution, as data for this limited period may not be representative of a trend consistent with the results presented or otherwise predictive of future results. Seasonal fluctuations in pharmaceutical sales, for example, may affect future prescription trends of Vascepa, as could changes in prescriber sentiment and other factors. We believe investors should consider our results over several quarters, or longer, before making an assessment about potential future performance.

The commercialization of a new pharmaceutical product is a complex undertaking, and our ability to effectively and profitably commercialize 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*.

In August 2015, we and our co-promotion partner began communicating ANCHOR clinical trial data to targeted healthcare professionals. Such qualified communications are being made pursuant to the August 7, 2015 federal district court declaration allowing truthful and non-misleading promotion of the FDA-reviewed and agreed effects of Vascepa demonstrated in the ANCHOR clinical trial and presentation of the current state of scientific research related to the potential of Vascepa to reduce the risk of cardiovascular disease including through use of peer-reviewed scientific publications of available data.

Commercialization Outside the United States

In February 2015, we announced an exclusive agreement with Eddingpharm to develop and commercialize Vascepa capsules in the territories of Mainland China, Hong Kong, Macau and Taiwan (the China Territory) for uses that are currently commercialized and under development by us in the United States based on the MARINE, ANCHOR and ongoing REDUCE-IT clinical trials of Vascepa.

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Under the agreement, Eddingpharm is responsible for development and commercialization activities in the China Territory and associated expenses. We will provide development assistance and be responsible for supplying the product. Terms of the agreement include up-front and milestone payments to us of up to $169.0 million, including a non-refundable $15.0 million up-front payment received at closing, and development, regulatory and sales-based milestone payments of up to an additional $154.0 million. Eddingpharm will also pay us tiered double-digit percentage royalties on net sales of Vascepa in the China Territory escalating to the high teens. We will supply finished product to Eddingpharm under negotiated supply terms.

We continue to assess other partnership opportunities for licensing Vascepa in other territories outside of the United States.

Research and Development

REDUCE-IT is the first prospective cardiovascular outcomes study of any drug in a population of patients who, despite stable statin therapy, have elevated triglyceride levels. REDUCE-IT is a multinational, prospective, randomized, double-blind, placebo-controlled study designed to assess the cumulative effect on the rate of cardiovascular events for patients treated with Vascepa as an add-on to statin therapy compared to the corresponding rate of cardiovascular events for patients treated with placebo on top of statin therapy. Based on the results of REDUCE-IT, we may seek additional indications for Vascepa beyond the indications studied in the ANCHOR or MARINE trials.

REDUCE-IT is designed to enroll 8,000 patients, of which over 7,700 patients have been enrolled. We currently estimate that we will complete patient enrollment in this study near the end of 2015.

Completion of the REDUCE-IT study is designed to occur 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 and safety 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, or 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 and it is our expectation that the trial will run to completion. Amarin remains blinded to all data from the study. Unless overwhelming efficacy and safety is declared by the DMC at the interim look or the study is halted due to a patient safety concern, Amarin personnel will remain blinded to the efficacy and safety data from the REDUCE-IT study until the study is complete. The DMC has periodically reviewed unblinded safety data since initiation of the REDUCE-IT study in 2011 and, after each such meeting to date, has recommended that the study be continued as planned. The pre-specified interim review at 60% of the target aggregate number of cardiovascular events will involve a look by the DMC in closed session at all efficacy and safety data available from the REDUCE-IT study at that time. Interim looks by independent DMCs are common in large, long-term outcomes studies. By design, it is most common for cardiovascular outcomes studies not to be stopped upon an interim look.

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. Our scientific rationale for the REDUCE-IT study is also supported by research on the putative cardioprotective effects of EPA as presented in scientific literature. It is possible that the effects of EPA may be due

not to a single mode of action, such as triglyceride lowering, but rather to multiple mechanisms working together. Studies in the scientific literature explore potentially beneficial effects of EPA on multiple atherosclerosis processes, including endothelial function, oxidative stress, foam cell formation, inflammation/cytokines, plaque formation/progression, platelet aggregation, thrombus formation, and plaque rupture. The REDUCE-IT study is needed to determine the clinical benefit, if any, of EPA therapy in statin-treated patients with elevated triglyceride levels.

Commercial Supply

To date, all of our active pharmaceutical ingredient, or API, that has been utilized in product sold has been manufactured by two suppliers: Nisshin Pharma, Inc., or Nisshin, and Chemport, Inc., or Chemport. A significant portion of such API was purchased from Nisshin at a price that is higher than expected future average API costs. During 2015, we began purchasing API from a third supplier, Finorga SAS, or Novasep. The amount of supply we seek to purchase in future periods will depend on the level of growth of Vascepa revenues and minimum purchase commitments with certain suppliers.

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Financial Position

We believe that our cash and cash equivalents balance of $119.0 million as of September 30, 2015 is sufficient to fund our projected operations for at least the next twelve months. Included in our cash balance as of September 30, 2015 was a $15.0 million non-refundable, up-front payment we received upon the execution of our first ex-U.S. licensing agreement in China and surrounding territories and net proceeds of $57.7 million we received from the issuance and sale of our Series A Preference Shares.

Financial Operations Overview

Product Revenue, net. All of our product 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. We commenced our commercial launch in the United States in January 2013. In accordance with U.S. Generally Accepted Accounting Principles (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, 2015, product returns were de minimis.

Licensing revenue. Licensing revenue currently consists of revenue attributable to the receipt of an up-front, non-refundable payment related to a Vascepa license agreement in China, which is being recognized over the estimated period in which we are required to provide regulatory and development support and clinical and commercial supply pursuant to the agreement, which is currently anticipated to be a period of approximately 16 years.

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.

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 and co-promotion fees payable to Kowa Pharmaceuticals America, Inc. Other costs primarily include facility costs and professional fees for accounting, consulting and legal services.

Research and Development Expense. Research and development expense consists primarily of fees paid to professional service providers in conjunction with independent monitoring of our clinical trials and acquiring and evaluating data in conjunction with our clinical trials, fees paid to independent researchers, costs of qualifying contract manufacturers, services expenses incurred in developing and testing products and product candidates, salaries and related expenses for personnel, including stock-based compensation expense, costs of materials, depreciation, rent, utilities and other facilities costs. In addition, research and development expenses include the cost to support current development efforts, including patent costs and milestone payments, as well as the cost to support regulatory and development activities related to our development and commercialization agreement with our international partner, Eddingpharm. We expense research and development costs as incurred. In addition, research and development costs include the costs of product supply we received from suppliers when such receipt is prior to regulatory approval of the supplier.

(Loss) Gain on Change in Fair Value of Derivative Liabilities. (Loss) gain on change in fair value of derivative liabilities is comprised of: (i) the change in fair value of the warrant derivative liability, (ii) the change in fair value of the derivative liability related to the change in control provision associated with the December 2012 financing with BioPharma Secured Debt Fund II Holdings Cayman LP, or BioPharma, (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) the change in fair value of the derivative liability related to the preferred stock purchase option.

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. Interest expense under our exchangeable notes includes the amortization of the conversion option related to our exchangeable debt, the amortization of the related debt discounts and debt obligation coupon interest. Interest expense under our BioPharma financing arrangement is calculated based on an estimated repayment schedule. Interest income consists of interest earned on our cash and cash equivalents. Other (expense) income, net, consists primarily of foreign exchange losses and gains.

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Critical Accounting Policies and Significant Judgments and Estimates

Our discussion and analysis of our financial condition and results of operations is based on our condensed 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 condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our condensed 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 $54.6 million and $37.7 million based on sales to Distributors during the nine months ended September 30, 2015 and 2014, respectively. Through September 30, 2015, 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.

When evaluating multiple-element arrangements, we identify the deliverables included within the agreement and evaluate which deliverables represent separate units of accounting based on whether the delivered element has stand-alone value to the collaborator or if the arrangement includes a general right of return for delivered items. We may receive up-front, non-refundable payments when licensing our intellectual property in conjunction with research and development agreements. In determining the units of accounting, we evaluate whether the license has stand-alone value from the undelivered elements to the collaborative partner based on the consideration of the relevant facts and

circumstances for each arrangement. Factors considered in this determination include the stage of development of the license delivered, research and development capabilities of the partner and the ability of partners to develop and commercialize Vascepa independently.

When we believe a license to our intellectual property does not have stand-alone value from the other deliverables to be provided in the arrangement, we generally recognize revenue attributable to the license over the contractual or estimated performance period. Any unrecognized portion of license revenue is classified within deferred revenue in the accompanying condensed consolidated balance sheets. When we believe a license to our intellectual property has stand-alone value, we recognize revenue attributed to the license upon delivery. The periods over which revenue is recognized is subject to estimates and may change over the course of the agreement. Such a change could have a material impact on the amount of revenue we record in future periods.

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 various valuation techniques. 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 derivative liabilities 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

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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 certain outstanding warrants (extinguished as of September 30, 2015), the change in control provision associated with our December 2012 debt financing and the change in control provision associated with our May 2014 exchangeable senior notes.

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, Nisshin was the only FDA-approved supplier of API for Vascepa. In 2013, the FDA qualified additional API suppliers to produce Vascepa with approval of our sNDAs covering Chemport, Slanmhor Pharmaceutical, Inc., or Slanmhor, in a consortium which included Novasep as the manufacturer for Slanmhor, and a fourth API supplier which we subsequently reached mutual agreement to terminate due to production challenges. All supply purchases from API suppliers prior to FDA approval of these API suppliers in 2013 were 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. 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. 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 us in our 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. Our 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. We have been historically profitable in the United States. When making our assessment about the realization of its U.S. deferred tax assets as of September 30, 2015, we considered all available evidence, placing particular weight on evidence that could be objectively verified. The evidence considered included the (i) historical profitability of our 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 our assessment, we concluded that the U.S. deferred tax assets are more likely than not to be realizable as of September 30, 2015. The majority of our deferred tax assets are held outside of the United States, for which we have

established a full valuation allowance. 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 the Financial Accounting Standards Board, or FASB, and are adopted by us as of the specified effective date. We considered the following recent accounting pronouncements which were not yet adopted as of September 30, 2015:

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, and is effective for annual periods beginning after December 15, 2016 (the original effective date). In April 2015, the FASB issued a proposal, which was subsequently adopted in July 2015, to defer the original effective date of this standard by one year, such that the amendment is effective for our

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fiscal year beginning January 1, 2018. Early adoption is permitted, but not before the original effective date. We are 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. We are required to adopt this standard in the first quarter of fiscal 2016 and early adoption is permitted. This standard is not expected to 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 fiscal years ending after December 15, 2016, and for annual 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.

In April 2015, the FASB issued ASU No. 2015-03, *Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs*. The amendments in this ASU require that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. We are required to adopt this standard in the first quarter of fiscal 2016 on a retrospective basis. The implementation of this standard will result in the reclassification of certain debt issuance costs from other assets to a reduction in the carrying amount of the related debt liability within the condensed consolidated balance sheets.

In July 2015, the FASB issued Accounting Standards Update (ASU) No, 2015-11, *Inventory (Topic 330): Simplifying the Measurement of Inventory*. The amendments in this ASU require that in-scope inventory should be measured at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The amendments do not apply to inventory that is measured using last-in, first-out (LIFO) or the retail inventory method but applies to all other inventory, which include inventory that is measured using first-in, first-out (FIFO) or average cost. This standard is effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. 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.

We believe that the impact of other recently issued but not yet adopted accounting pronouncements will not have a material impact on condensed 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, 2015 and September 30, 2014

Product Revenue, net. We recorded product revenue of $21.3 million and $14.1 million during the three months ended September 30, 2015 and 2014, respectively, an increase of $7.2 million, or 51%. This increase in revenue was driven by an increase in estimated normalized total Vascepa prescriptions of approximately 67,000 and 63,000 based on data provided by Symphony Health Solutions and IMS Health, respectively, representing growth of 51% and 56%, respectively, over the three months ended September 30, 2014. The level of inventory held by our customers as of September 30, 2015 approximated the inventories held as of September 30, 2014 based on days on hand. All of our product revenue in the three months ended September 30, 2015 and 2014 was derived from product sales of Vascepa, net of allowances, discounts, incentives, rebates, chargebacks and returns. Through September 30, 2015, product returns of Vascepa 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, 2015 and 2014, our net product revenue included an adjustment for co-pay mitigation rebates provided by us to commercially insured patients. Such rebates are intended to offset the differential for patients of Vascepa not covered by commercial insurers at the time of launch on Tier 2 for formulary purposes, resulting in higher co-pay

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amounts 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. Since launch, certain third-party payors have added Vascepa to their Tier 2 coverage, which results in lower co-payments for patients covered by these third-party payors. In connection with 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 a result of expanded commercial coverage and improved formulary positioning, rebates provided for in 2015 will be higher than in prior periods resulting in a slight decrease in the net selling price of Vascepa.

As is typical for the pharmaceutical industry, the majority of Vascepa sales are to major commercial wholesalers which then resell Vascepa to retail pharmacies.

Licensing Revenue. Licensing revenue during the three months ended September 30, 2015 was $0.2 million. We did not record licensing revenue prior to 2015. Licensing revenue relates to the amortization of a $15.0 million up-front payment received in February 2015 associated with a Vascepa licensing agreement for the China Territory. The up-front payment is being recognized over the estimated period in which we are required to provide regulatory and development support and clinical and commercial supply, which is currently anticipated to be a period of approximately 16 years. The amount of licensing revenue recorded may be variable from period to period based on changes in estimates of the timing and level of support required.

Cost of Goods Sold. Cost of goods sold during the three months ended September 30, 2015 and 2014 was $7.5 million and $5.4 million, respectively, an increase of $2.1 million, or 39%. 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 of API included in inventory. This average cost reflects the actual purchase price of Vascepa API.

The API included in the calculation of the average cost of goods sold during the nine months ended September 30, 2015 and 2014 was sourced from three API suppliers. The contracted cost of supply from our initial API supplier is higher than the contracted cost from our other API suppliers. 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. As of September 30, 2015, we classified all of our inventory as current. As a result of lower inventory balances on hand at the end of 2014 compared to the end of 2013 as well as anticipated increases in revenue during 2015 compared to 2014, we anticipate purchasing more API during 2015 than in 2014 with the amount of such purchases dependent on the rate of our revenue growth.

Our gross margin on product sales for the three months ended September 30, 2015 and 2014 was 65% and 62%, 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, 2015 and 2014 was $26.7 million and $19.3 million, respectively, an increase of $7.4 million, or 38%. Selling, general and administrative expenses for the three months ended September 30, 2015 and 2014 are summarized in the table below (in thousands):

	Three Months Ended September 30,	
	2015	**2014**
Selling, general and administrative expense (1)	$ 21,536	$ 17,669
Co-promotion fees (2)	2,077	615
Non-cash stock based compensation expense (3)	3,114	1,312
Non-cash warrant related compensation income		(326)
Total selling, general and administrative expense	$ 26,727	$ 19,270

(1) Selling, general and administrative expense, excluding non-cash compensation charges for stock compensation and warrants and co-promotion fees, for the three months ended September 30, 2015 and 2014 was $21.5 million and $17.7 million, respectively, an increase of $3.8 million, or 21%. The increase is due primarily to increased sales and marketing spend in support of expanded Vascepa promotion following the federal court declaration on August 7, 2015 allowing communication of truthful and non-misleading ANCHOR clinical trial data to be communicated to healthcare professionals.

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(2) Co-promotion fees payable to Kowa Pharmaceuticals America, Inc. were $2.1 million and $0.6 million in the three months ended September 30, 2015 and 2014, respectively, an increase of $1.5 million, or 250%. Kowa Pharmaceuticals America, Inc. commenced its co-promotion efforts in May 2014.

(3) Stock-based compensation expense for the three months ended September 30, 2015 and 2014 was $3.1 million and $1.3 million, respectively, an increase of $1.8 million, or 138%, primarily due to an increase in new stock option and restricted stock awards granted to attract and retain qualified employees.

Research and Development Expense. Research and development expense for the three months ended September 30, 2015 and 2014 was $13.1 million and $14.5 million, respectively, a decrease of $1.4 million, or 10%. Research and development expenses for the three months ended September 30, 2015 and 2014 are summarized in the table below (in thousands):

	Three Months Ended September 30,	
	2015	2014
REDUCE-IT study (1)	$ 9,392	$ 11,753
Regulatory filing fees and expenses (2)	661	385
Internal staffing, overhead and other (3)	2,234	1,709
Research and development expense, excluding non-cash expense	12,287	13,847
Non-cash stock-based compensation (4)	805	610
Total research and development expense	$ 13,092	$ 14,457

The decrease in research and development expenses for the quarter ended September 30, 2015, as compared to the prior year period, is primarily due to quarterly variability in costs related to the REDUCE-IT study, including the timing of shipment of clinical trial materials.

(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 7,700 patients enrolled in REDUCE-IT. We estimate that we will complete patient enrollment in this study near the end of 2015. For the three months ended September 30, 2015 and 2014, we incurred expenses through our CRO in connection with this trial of approximately $7.5 million and $9.5 million, respectively. Inclusive of CTM costs, the combined CRO and CTM costs during the three months ended September 30, 2015 and 2014 for REDUCE-IT were approximately $9.4 million and $11.8 million, respectively. The decrease in expenses in 2015 as compared to 2014 is primarily the result of timing variability for REDUCE-IT costs. 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. Based on our current assumptions of CRO and CTM costs, we estimate that we will incur $30 million to $40 million in annual costs through study completion. Amarin remains blinded to all data from the study and currently expects the study to be completed in 2017. There is a scheduled interim review of the efficacy and safety results of the study which review we estimate will occur in 2016 upon reaching 60% of the target aggregate number of cardiovascular events for the study. It is our expectation that this trial will run to completion as is typical for cardiovascular outcome studies. We anticipate that our costs for this outcomes study will continue to represent the most significant component of our research and development expenditures.

(2) The regulatory filing fees in each of the quarters ended September 30, 2015 and 2014 included annual FDA fees for maintaining manufacturing sites.

(3) 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. Also included are costs related to qualifying suppliers and legal costs.

(4) 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.

(Loss) Gain on Change in Fair Value of Derivative Liabilities. (Loss) gain on change in fair value of derivative liabilities for the three months ended September 30, 2015 was a loss of $0.2 million versus a gain of $4.5 million in the prior year period. (Loss) gain on change in fair value of derivative liabilities is comprised of (i) the change in fair value of the warrant derivative liability, (ii) the change in fair value of the derivative liability related to the change in control provision associated with the December 2012

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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) the change in fair value of the derivative liability related to the preferred stock purchase option.

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. In October 2014, we 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. Of the 8,087,388 warrants outstanding as of December 31, 2014, 1,844,585 warrants were exercised and the remaining 6,242,803 warrants expired on February 27, 2015. As such, no warrants were outstanding as of September 30, 2015 and no gain or loss was recognized for the three months ended September 30, 2015. The fair value of the warrant derivative liability as of 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 three months ended September 30, 2014. The change in fair value of the warrant derivative liability for the quarter ended September 30, 2014 is due primarily to the change 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 repay $150 million, less any previously repaid amount. 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. As of June 30, 2015, the fair value of the derivative was determined to be $5.6 million, and as of September 30, 2015, the fair value of the derivative was determined to be $5.1 million. As such, we recognized a $0.5 million gain on change in fair value of derivative liability for the three months ended September 30, 2015. As of June 30, 2014, the fair value of the derivative was determined to be $6.1 million, and as of September 30, 2014, the fair value of the derivative was determined to be $4.6 million. As such, we recognized a $1.5 million gain on change in fair value of derivative liability for the three months ended September 30, 2014.

Our 2014 Notes, issued in May 2014, 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. As of June 30, 2015, the fair value of the derivative was determined to be $1.1 million, and as of September 30, 2015, the fair value of the derivative was determined to be $1.8 million. As such, we recognized a $0.7 million loss on change in fair value of derivative liability for the three months ended September 30, 2015. As of June 30, 2014, the fair value of the derivative was determined to be $3.3 million, and as of September 30, 2014, the fair value of the derivative was determined to be $4.4 million. As such, we recognized a $1.1 million loss on change in fair value of derivative liability for the three months ended September 30, 2014.

Any changes in the assumptions used to value the derivative liabilities could result in a material change to the carrying value of such liabilities.

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Interest Expense, net. Net interest expense for the three months ended September 30, 2015 and 2014 was $5.1 million and $4.9 million, respectively, an increase of $0.2 million, or 4%. Net interest expense for the three months ended September 30, 2015 and 2014 is summarized in the table below (in thousands):

	Three Months Ended September 30,	
	2015	2014
Exchangeable senior notes (1):		
Amortization of debt discounts	$ 1,595	$ 1,425
Contractual coupon interest	1,313	1,313
Total exchangeable senior notes interest expense	2,908	2,738
Long-term debt BioPharma financing (2):		
Cash interest current	1,674	1,415
Cash interest deferred		282
Non-cash interest	487	453
Total long-term debt interest expense	2,161	2,150
Other interest expense	5	
Total interest expense	5,074	4,888
Interest income (3)	(13)	(12)
Total interest expense, net	$ 5,061	$ 4,876

(1) Cash and non-cash interest expense related to the exchangeable senior notes for the three months ended September 30, 2015 and 2014 was $2.9 million and $2.7 million, respectively.

(2) Cash and non-cash interest expense related to the BioPharma financing for the three months ended September 30, 2015 and 2014 was $2.2 million and $2.2 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, 2015 and 2014 was $0.01 million in each year. Interest income represents income earned on cash balances.

Other (Expense) Income, net. Other (expense) income, net, for the three months ended September 30, 2015 was expense of $0.1 million versus expense of $0.2 million in the prior year period. Other (expense) income, net, primarily consists of losses and gains on foreign exchange transactions.

Benefit from (Provision for) Income Taxes. Benefit from (provision for) income taxes for the three months ended September 30, 2015 was a $0.5 million benefit versus a $0.4 million provision in the prior year period. The current benefit (provision) relates entirely to the U.S. subsidiary operations. We are profitable in the United States as a result of intercompany transactions between our U.S. subsidiary and our other companies.

Comparison of Nine Months Ended September 30, 2015 and September 30, 2014

Product Revenue, net. We recorded product revenue of $54.6 million and $37.7 million during the nine months ended September 30, 2015 and 2014, respectively, an increase of $16.9 million, or 45%. This increase in revenue was driven by an increase in estimated normalized total Vascepa prescriptions of approximately 194,000 and 186,000 based on data provided by Symphony Health Solutions and IMS Health, respectively, representing growth of 58% and 65%, respectively, over the nine months ended September 30, 2014. The difference in the percentage of revenue growth as compared to the percentage of prescription growth is primarily due to a change in revenue recognition methodology in 2014 as described below. The level of inventory held by our customers as of September 30, 2015 approximated the inventories held as of September 30, 2014 based on days on hand. All of our product revenue in the nine months ended September 30, 2015 and 2014 was derived from product sales of Vascepa, net of allowances, discounts, incentives, rebates, chargebacks and returns. In accordance with GAAP, prior to 2014, product revenue was recognized based on the resale of Vascepa for the purposes of filling patient prescriptions and not based on sales to our Distributors. During the three months ended March 31, 2014, we concluded that we had developed sufficient history such that we can reliably estimate returns and, as a result, began to recognize product revenue based on sales to our Distributors. Through September 30, 2015, product returns of Vascepa 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 nine months ended September 30, 2015 and 2014, our net product revenue included an adjustment for co-pay mitigation rebates provided by us to commercially insured patients. Such rebates are intended to offset the differential for patients of

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Vascepa not covered by commercial insurers at the time of launch on Tier 2 for formulary purposes, resulting in higher co-pay amounts 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. Since launch, certain third-party payors have added Vascepa to their Tier 2 coverage, which results in lower co-payments for patients covered by these third-party payors. In connection with 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 a result of expanded commercial coverage and improved formulary positioning, rebates provided for in 2015 will be higher than in prior periods resulting in a slight decrease in the net selling price of Vascepa.

As is typical for the pharmaceutical industry, the majority of Vascepa sales are to major commercial wholesalers which then resell Vascepa to retail pharmacies.

Licensing Revenue. Licensing revenue during the nine months ended September 30, 2015 was $0.5 million. We did not record licensing revenue prior to 2015. The licensing revenue relates to the amortization of a $15.0 million up-front payment received in February 2015 associated with a Vascepa licensing agreement for the China Territory. The up-front payment is being recognized over the estimated period in which we are required to provide regulatory and development support and clinical and commercial supply, which is currently anticipated to be a period of approximately 16 years. The amount of licensing revenue recorded may be variable from period to period based on changes in estimates of the timing and level of support required.

Cost of Goods Sold. Cost of goods sold during the nine months ended September 30, 2015 and 2014 was $19.5 million and $14.6 million, respectively, an increase of $4.9 million, or 34%. 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 of API included in inventory. This average cost reflects the actual purchase price of Vascepa API.

The API included in the calculation of the average cost of goods sold for the nine months ended September 30, 2015 and 2014 was sourced from three API suppliers. The contracted cost of supply from our initial API supplier was higher than the contracted cost from our other API suppliers. 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. As of September 30, 2015, we classified all of our inventory as current. As a result of lower inventory balances on hand at the end of 2014 compared to the end of 2013 as well as anticipated increases in revenue during 2015 compared to 2014, we anticipate purchasing more API during 2015 than in 2014 with the amount of such purchases dependent on the rate of our revenue growth.

Our gross margin on product sales for the nine months ended September 30, 2015 and 2014 was 64% and 61%, 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, 2015 and 2014 was $77.5 million and $60.9 million, respectively, an increase of $16.6 million, or 27%. Selling, general and administrative expenses for the nine months ended September 30, 2015 and 2014 are summarized in the table below (in thousands):

	Nine Months Ended September 30,	
	2015	2014
Selling, general and administrative expense (1)	$ 64,547	$ 56,189
Co-promotion fees (2)	5,265	919
Non-cash stock based compensation expense (3)	7,719	4,344
Non-cash warrant related compensation income	(9)	(503)
Total selling, general and administrative expense	$ 77,522	$ 60,949

(1) Selling, general and administrative expense, excluding non-cash compensation charges for stock compensation and warrants and co-promotion fees, for the nine months ended September 30, 2015 and 2014 was $64.5 million and $56.2 million, respectively, an increase of $8.3 million, or 15%. The increase is due primarily to increased sales and marketing spend in support of expanded Vascepa promotion following the federal court declaration on August 7, 2015 allowing communication of truthful and non-misleading ANCHOR clinical trial data to be communicated to healthcare professionals, as well as higher legal costs associated with various legal matters, which costs vary from period to period.

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(2) Co-promotion fees payable to Kowa Pharmaceuticals America, Inc. were $5.3 million and $0.9 million in the nine months ended September 30, 2015 and 2014, respectively, an increase of $4.4 million, or 489%. Kowa Pharmaceuticals America, Inc. commenced its co-promotion efforts in May 2014.

(3) Stock-based compensation expense for the nine months ended September 30, 2015 and 2014 was $7.7 million and $4.3 million, respectively, an increase of $3.4 million, or 79%, primarily due to an increase in new stock option and restricted stock awards granted to attract and retain qualified employees.

Research and Development Expense. Research and development expense for the nine months ended September 30, 2015 and 2014 was $37.7 million and $37.9 million, respectively, a decrease of $0.2 million, or 1%. Research and development expenses for the nine months ended September 30, 2015 and 2014 are summarized in the table below (in thousands):

	Nine Months Ended September 30,	
	2015	**2014**
REDUCE-IT study (1)	$ 25,952	$ 28,409
Regulatory filing fees and expenses (2)	1,517	1,383
Internal staffing, overhead and other (3)	7,788	6,170
Research and development expense, excluding non-cash expense	35,257	35,962
Non-cash stock-based compensation (4)	2,458	1,929
Total research and development expense	$ 37,715	$ 37,891

The decrease in research and development expenses for the nine months ended September 30, 2015, as compared to the prior year period, is primarily due to quarterly variability in costs related to the REDUCE-IT study partially offset by an increase in internal staffing and overhead and non-cash stock-based compensation.

(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 CRO through which all costs for this outcomes study are incurred with the exception of costs for 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 7,700 patients enrolled in REDUCE-IT. We estimate that we will complete patient enrollment in this study near the end of 2015. For the nine months ended September 30, 2015 and 2014, we incurred expenses through our CRO in connection with this trial of approximately $21.3 million and $22.3 million, respectively. Inclusive of CTM costs, the combined CRO and CTM costs during the nine months ended September 30, 2015 and 2014 for REDUCE-IT were approximately $26.0 million and $28.4 million, respectively. The decrease in expenses in 2015 as compared to 2014 is primarily the result of timing variability for REDUCE-IT costs. 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 we will incur $30 million to $40 million in annual costs through study completion. Amarin remains blinded to all data from the study and currently expects the study to be completed in 2017. There is a scheduled interim review of the efficacy and safety results of the study which review we estimate will occur in 2016 upon reaching 60% of the target aggregate number of cardiovascular events for the study. It is our expectation that this trial will run to completion as is typical for cardiovascular outcome studies. We anticipate that our costs for this outcomes study will continue to represent the most significant component of our research and development expenditures.

(2) The regulatory filing fees in each of the nine months ended September 30, 2015 and 2014 included annual FDA fees for maintaining manufacturing sites.

(3) 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. Also included are costs related to qualifying suppliers and legal costs.

(4) 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.

(Loss) Gain on Change in Fair Value of Derivative Liabilities. (Loss) gain on change in fair value of derivative liabilities for the nine months ended September 30, 2015 was a loss of $0.4 million versus a gain of $11.9 million in the prior year period. (Loss) gain on change in fair value of derivative liabilities is comprised of (i) the change in fair value of the warrant derivative liability, (ii) the change in fair value of the derivative liability related to the change in control provision associated with the December 2012

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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) the change in fair value of the derivative liability related to the preferred stock purchase option.

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 as of December 31, 2014 was $0.1 million and we recognized a $0.1 million gain on change in fair value of derivative liability for the nine months ended September 30, 2015 for these warrants. The fair value of the warrant derivative liability as of 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. The change in fair value of the warrant derivative liability for the nine months ended September 30, 2015 is due to the expiration of the warrants and the resulting extinguishment of the liability, while the change in fair value for the nine months ended September 30, 2014 is due primarily to the change in the price of our common stock on the date of valuation. In October 2014, we 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. Of the 8,087,388 warrants outstanding as of December 31, 2014, 1,844,585 warrants were exercised and the remaining 6,242,803 warrants expired on February 27, 2015. As such, no warrants were outstanding as of September 30, 2015.

Our December 2012 financing agreement with BioPharma contains a redemption feature whereby, upon a change of control, we would be required to repay $150 million, less any previously repaid amount. 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. As of December 31, 2014, the fair value of the derivative was determined to be $4.8 million, and as of September 30, 2015, the fair value of the derivative was determined to be $5.1 million. As such, we recognized a $0.3 million loss on change in fair value of derivative liability for the nine months ended September 30, 2015. As of December 31, 2013, the fair value of the derivative was determined to be $11.1 million, and as of September 30, 2014, the fair value of the derivative was determined to be $4.6 million. As such, we recognized a $6.5 million gain on change in fair value of derivative liability for the nine months ended September 30, 2014.

Our 2014 Notes, issued in May 2014, 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. As of December 31, 2014, the fair value of the derivative was determined to be $2.6 million, and as of September 30, 2015, the fair value of the derivative was determined to be $1.8 million. As such, we recognized a $0.8 million gain on change in fair value of derivative liability for the nine months ended September 30, 2015. As of September 30, 2014, the fair value of the derivative was determined to be $4.4 million and we recognized a $0.9 million loss on change in fair value of derivative liability for the nine months ended September 30, 2014.

In connection with the closing of a private placement transaction in March 2015, we recorded a derivative liability pursuant to a pre-existing contractual right. This preferred stock purchase option was determined to be a derivative liability effective March 5, 2015, the date in which the private placement was initially subscribed. The fair value of

this liability was calculated using a Black-Scholes model and was determined to be $0.9 million at inception and was charged to accumulated deficit as a deemed non-cash dividend. The liability was then marked to fair value through March 30, 2015, the date on which we executed a subscription agreement with the investor, resulting in a charge of $0.9 million through (loss) gain on change in fair value of derivatives in the nine months ended September 30, 2015. The liability was reclassified to permanent equity on such date.

Any changes in the assumptions used to value the derivative liabilities could result in a material change to the carrying value of such liabilities.

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 recorded a gain on extinguishment of the original notes of $38.0 million in the nine months ended September 30, 2014. There was no such gain in the nine months ended September 30, 2015.

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Interest Expense, net. Net interest expense for the nine months ended September 30, 2015 and 2014 was $14.8 million and $13.6 million, respectively, an increase of $1.2 million, or 9%. Net interest expense for the nine months ended September 30, 2015 and 2014 is summarized in the table below (in thousands):

	Nine Months Ended September 30,	
	2015	2014
Exchangeable senior notes (1):		
Amortization of debt discounts	$ 4,597	$ 2,756
Contractual coupon interest	3,938	3,937
Total exchangeable senior notes interest expense	8,535	6,693
Long-term debt BioPharma financing (2):		
Cash interest current	4,777	3,772
Cash interest deferred	112	1,728
Non-cash interest	1,392	1,435
Total long-term debt interest expense	6,281	6,935
Other interest expense	10	1
Total interest expense	14,826	13,629
Interest income (3)	(73)	(64)
Total interest expense, net	$ 14,753	$ 13,565

(1) Cash and non-cash interest expense related to the exchangeable senior notes for the nine months ended September 30, 2015 and 2014 was $8.5 million and $6.7 million, respectively.

(2) Cash and non-cash interest expense related to the BioPharma financing for the nine months ended September 30, 2015 and 2014 was $6.3 million and $6.9 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 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 nine months ended September 30, 2015 and 2014 was $0.07 million and $0.06 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, 2015 was expense of $0.1 million versus income of $4.0 million in the prior year period. Other (expense) income, net, in the nine months ended September 30, 2015 primarily consists of losses and gains on foreign exchange transactions. Other (expense) income, net in the nine months ended September 30, 2014 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.

Benefit from (Provision for) Income Taxes. Benefit from (provision for) income taxes for the nine months ended September 30, 2015 was a $1.5 million benefit versus a $1.3 million provision in the prior year period. The current benefit (provision) relates entirely to the U.S. subsidiary operations. We are profitable in the United States as a result of intercompany transactions between our U.S. subsidiary and our other companies.

Liquidity and Capital Resources

Our sources of liquidity as of September 30, 2015 include cash and cash equivalents of $119.0 million. In February 2015, we received a $15.0 million non-refundable, up-front payment upon the execution of our first ex-U.S. licensing agreement which agreement covers China and surrounding territories. In March 2015, we entered into a subscription agreement with four institutional investors for the issuance and sale of our Series A Preference Shares resulting in net proceeds to us of $52.0 million. Also in March 2015, we entered into a separate subscription agreement with an existing investor, Sofinnova Venture Partners VII L.P. (Sofinnova), for the issuance and sale of our Series A Preference Shares resulting in net proceeds to us of $5.7 million upon closing of the private placement in July 2015. Both the $15.0 million up-front payment from the ex-U.S. licensing agreement and the $57.7 million in net

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proceeds from the issuance and sale of Series A Preference Shares are included in our September 30, 2015 cash balance. Our projected uses of cash include commercialization of Vascepa , 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 condensed consolidated statements of cash flows, are summarized in the following table (in thousands):

	Nine Months Ended September 30,	
	2015	2014
Cash (used in) provided by continuing operations:		
Operating activities	$ (60,100)	$ (58,685)
Investing activities	(10)	
Financing activities	59,547	2,606
Decrease in cash and cash equivalents	$ (563)	$ (56,079)

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 associated with Vascepa patent rights, 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, 2015, the net remaining amount to be repaid to BioPharma is $139.4 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 maximum amount payable under the contractual threshold for 2015 is $15.0 million. The quarterly repayments through September 30, 2015 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 and no cliff payment of the remaining balance is due except in the event of Company default or Company change of control. 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, 2017, January 19, 2022 and January 19, 2027, the holders of the notes may require that we repurchase in cash the principal amount of the notes plus accrued and unpaid interest. At any time prior to January 15, 2032, upon certain circumstances, which circumstances include our issuing a notice of redemption to the note holders, the price of our shares trading above 130% of the exchange price, or certain other events defined in the note agreement, the holders of the notes may elect to convert the notes. The exchange rate for conversion is 113.4752 ADSs per $1,000 principal amount of the notes (equivalent to an initial exchange price of approximately $8.8125 per ADS), subject to adjustment in certain circumstances, including adjustment if we pay cash dividends. Upon exchange, the notes may be settled, at our election, subject to certain conditions, in cash, ADSs or a combination of cash and ADSs.

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

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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 initial exchange rate is 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.

On March 30, 2015, in connection with the closing of the initial private placement, and pursuant to a pre-existing contractual preemptive right to participate in certain private placement transactions effected by us, we entered into a separate subscription agreement with an existing investor, Sofinnova Venture Partners VII L.P. (Sofinnova), for the purchase of an additional 38,867,180 restricted ADSs, each representing one (1) share of our Series A Preference Shares, at the same price per share and otherwise on substantially the same terms as the initial private placement, for potential proceeds of $5.8 million. In accordance with applicable marketplace rules of the NASDAQ Stock Market, the consummation of the second private placement was conditioned upon approval by our shareholders at a future meeting of our shareholders. Such approval was received at our Annual General Meeting of Shareholders on July 6, 2015 and as a result, the closing of this second private placement occurred on July 10, 2015. We issued 38,867,180 restricted ADSs, each representing one Series A Preference Share, which may be consolidated and redesignated from time to time up to a maximum of 3,886,718 ordinary shares, each ordinary share to be represented by one ADS (see Note 8 Equity). For each restricted ADS, Sofinnova paid a negotiated price of $0.15 (equating to $1.50 on an as converted to ordinary share basis) resulting in gross proceeds to us of $5.8 million. Dr. James Healy, a member of our Board, is a managing member of Sofinnova Management VII, L.L.C., the general partner of Sofinnova.

As of September 30, 2015, we had cash and cash equivalents of $119.0 million, a decrease of $0.5 million from December 31, 2014. The decrease is primarily due to the net proceeds from equity financings of $57.7 million and a $15.0 million up-front payment received from an ex-U.S. licensing agreement offset by net cash used in operating activities in support of the continued commercialization of Vascepa and the continued funding of REDUCE-IT, less accounts receivable collections. We have incurred annual operating losses since our inception and, as a result, we had an accumulated deficit of $1.1 billion as of September 30, 2015. We believe that our cash and cash equivalents balance of $119.0 million as of September 30, 2015 will be sufficient to fund our projected operations for at least the next twelve months. We anticipate that quarterly net cash outflows in future periods will be variable.

Contractual Obligations

We have Vascepa API supply agreements with three independent companies from which we purchase qualified API supply: Nisshin, Chemport and Finorga SAS, or Novasep. We also have encapsulation agreements with three FDA-approved commercial API encapsulators for Vascepa manufacturing: Patheon, Inc. (formerly Banner Pharmacaps), Catalent Pharma Solutions, and Capsugel Plöermel SAS, LLC, or Capsugel. Our agreements with Chemport, Novasep, and Capsugel contain minimum annual purchase levels to enable us to maintain certain supply exclusivity and also contain a provision that any shortfall in the minimum purchase commitments is payable in cash. Each supplier is required to meet certain performance obligations and the agreements may be terminated by us in the event of non-performance.

We have operating lease costs consisting of leases for facilities in Dublin, Ireland and Bedminster, NJ.

We have 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 ADSs.

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 in each of the nine months ended September 30, 2015 and 2014. 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 $11.4 million as of September 30, 2015). Additionally, upon receipt of a marketing approval in the United States or Europe for a further indication of Vascepa (or further indication of any other product using Amarin Neuroscience intellectual property), we must make an aggregate stock or cash payment (at the sole option of each of the sellers) of £5 million (approximately $7.6 million as of September 30, 2015) for each of the two potential market approvals (i.e. £10 million maximum, or approximately $15.2 million as of September 30, 2015).

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In January 2015, we granted a total of 5,455,500 performance-based RSUs (PSUs) to employees for the right to receive payment in the form of ordinary shares, or any combination of cash and shares. Payment in the form of ordinary shares was subject to shareholder approval of a sufficient increase in the number of shares reserved for issuance under the Amarin Corporation plc 2011 Stock Incentive Plan. Such shareholder approval was obtained at our Annual General Meeting on July 6, 2015.

We have recorded a liability of $0.4 million for uncertain tax positions in other long-term liabilities as of September 30, 2015. We are not able to reasonably estimate in which future periods these amounts will ultimately be settled.

We do not enter into financial instruments for trading or speculative purposes. As of September 30, 2015, we had no outstanding forward exchange contracts.

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 March 3, 2015.

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

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities Exchange Act of 1934 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, 2015, 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 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, 2015, 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, 2015, 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.

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PART II

Item 1. ***Legal Proceedings***

In the ordinary course of business, we are from time to time involved in lawsuits, claims, investigations, proceedings, and threats of litigation relating to our business. Item 3. Legal Proceedings of our Annual Report on Form 10-K for the fiscal year ended December 31, 2014 includes a discussion of our current legal proceedings. There have been no material changes to those disclosures as of the date of this filing other than as set forth below.

On May 7, 2015, we and a group of independent physicians filed a federal lawsuit to permit us to share truthful and non-misleading information, including, but not limited to, the ANCHOR trial clinical data, with healthcare professionals in the United States about certain uses of Vascepa not included with approved FDA labeling of Vascepa and thus not permitted under the FDA s interpretation of applicable law. The lawsuit, captioned *Amarin Pharma, Inc., et al. v. Food & Drug Administration, et al.* (1:15-cv-03588-PAE), was filed in the United States District Court for the Southern District of New York and seeks a judicial declaration based on several legal theories. On August 7, 2015, the Court granted our request for preliminary relief in this litigation through a declaratory judgment that confirmed that we may engage in truthful and non-misleading speech promoting the off-label use of Vascepa, i.e., to treat patients with persistently high triglycerides, and such speech may not form the basis of a misbranding action under the Federal Food and Drug Cosmetic Act. FDA did not appeal the Court s preliminary ruling prior to the October 6, 2015 deadline for appeal. The underlying litigation has been stayed for settlement discussion and the parties are working toward settlement. We cannot predict the outcome of settlement negotiations or this litigation.

On May 28, 2015, the U.S. District Court for the District of Columbia granted our motion for summary judgment in our lawsuit against the FDA, captioned *Amarin Pharmaceuticals Ireland Ltd. v. Food & Drug Administration, et al.*, Civ. A. No. 14-0324 (D.D.C.). This lawsuit sought an order requiring FDA to recognize five-year, New Chemical Entity (NCE) marketing exclusivity for Vascepa. The decision vacated the FDA s denial of our claim for such exclusivity and remanded to the FDA for proceedings consistent with the decision. On July 22, 2015, Watson Laboratories Inc., the purported first Vascepa ANDA filer, sought to intervene and appeal the Court s decision. We intend to continue to litigate the case vigorously, but cannot predict the outcome of this litigation. FDA did not appeal the Court s decision prior to the July 28, 2015 deadline for appeal.

Based on the May 28, 2015, U.S. District Court for the District of Columbia order granting our motion for summary judgment in the NCE litigation, on June 26, 2015, the parties to the related Vascepa patent litigation that followed acceptance by FDA of abbreviated new drug applications, or ANDAs, to Vascepa agreed to a full stay of proceeding in that patent litigation. Based on subsequent FDA notification to the ANDA filers that FDA had changed the status of their ANDAs to submitted, but no longer accepted, we believe the statutory basis for the patent litigation (accepted ANDAs) no longer exists. Thus, on July 24, 2015, we moved to dismiss the pending patent infringement lawsuits against each of the Vascepa ANDA applicants. We intend to vigorously enforce our intellectual property rights relating to Vascepa consistent with the time period contemplated by the Hatch-Waxman Act, but we cannot predict the outcome of these lawsuits. We cannot predict the outcome of this motion to dismiss or litigation. If the motion to dismiss is granted, we plan to defend the exclusivity of Vascepa through patent litigation after notification that FDA has accepted an ANDA application related to Vascepa which, assuming NCE exclusivity, we would expect no sooner than late July 2016.

On June 29, 2015, the U.S. District Court for the District of New Jersey granted our motion to dismiss the putative consolidated class action lawsuit captioned *In re Amarin Corporation plc, Securities Litigation,* No. 3:13-cv-06663 (D.N.J. Nov. 1, 2013). The class action was dismissed without prejudice with leave for plaintiffs to file an amended

complaint. The lawsuit sought unspecified monetary damages and attorneys fees and costs alleging that we and certain of our 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 potential approval. On July 29, 2015, plaintiffs filed an amended complaint alleging facts similar to those in the original complaint. Like the first complaint, the amended complaint seeks unspecified monetary damages and attorneys fees and costs. We believe we have valid defenses and will continue to vigorously defend against this lawsuit, but cannot predict the outcome. We have insurance coverage that is anticipated to cover any significant loss exposure that may arise from this action.

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, 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.

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*Those risk factors below denoted with a * are newly added or have been materially updated from our Annual Report on Form 10-K filed with the SEC on March 3, 2015.*

Risks Related to the Commercialization and Development of Vascepa

We are substantially dependent upon sales of Vascepa in the United States.

As a result of our reliance on a single product, Vascepa (icosapent ethyl) capsules, 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. If commercialization efforts for Vascepa are not successful, our business will be materially and adversely affected.

Even if we are able to develop Vascepa outside the United States or 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 with development, 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 markets and products we develop could constrain our ability to generate revenues and achieve profitability.

The uncertain effect of Vascepa on its ultimate targeted clinical benefit makes it more difficult to achieve a level of market acceptance by physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

In January 2013, we launched Vascepa based on FDA approval of our MARINE indication, for use as an adjunct to diet to reduce triglyceride levels in adult patients with severe (TG ³500 mg/dL) hypertriglyceridemia. Approximately 4.0 million people in the United States have severely high triglyceride levels (TG ≥500 mg/dL), commonly known as very high triglyceride levels. 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. A secondary goal for this patient population is to reduce cardiovascular risk. The effect of Vascepa on cardiovascular mortality and morbidity, or the risk for pancreatitis, in patients with hypertriglyceridemia has not been determined and our FDA-approved labeling and promotional efforts state these facts.

In August 2015, based on a federal court order, we also began marketing Vascepa in the United States to healthcare professionals for the treatment of patients with high (TG ³200 mg/dL and <500 mg/dL) triglyceride levels who are also on statin therapy for elevated low-density lipoprotein cholesterol, or LDL-C, levels, based on results from the ANCHOR study of Vascepa. It is estimated that approximately 40 million adults in the United States have high triglyceride levels (TG ≥200 mg/dL), and many patients with high triglycerides also have other lipid level abnormalities such as high cholesterol and are on statin therapy. FDA did not approve Vascepa for use in this population due to the uncertain effect of pharmaceutically induced triglyceride reduction in this patient population on cardiovascular risk reduction, the ultimate targeted clinical benefit. Our promotional efforts disclose this fact and the current state of research on both triglyceride reduction and the active pharmaceutical ingredient in Vascepa, EPA, as each relate to the potential of Vascepa to reduce cardiovascular risk.

The uncertainties around the ultimate clinical benefit of Vascepa make it more difficult for Vascepa to gain 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 in ANCHOR patients 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;
- publicity concerning Vascepa or competing products;
- the ultimate outcome or settlement terms of our pending litigation to expand our ability to promote Vascepa in the United States outside of FDA-approved labeling and the related perception thereof;

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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 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. under a co-promotion agreement we entered into in March 2014. Under the agreement, approximately 250 Kowa Pharmaceuticals America, Inc. 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.

We are also expanding our commercialization activities to markets outside of the United States through partnering arrangements. On February 26, 2015, we entered into a Development, Commercialization and Supply Agreement (the DCS Agreement) with Eddingpharm (Asia) Macao Commercial Offshore Limited (Eddingpharm) related to the development and commercialization of Vascepa in Mainland China, Hong Kong, Macau and Taiwan (the China Territory). Under the DCS Agreement, Eddingpharm will be solely responsible for development and commercialization activities in the China Territory and associated expenses. Significant commercialization of Vascepa in the China Territory is several years away. If Eddingpharm is not able to effectively develop and commercialize Vascepa in the China Territory, we may not be able to generate revenue from the DCS Agreement resulting from the sale of Vascepa in the China Territory.

We have limited experience working with ex-U.S. partners such as Eddingpharm to develop and market our products in foreign countries. In order for Eddingpharm, or us, to market and sell Vascepa in any country outside of the United States for any indication, it will be necessary to obtain regulatory approval from the appropriate regulatory authorities. The requirements and timing for regulatory approval vary widely from country to country and may in some cases be different than or more rigorous than requirements in the United States. Any failure by us or Eddingpharm to obtain approval for Vascepa in any countries outside of the United States in a timely manner may limit the commercial success of Vascepa and our ability to grow our revenues.

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 the court declaration that we believe enables us to expand marketing efforts for Vascepa, 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 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;

an inability by us or our partners to obtain regulatory and marketing approval or establish marketing channels in foreign jurisdictions; and

unforeseen costs and expenses associated with operating a new independent sales and marketing organization.

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.

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We expect final positive results from the REDUCE-IT outcomes study will be required for FDA-approved label expansion for Vascepa.

Since January 2013 we have marketed Vascepa for use in the FDA-approved MARINE indication in the United States.

In April 2015, we received a CRL from the FDA on our Supplemental New Drug Application, or sNDA, that sought approval for the use of Vascepa in patients with high triglyceride levels (TG ³200 mg/dL and <500 mg/dL) who are also on statin therapy, which we refer to as the ANCHOR indication. In regulatory dialogue, the FDA acknowledged that the results of the ANCHOR trial as we presented them to FDA were valid and truthful in that, for example, Vascepa reduced triglyceride levels compared to placebo in patients treated in the ANCHOR study. The clinical rationale for reducing serum triglycerides with Vascepa and modifying other lipid/lipoprotein parameters shown in ANCHOR among statin-treated patients with triglycerides 200-499 mg/dL is to reduce cardiovascular risk. In not approving our ANCHOR sNDA, the FDA concluded that, for regulatory approval purposes, there are insufficient data at this time to support a drug-induced change in serum triglycerides as a surrogate for reducing cardiovascular risk in the ANCHOR population. The FDA did not determine that the drug-induced effects of Vascepa, which go beyond triglyceride-lowering, would not actually reduce cardiovascular risk in this population.

In August 2015, based on a federal court order, we began marketing Vascepa in the United States to healthcare professionals for the treatment of patients in the ANCHOR population through use of a set of qualified statements that reflect the current state of research related to this use. While an indication for this patient population has yet to be granted, our ability to reach full potential in the commercialization of Vascepa in the United States is dependent upon marketing claims associated with Vascepa that are granted with the approval of an indication statement by the FDA.

Based on our communications with the FDA, we expect that final positive results from the REDUCE-IT outcomes study will be required for FDA approval of a new indication or other label expansion for Vascepa. Any delay in obtaining, or an inability to obtain, further expansion of our marketing approval rights with an FDA approval 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 any expanded indication takes too long, we may miss market opportunities and give other companies the ability to develop competing products or establish market dominance. If the FDA does not approve any expanded indication at all, it could have a material impact on our future results of operations and financial condition. Additionally, the terms of any approvals, including the approval received from the FDA in July 2012 for the MARINE indication, may prove to not have the scope or breadth needed for us to successfully commercialize Vascepa or become profitable.

Our lawsuit to allow for promotion of truthful and non-misleading information to healthcare professionals in the United States about uses of Vascepa may not achieve its intended goal.

On May 7, 2015, we and a group of independent physicians filed a lawsuit in federal court to permit us to promote to healthcare professionals certain uses of Vascepa that reflect recognized medical practice but are not covered by current FDA-approved labeling for the drug, so long as the promotion is truthful and non-misleading. The uses at issue are consistent with multiple national and international treatment guidelines and relevant to tens of millions of patients in the United States at risk of cardiovascular disease. Because, for example, the efficacy results from the ANCHOR trial have not been approved by the FDA for inclusion in FDA labeling of Vascepa, truthful and non-misleading promotion of such information is considered off-label and thus illegal under FDA s interpretation of its regulatory structure. The lawsuit, captioned *Amarin Pharma, Inc. et al. v. Food & Drug Administration, et al*., was

filed in the United States District Court for the Southern District of New York and seeks a judicial declaration based on applicable precedent, First Amendment freedom of speech principles and Fifth Amendment restrictions against overly vague laws. The lawsuit seeks a declaration to permit promotion of the FDA-reviewed and agreed effects of Vascepa demonstrated in the ANCHOR clinical trial and use of peer-reviewed scientific publications that present the current state of scientific research related to the potential of Vascepa to reduce the risk of cardiovascular disease. The physicians in the suit regularly treat patients at risk of cardiovascular disease and, as the complaint contends, have First Amendment rights to receive accurate information. The goal of the lawsuit is to supply accurate information to physicians about Vascepa so they can make informed decisions on how to treat patients based on current, scientific data and consistent with numerous national and international cardiovascular treatment guidelines and position statements.

In connection with this litigation, the FDA sent a detailed letter to us on June 5, 2015 that confirmed the validity of the ANCHOR trial results. The letter also sought to clarify how, in the FDA s view, applicable law and FDA policies apply to the communications proposed in Amarin s complaint. FDA stated in this letter that it did not have concerns with much of the information Amarin proposed to communicate and provided Amarin with guidance on the FDA s view of lawful, but limited paths for the dissemination and communication to healthcare professionals of the effects of Vascepa demonstrated in the ANCHOR clinical trial and use of peer-reviewed scientific publications in the context of appropriate disclaimers. The litigation continued after receipt of this

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letter because significant issues remained despite the significant steps forward provided by the June 5 letter. Such issues included, but were not limited to, the ability of Amarin to engage in a full and truthful dialogue with healthcare professionals about the success of the ANCHOR trial and the potential effectiveness of Vascepa as a treatment to reduce cardiovascular risk.

On August 7, 2015, we were granted the request we made for preliminary relief in this litigation through the Court s declaratory judgment that confirmed we may engage in truthful and non-misleading speech promoting the off-label use of Vascepa to healthcare professionals, i.e., to treat patients with persistently high triglycerides, and that such speech may not form the basis of a misbranding action under the Federal Food and Drug Cosmetic Act. FDA did not appeal the Court s preliminary ruling prior to the October 6, 2015 deadline for appeal. The underlying litigation has been stayed for settlement discussion and the parties are working toward settlement. We cannot predict the outcome of settlement negotiations or this litigation. The legal process can be unpredictable, costly and time-consuming and even if we are successful the remedies available to us may be less beneficial to us than we currently believe.

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 sells Lovaza®, a prescription-only omega-3 fatty acid indicated for patients with severe hypertriglyceridemia was approved by FDA in 2004 and has been on the market in the United States since 2005. As described below, multiple generic versions of Lovaza are now available in the United States. Other large companies with competitive products include AbbVie, Inc., which currently sells Tricor® and Trilipix® for the treatment of severe hypertriglyceridemia and mixed dyslipidemia and Niaspan®, which is primarily used to raise HDL-C, but is also used to lower triglycerides. Generic versions of Tricor, Trilipix, and Niaspan are also now available in the United States. In addition, in May 2014, Epanova® (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 versions 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 U.S. market with a generic version of Lovaza in the first quarter of 2015, the details of which are not known to us. In the first quarter of 2015, Prasco Labs announced it also has a generic version of Lovaza.

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, Resolvyx Pharmaceuticals, or Resolvyx, 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; Resolvyx 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 to conduct a human study in the treatment of severe hypertriglyceridemia. Isis Pharmaceuticals announced favorable Phase 2 results of ISIS-APOCIII$_{Rx}$ 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.

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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. Under applicable regulations, subject to our related litigation with FDA over NCE marketing exclusivity, such three-year exclusivity would have extended through July 25, 2015 and be supplemented by a 30-month stay that we believe would have extended into September 2016, if the related Vascepa patent litigation were not resolved against us sooner.

NCE marketing exclusivity, not granted to Vascepa at this time, 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 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 within 45 days, and Amarin may also be afforded a judicial extension if applicable requirements are met. This three-year form of exclusivity may also not prevent the FDA from approving an NDA that relies only on its own data to support the change or innovation.

On February 27, 2014, we commenced a lawsuit against the FDA, 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 to our situation. Our complaint requested 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.

On May 28, 2015, the U.S. District Court for the District of Columbia granted our motion for summary judgment in this lawsuit. The decision vacated the FDA s denial of our claim for such exclusivity and remanded to the FDA for proceedings consistent with the decision. On July 22, 2015, Watson Laboratories Inc., or Watson, the purported first Vascepa ANDA filer, sought to intervene and appeal the Court s decision. FDA did not appeal the Court s decision prior to the July 28, 2015 deadline for appeal and has joined in our opposition to Watson s sought intervention and appeal. The legal process can be unpredictable, costly and time-consuming. We intend to continue to litigate the case vigorously, but cannot predict its outcome.

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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.

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 received six paragraph IV notices notifying us of submitted ANDAs to Vascepa under the Hatch-Waxman Amendments based on the FDA s determination that we were entitled to three, and not five-year exclusivity. As a result, until recently, we have been engaged in costly litigation with the ANDA applicants to protect our patent rights.

Based on the May 28, 2015, U.S. District Court for the District of Columbia order granting our motion for summary judgment in the NCE litigation, the parties to the related Vascepa patent litigation that followed acceptance by FDA of abbreviated new drug applications, or ANDAs, to Vascepa agreed to a stay of proceeding in that patent litigation pending a new FDA determination on Vascepa exclusivity. Based on subsequent FDA notification to the ANDA filers that FDA had changed the status of their ANDAs to submitted, but no longer accepted, we believe the statutory, constructive infringement basis for the patent litigation (accepted ANDAs) no longer exists. Thus, on July 24, 2015, we moved to dismiss the pending patent infringement lawsuits against each of the Vascepa ANDA applicants. Under the terms of the parties agreement to stay this litigation, proceedings related to our motion to dismiss continue; the motion to dismiss is not subject to the stay. We cannot predict the outcome of this motion to dismiss or litigation. The legal process can also be costly and time-consuming. If the motion to dismiss is granted, we plan to defend the exclusivity of Vascepa through patent litigation after notification that FDA has accepted an ANDA application related to Vascepa which, assuming NCE exclusivity, we would expect no sooner than late July 2016.

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 introduce 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 IV 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

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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 and because FDA is not accepting ANDAs after submission at this time, 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.

Vascepa is a prescription-only omega-3 fatty acid product. Omega-3 fatty acids are also marketed by other companies as non-prescription dietary supplements. As a result, Vascepa is 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 the preliminary ruling in our First Amendment litigation, we may now make this claim to healthcare professionals subject to certain qualifications. 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 and pharmacists may recommend these commercial alternatives instead of writing or filling 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.

We may not be successful in our Vascepa co-promotion effort with Kowa Pharmaceuticals America, Inc.

In March 2014, we entered into a co-promotion agreement with Kowa Pharmaceuticals America, Inc. to co-promote Vascepa in the United States under which approximately 250 Kowa Pharmaceuticals America, Inc. 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, Inc., 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 current and sought marketing rights 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 marketing rights we currently have or, if approved, an indication based on a successful outcome of the REDUCE-IT study. 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, the number of actual patients with conditions within the scope of our marketing efforts may be smaller than we anticipate. If any such marketing right or approved indication is narrower than we anticipate, the market potential for our product would suffer.

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Our SPA agreement for ANCHOR was 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. In April 2015, we received a CRL from the FDA stating that the FDA determined not to approve label expansion reflecting the ANCHOR clinical trial efficacy data at this time.

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.

The commercial value to us of sales of Vascepa under the DCS Agreement with Eddingpharm may be smaller than we anticipate.

There can be no assurance as to the adequacy for commercial success under the DCS Agreement with Eddingpharm. Even if we and Eddingpharm obtain marketing approval in countries within the China Territory, applicable regulatory agencies 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 any indications for which we may gain approval in these countries, 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 in these countries for our product would suffer.

Our products and marketing efforts are 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-healthcare provider and 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. Our recent First Amendment ruling may cause the government to scrutinize our promotional efforts or otherwise monitor our business more closely. 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 and we

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believe that we have demonstrated to FDA that we have adequately responded to these observations. 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 held responsible for the non-compliance of our partners, such as Kowa Pharmaceuticals America, Inc. 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. In addition, all of the above factors may also apply to any regulatory approval for Vascepa obtained within the China Territory under the DCS agreement with Eddingpharm. Given our inexperience with marketing and commercializing products in the China Territory, we will need to rely on Eddingpharm to assist us in dealing with any such issues.

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products. If we or Kowa Pharmaceuticals America, Inc. are found to have improperly promoted uses of Vascepa, we may become subject to significant fines and other liability. The government may seek to find means to prevent our promotion of truthful and non-misleading information beyond our current court ruling.

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products. In particular, in general, the U.S. government s position has been that a product may not be promoted for uses that are not approved by the FDA as reflected in the product s approved labeling. The government s current position is not clear. Even though we received FDA marketing approval for Vascepa for the MARINE indication and we believe our recent First Amendment court ruling affords us a limited degree of protection for other promotional efforts, 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 or our court ruling. If we are found to have promoted Vascepa outside the terms of the court ruling or in violation of what the government may determine to be acceptable, we may become subject to significant government fines and other related liability. The government may also seek to hold us responsible for the non-compliance of our co-promotion partner, Kowa Pharmaceuticals America, Inc., or our ex-U.S. commercialization partner, Eddingpharm. 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.

Even though we have the benefit of a preliminary ruling and may be ultimately successful with a final settlement or final ruling in our current litigation related to promotion beyond FDA-approved labeling, our promotion would still be

subject to a high, perhaps abnormally high, degree of scrutiny to ensure that our promotion remains within the permitted scope. Likewise, the government may seek to find other means to prevent our promotion of truthful and non-misleading information.

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-

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label simvastatin therapy on cardiovascular outcomes. The addition of fenofibrate did not show any treatment benefit on cardiovascular outcomes over simvastatin monotherapy in this study. In 2011, the results of the AIM-HIGH trial were published. This trial studied the effect of adding a second lipid-altering agent, extended-release niacin, to simvastatin therapy on cardiovascular outcomes in people at high risk for cardiovascular events. No significant incremental treatment benefit with extended-release niacin was observed. In addition, in September 2012, researchers published in the *Journal of the American Medical Association,* or *JAMA,* the results of a retrospective meta-analysis of twenty previously conducted studies regarding the use of omega-3 supplements across various patient populations. This meta-analysis suggested that the use of such supplements was not associated with a lower risk of all-cause death, cardiac death, sudden death, heart attack, or stroke. We believe the results of these studies may not be directly applicable to the use of Vascepa over time. For instance, the outcomes studies for fenofibrates and niacin were conducted in patient populations in which the majority of patients studied had triglycerides below 200 mg/dL and fenofibrates and niacin are believed to work differently than Vascepa in the body and do not have as favorable a side-effect profile, and nineteen of the twenty studies included in the *JAMA* meta-analysis involved the use of omega-3 supplements containing a mixture of EPA and DHA, and most were evaluated at relatively lower doses. In addition, in May 2013, *The New England Journal of Medicine* published the results of an outcome study of 1 gram per day of an omega-3 acid ethyl ester composition. In that study, the composition failed to show a benefit in reducing the rate of death from cardiovascular causes or hospitalization for cardiovascular causes when administered to patients with cardiovascular risk factors under different study conditions than in the REDUCE-IT study. Vascepa is comprised of highly-pure ethyl-EPA, and has been approved by the FDA for use in adult 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.

Further, FDA determined that JELIS results could not be used as support for or against the use of triglyceride levels as a surrogate for cardiovascular risk reduction. Patients treated with EPA and statin in JELIS achieved triglyceride levels that were only 5% lower, on average, than those achieved among patients treated with statin alone; however, the reduction in cardiovascular risk in the primary endpoint analysis was 19%. Likewise, within the primary and secondary prevention sub-analyses, triglyceride levels were lowered only 5% on average in the EPA plus statin group compared with the statin alone group; however, the relative risk reduction was 53% in the primary prevention population with elevated triglyceride ($\geq$ 150mg/dL) and low HDL-C ($\leq$ 40mg/dL) levels and 23% in the secondary prevention population with established coronary artery disease. These large differences in magnitude between triglyceride reduction and risk reduction in JELIS suggest that the effects of EPA on triglyceride levels alone may not be responsible for, or predict, the observed differences in cardiovascular events between treatment groups in JELIS. JELIS was not designed to evaluate primary and secondary prevention populations. It is possible that the putative cardioprotective effects of EPA observed in JELIS are due not to a single mode of action, such as triglyceride lowering, but rather to multiple mechanisms working together, such as purported beneficial effects on multiple atherosclerosis processes, including endothelial function, oxidative stress, foam cell formation, inflammation/cytokines, plaque formation/progression, platelet aggregation, thrombus formation, and plaque rupture.

The REDUCE-IT study is needed to determine the clinical benefit, if any, of EPA therapy in statin-treated patients with elevated triglyceride levels.

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.

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The prospective interim efficacy and safety analysis of the REDUCE-IT cardiovascular outcomes trial may not be completed in the contemplated timeframe in 2016 and may not demonstrate to the independent committee monitoring the study a sufficient benefit risk result to warrant the independent committee recommending stopping the study early for overwhelming efficacy. The study may also be stopped for futility or for safety concerns.

In accordance with the SPA agreement for our REDUCE-IT cardiovascular outcomes trial, an interim review of the efficacy and safety 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 study s independent data monitoring committee (DMC) to occur during 2016 based on our understanding of the current event rates in the study and expected future event rates. It may actually take longer to reach the targeted number of events, which would delay the DMC assessment of data for the interim analysis.

Further, as is typical of interim analyses, the statistical threshold for defining overwhelming efficacy on the primary endpoint that would call for stopping the study early in connection with such analysis is considerably higher than the threshold for defining statistical significance after the expected completion of the study in 2017. We do not expect the study to be stopped due to overwhelming efficacy at this interim look. For example, even if the appropriate studied cardiovascular events in the trial occur at sufficiently low rates in the active, Vascepa, group as compared to the placebo group such that the study would be a success at completion, the more rigorous statistical analysis applied by the DMC at the interim analysis may not warrant stoppage of the study for overwhelming efficacy in connection with the interim analysis. The study may also be stopped pursuant to recommendation by the DMC at this interim analysis for lack of signals of a favorable result at completion, so called stoppage for futility.

Moreover, it is the DMC that will make the formal recommendation as to whether to stop the study early or continue as planned. Amarin is blinded to the interim analysis and is informed by the DMC of the recommendation to stop the study or to continue as planned. The DMC may consider factors outside the pre-specified statistical analysis plan when assessing whether to continue the study as planned. For example, even if study results are sufficiently positive at the interim analysis to demonstrate overwhelming efficacy, the DMC at its discretion may recommend continuation of the study as planned with the goal of arriving at more robust results at the planned study completion if they believe that waiting for more robust results outweighs the potential medical benefit of stopping and unblinding the study early.

The DMC has multiple times per year assessed safety data generated in the ongoing study and has thus far recommended to continue the study as planned. Thus, multiple safety analyses to date have not warranted study stoppage. Nevertheless, the study may be stopped at any time based on recommendations of the DMC due to safety concerns identified by the DMC during its ongoing and regularly scheduled safety data assessments.

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 China Territory under the DCS Agreement with Eddingpharm, 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.

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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 further 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.

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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, Inc., 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 terminated our agreement with BASF due to its inability to meet the agreement requirements, may enter into a new development and supply agreement with BASF, and may purchase API from BASF. In 2014, we obtained sNDA approval of a fourth supplier of API, which includes the manufacturing facility of Finorga SAS (Novasep). 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

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

We currently have encapsulation agreements with three commercial API encapsulators for the encapsulation of Vascepa: Patheon, Inc. (formerly Banner Pharmacaps), Catalent Pharma Solutions, and Capsugel US, LLC. These companies have qualified their manufacturing processes and are capable of manufacturing Vascepa. There can be no guarantee that additional other suppliers with which we have contracted to encapsulate API will be qualified to manufacture the product to our specifications or that these and any future suppliers will have the manufacturing capacity to meeting anticipated demand for Vascepa. We cannot assure you that we can contract with any future manufacturer on acceptable terms or that any such alternative supplier will not require capital investment from us in order for them to meet our requirements.

We may not be able to maintain our exclusivity with our 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. 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.

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Furthermore, the FDA and foreign regulatory agencies require that we be able to consistently produce the API and the finished product in commercial quantities and of specified quality on a repeated basis, including proven product stability, and document our ability to do so. This requirement is referred to as process validation. This includes stability testing, measurement of impurities and testing of other product specifications by validated test methods. If the FDA does not consider the result of the process validation or required testing to be satisfactory, the commercial supply of Vascepa may be delayed, or we may not be able to supply sufficient quantities of Vascepa to meet anticipated demand.

The FDA and similar foreign regulatory bodies may also implement new standards, or change their interpretation and enforcement of existing standards and requirements, for manufacture, packaging or testing of products at any time. If we are unable to comply, we may be subject to regulatory, civil actions or penalties which could significantly and adversely affect our business.

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

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

We are dependent upon our collaboration with Eddingpharm to commercialize Vascepa in certain regions outside of the United States, and if Eddingpharm fails to successfully fulfill its obligations, or is ineffective in its commercialization of Vascepa in the China Territory, or if our collaboration is terminated, our plans to commercialize Vascepa outside of the United States may be adversely affected.

In February 2015, we entered into the DCS Agreement with Eddingpharm, under which we granted exclusive rights to Eddingpharm to develop and commercialize Vascepa in the China Territory. We are dependent on Eddingpharm for certain regulatory filings outside of the United States with respect to Vascepa and the commercialization of Vascepa outside of the United States. If Eddingpharm fails to perform its obligations under the DCS Agreement or is ineffective in its commercialization of Vascepa in the China Territory or if we fail to effectively manage our relationship with Eddingpharm, our ability to and the extent to which we commercialize and obtain certain regulatory approvals of Vascepa outside of the United States would be significantly harmed.

In addition, Eddingpharm has the right to terminate the agreement under certain conditions. If Eddingpharm terminates the DCS Agreement, we would be required to either enter into alternative arrangements with third parties to commercialize Vascepa in the China Territory, which we may be unable to do, or to increase our internal infrastructure, both of which would likely result in significant additional expense and delay or termination of our Vascepa clinical development programs outside of the United States.

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.

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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 45 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 45 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,
- 3 additional patents 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,
- 2 additional patents 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,
- 1 additional patent related to a pharmaceutical composition comprised of free fatty acids and uses thereof to treat both the MARINE and ANCHOR patient populations with a term that expires in 2030, and
- 1 additional patent related to a formulation of EPA/DHA and uses thereof 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.

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 sought injunctive relief and monetary damages for infringement of Amarin s U.S. Patent No. 8,663,662. The complaint alleged 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,

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and no more than about 30% DHA. In November 2014, based on a representation from AstraZeneca Pharmaceuticals LP that the commercial launch of Epanova was not imminent, the court dismissed our complaint, without prejudice (i.e., preserving our ability to later re-file the suit). The court required the defendant to notify us before any product launch. We intend 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.

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

If the estimates we make, or the assumptions on which we rely, in preparing our projected guidance prove inaccurate, our actual results may vary from those reflected in our projections and accruals.

Further, in November 2015, we issued financial guidance, including expected fourth quarter 2015 total revenues and net revenue, which is based on estimates and the judgment of management. Because of the inherent nature of estimates, there could be significant differences between our estimates and the actual amount of product demand. If, for any reason, we are unable to realize our projected revenue, we may not realize our publicly announced financial guidance. If we fail to realize or if we change or update any element of our publicly disclosed financial guidance or other expectations about our business, our stock price could decline in value.

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We and certain of our current and former executive officers have been named as defendants in a class action lawsuit 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 a class action lawsuit that generally alleges 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 engaged in a vigorous defense of this lawsuit. On June 29, 2015, the Court granted our motion to dismiss the class action without prejudice. The Court held that the plaintiffs failed to state a claim upon which relief could be granted and plaintiffs were given 30 days to refile an amended complaint.

On July 29, 2015, the plaintiffs filed an amended complaint. We will continue with our vigorous defense. However, we are unable to predict the outcome of this matter at this time. Moreover, while we expect insurance to cover any financial exposure from this litigation, the conclusion of this matter 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. In keeping with our 2009 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.

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.

In 2011 and early 2012, but not after, we received several communications on behalf of the former shareholders of Ester asserting that we are in breach of our agreement with them as it relates to alleged rights to share in the value of EN101 due to the fact that Yissum terminated its license. We do not believe the circumstances presented constitute a breach of the agreement. If the dispute arises again, we plan to defend our position vigorously, but there can be no assurance as to the outcome of this dispute.

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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, our inability to obtain FDA approval for the ANCHOR indication before the REDUCE-IT outcomes trial is completed successfully could have an adverse impact on our ability to retain and recruit qualified personnel. In addition, in October 2013, we eliminated approximately 50% of our staff positions worldwide as part of a restructuring following the FDA advisory committee s recommendation against the potential Vascepa label expansion. The restructuring could 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% of gross product sales for each of the nine months ended September 30, 2015 and 2014, and represented 95% and 96% of the gross accounts receivable balance as of September 30, 2015 and 2014, 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.

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, 2014, 2013, and 2012, we reported losses of approximately $56.4 million, $166.2 million, and $179.2 million, respectively, and we had an accumulated deficit as of December 31, 2014 of $970.2 million. For the nine months ended September 30, 2015 and 2014, we reported losses of approximately $127.2 million and $36.7 million, respectively and we had an accumulated deficit as of September 30, 2015 of $1.1 billion. 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,

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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.

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 commercial launch of Vascepa in 2013 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 with ANCHOR data and seek to obtain additional regulatory approval of Vascepa from 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. Vascepa sales are 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, Inc.;

the timing and ability of Eddingpharm to development and commercialize Vascepa in the China Territory, including obtaining necessary regulatory approvals and establishing marketing channels;

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

the results of the REDUCE-IT study or post-approval studies for Vascepa;

outcomes of litigation and other legal proceedings, including the lawsuit against the FDA to expand marketing claims for Vascepa, our NCE litigation, shareholder litigation, regulatory matters and tax matters; and

our regulatory dialogue on the REDUCE-IT study.

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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 $119.0 million as of September 30, 2015 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;
- the costs associated with commercializing Vascepa 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, Inc., 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 costs associated with litigation and other legal proceedings, including the lawsuit against the FDA to expand marketing claims for Vascepa, our NCE litigation, 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.

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.

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 Secured Debt Fund II Holdings Cayman LP, or 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.

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.

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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, Inc. 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.

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, 2015 we had 183,486,827 common shares outstanding including 182,530,173 shares held as ADSs and 956,654 held as common shares (which are not held in the form of 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 March 2015 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;

litigation and regulatory developments in the United States affecting our Vascepa promotional rights, and regulatory developments in 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.

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The number of our ordinary shares, or ADSs representing such ordinary shares, outstanding may increase substantially as a result of our March 2015 private placement and the later consolidation and redesignation of the Series A Preference Shares represented by Preference ADSs issued thereunder, and some of the investors may then beneficially own significant blocks of our ordinary shares; the ordinary shares and Series A Preference Shares resulting from the private placement will be generally available for resale in the public market upon registration under the Securities Act.

In March and July 2015, we completed two private placements of American Depositary Shares representing 352,150,790 and 38,867,180 Series A Preference Shares, respectively, each ten (10) of which may be consolidated and redesignated into one (1) ordinary share in the capital of the Company. During the three months ended June 30, 2015, 62,833,330 preferred shares were converted, resulting in the issuance of 6,283,333 ordinary shares. The consolidation and redesignation of the Series A Preference Shares currently outstanding would result in an additional 32,818,464 ordinary shares outstanding, resulting in substantial dilution to shareholders who held our ordinary shares or ADSs representing such ordinary shares prior to the private placement. Although the Series A Preference Shares do not have voting rights, in general, upon consolidation and redesignation into ordinary shares some of the investors in the private placement could then have significant influence over the outcome of any shareholder vote, including the election of directors and the approval of mergers or other business combination transactions.

Pursuant to the securities subscription agreement that we entered into with the investors in the private placement, we agreed to file with the SEC a registration statement to register the resale of the Series A Preference Shares represented by American Depositary Shares issued in the private placement and the ordinary shares issuable upon the consolidation and consolidation and redesignation of such Series A Preference Shares. Upon such registration and subsequent consolidation and redesignation, these securities will become generally available for immediate resale in the public market. The market price of our ordinary shares could fall as a result of an increase in the number of shares available for sale in the public market.

Failure to comply with our obligations under the March 2015 securities subscription agreements could result in our becoming liable for damages to certain investors under these agreements, including specified liquidated damages, which could be material in amount.

Under the terms of the March 2015 securities subscription agreements, we are subject to various obligations, failure to comply with which could result in our becoming liable to certain investors under these agreement for damages, which could be material in amount.

For example, under each of these agreements we have agreed to file and maintain the effectiveness of certain resale registration statements for ADSs representing the ordinary shares underlying the Series A Preference shares we issued and sold under these agreements. Specifically, we have agreed to pay liquidated damages to the investors in the respective private placements if (a) the applicable resale registration statements we are required to file are not declared effective within 120 days after the closing of the applicable private placement, or (b) after effectiveness and subject to certain specified exceptions, we suspend the use of the applicable registration statement or the registration statement ceases to remain continuously effective as to all the securities for which it is required to be effective. We refer to each of these events as a registration default. Subject to the specified exceptions, for each 30-day period or portion thereof during which a registration default remains uncured, we are obligated to pay liquidated damages to each investor in cash in an amount equal to 1% of the aggregate subscription price paid by each such investor in the private placement, up to a maximum of 8% of such aggregate subscription price. These amounts could be material, and any liquidated damages we are required to pay could have a material adverse effect on our financial condition.

In addition, under the first March 2015 securities subscription agreement we are required to offer to certain investors party to that agreement an opportunity to participate in future equity and debt financings we may conduct from time to time, and to not publicly disclose the identity of the investors party to that agreement, subject to certain exceptions for disclosures required in securities filings and under applicable law. If we fail to comply with these obligations we could become liable to these investors for damages, including specified liquidated damages. For example, following certain public statements made by the Company on a quarterly conference call concerning the 2015 private placement, we agreed to specified liquidated damages in the event we are found to have violated the confidentiality provisions of the subscription agreement in the future.

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.

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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 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 or 2014. Our status as a PFIC is subject to change in 2015 and future years.

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

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).

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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 consists 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 us 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;
- limit our ability to raise additional funds by borrowing or engaging in equity sales in order to fund future working capital, capital expenditures, research and development and other general corporate requirements;
- require us to dedicate a substantial portion of our cash to service payments on our debt; or
- limit our flexibility to react to changes in our business and the industry in which we operate or to pursue certain strategic opportunities that may present themselves.

The accounting 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 condensed 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

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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.

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

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

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

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

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

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

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Issuer Purchases of Equity Securities

Shares purchased in the third quarter of 2015 are as follows:

Period	Total Number of Shares Purchased [1]	Average Price Paid per Share
July 1 31, 2015		
August 1 31, 2015		
September 1 30, 2015	17,734	$ 1.93
Total	17,734	$ 1.93

(1) Represents shares withheld to satisfy tax withholding amounts due from employees related to the receipt of stock which resulted from the exercise or vesting of equity awards.

Item 6. Exhibits

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

Exhibit Number	Description
31.1	Certification of Chief Executive Officer (Principal Executive Officer) pursuant to Section 302 of Sarbanes-Oxley Act of 2002
31.2	Certification of Vice President, Finance (Principal Financial Officer) pursuant to Section 302 of Sarbanes-Oxley Act of 2002
32.1	Certification of Chief Executive Officer (Principal Executive Officer) and Vice President, Finance (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

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Exhibit Number	Description
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

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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 4, 2015