
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2014

OR

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

For the transition period from _____ to _____

Commission File No. 000-21392

Amarin Corporation plc

(Exact Name of Registrant as Specified in its Charter)

England and Wales
(State or Other Jurisdiction of
Incorporation or Organization)

Not applicable
(I.R.S. Employer
Identification No.)

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

Dublin 2, Ireland
(Zip Code)

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

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

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

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

Large accelerated filer ☒ Accelerated filer ☐

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

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

172,440,450 shares held as American Depositary Shares (ADS), each representing one Ordinary Share, 50 pence par value per share, and 465,613 ordinary shares, were outstanding as of May 1, 2014.

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PART I

AMARIN CORPORATION PLC
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited, in thousands, except share amounts)

	March 31, 2014	December 31, 2013
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 164,278	\$ 191,514
Restricted cash	600	1,000
Accounts receivable	4,025	3,645
Inventory, current	21,830	21,209
Deferred tax asset	471	471
Other current assets	2,943	1,563
Total current assets	194,147	219,402
Property, plant and equipment, net	523	579
Inventory, long-term	—	5,482
Deferred tax asset	11,968	11,944
Other non-current assets	3,021	4,360
Intangible asset, net	10,548	10,709
TOTAL ASSETS	220,207	252,476
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current Liabilities:		
Accounts payable	4,823	6,375
Accrued interest payable	12,569	12,974
Warrant derivative liability	5,929	6,894
Deferred revenue	—	1,703
Accrued expenses and other liabilities	8,041	9,594
Total current liabilities	31,362	37,540
Long-Term Liabilities:		
Exchangeable senior notes	150,000	149,317
Long-term debt	88,207	87,717
Long-term debt redemption feature	7,600	11,100
Other long-term liabilities	632	658
Total liabilities	277,801	286,332
Commitments and contingencies (Note 7)		
Stockholders' Deficit:		
Common stock, £0.50 par, unlimited authorized; 172,906,063 issued, 172,885,984 outstanding at March 31, 2014; 172,691,063 issued, 172,670,984 outstanding at December 31, 2013	141,654	141,477
Additional paid-in capital	740,819	738,754
Treasury stock; 20,079 shares at March 31, 2014 and December 31, 2013	(217)	(217)
Accumulated deficit	(939,850)	(913,870)
Total stockholders' deficit	(57,594)	(33,856)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	\$ 220,207	\$ 252,476

See notes to condensed consolidated financial statements.

AMARIN CORPORATION PLC
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited, in thousands, except per share amounts)

	Three months ended March 31,	
	2014	2013
Product revenues	\$ 10,967	\$ 2,341
Less: Cost of goods sold	4,246	1,287
Gross margin	<u>6,721</u>	<u>1,054</u>
Operating expenses:		
Selling, general and administrative	20,585	39,267
Research and development	<u>11,707</u>	<u>21,838</u>
Total operating expenses	<u>32,292</u>	<u>61,105</u>
Operating loss	(25,571)	(60,051)
Gain on change in fair value of derivative liabilities	4,393	3,620
Interest expense, net	(4,393)	(8,860)
Other income (expense), net	<u>16</u>	<u>(124)</u>
Loss from operations before taxes	(25,555)	(65,415)
(Provision for) benefit from income taxes	<u>(425)</u>	<u>3,257</u>
Net loss	<u>\$ (25,980)</u>	<u>\$ (62,158)</u>
Loss per share:		
Basic	\$ (0.15)	\$ (0.41)
Diluted	\$ (0.15)	\$ (0.43)
Weighted average shares:		
Basic	172,872	150,430
Diluted	174,431	157,073

See notes to condensed consolidated financial statements.

AMARIN CORPORATION PLC
CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN DEFICIT
(Unaudited, in thousands, except share amounts)

	Common Shares	Common Stock	Additional Paid-in Capital	Treasury Shares	Accumulated Deficit	Total
At December 31, 2013	172,691,063	\$ 141,477	\$ 738,754	\$ (217)	\$ (913,870)	\$ (33,856)
Exercise of stock options	215,000	177	107	—	—	284
Tax benefits realized from stock-based compensation	—	—	1	—	—	1
Stock-based compensation	—	—	1,957	—	—	1,957
Loss for the period	—	—	—	—	(25,980)	(25,980)
At March 31, 2014	<u>172,906,063</u>	<u>\$ 141,654</u>	<u>\$ 740,819</u>	<u>\$ (217)</u>	<u>\$ (939,850)</u>	<u>\$ (57,594)</u>

See notes to condensed consolidated financial statements.

AMARIN CORPORATION PLC
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited, in thousands)

	Three Months Ended March 31, 2014	2013
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (25,980)	\$ (62,158)
Adjustments to reconcile loss to net cash used in operating activities:		
Depreciation and amortization	56	59
Stock-based compensation	1,957	4,874
Stock-based compensation—warrants	(72)	(451)
Excess tax provision (benefit) from stock-based awards	1	(678)
Accrued interest payable	(405)	2,124
Amortization of debt discount and debt issuance costs	1,173	4,204
Amortization of intangible asset	161	161
Gain on changes in fair value of derivative liabilities	(4,393)	(3,620)
Deferred income taxes	(24)	(3,949)
Shares issued for services	—	8
Change in lease liability	—	(7)
Changes in assets and liabilities:		
Restricted cash	400	(1,400)
Accounts receivable	(380)	(3,441)
Inventories	4,861	(6,173)
Other current assets	(1,380)	(3,798)
Other non-current assets	1,339	(383)
Deferred revenue	(1,703)	2,865
Accounts payable and other liabilities	(3,105)	12,128
Net cash used in operating activities	<u>(27,494)</u>	<u>(59,635)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of equipment	—	(14)
Net cash used in investing activities	<u>—</u>	<u>(14)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of stock options, net of transaction costs	285	439
Proceeds from exercise of warrants, net of transaction costs	—	70
Excess tax (provision) benefit from stock-based awards	(1)	678
Payments under capital leases	(26)	—
Net cash provided by financing activities	<u>258</u>	<u>1,187</u>
NET DECREASE IN CASH AND CASH EQUIVALENTS	(27,236)	(58,462)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	191,514	260,242
CASH AND CASH EQUIVALENTS, END OF PERIOD	<u>\$ 164,278</u>	<u>\$ 201,780</u>
Supplemental disclosure of cash flow information:		
Cash paid during the year for:		
Interest	<u>\$ 3,636</u>	<u>\$ 2,625</u>
Income taxes	<u>\$ 33</u>	<u>\$ 563</u>

See notes to condensed consolidated financial statements.

AMARIN CORPORATION PLC
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

(1) Nature of Business and Basis of Presentation

Nature of Business

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

The Company’s lead product, Vascepa® (icosapent ethyl) capsules, is approved by the U.S. Food and Drug Administration, or FDA, for use as an adjunct to diet to reduce triglyceride levels in adult patients with severe (TG \geq 500mg/dL) hypertriglyceridemia. Vascepa is available in the United States by prescription only. The Company began selling and marketing Vascepa in the United States in January 2013. The Company sells Vascepa principally to a limited number of major wholesalers, as well as selected regional wholesalers and specialty pharmacy providers, or collectively, its Distributors, that in turn resell Vascepa to retail pharmacies for subsequent resale to patients and health care providers. The Company markets Vascepa through its sales force of approximately 150 sales professionals, including sales representatives and their managers. The Company also recently entered into a co-promotion agreement with Kowa Pharmaceuticals America, Inc. (Kowa Pharmaceuticals America) under which approximately 250 Kowa Pharmaceuticals America sales representatives are expected to devote a substantial portion of their time to promoting Vascepa starting in May 2014. The Company operates in one business segment.

Triglycerides are fats in the blood. Hypertriglyceridemia refers to a condition in which patients have high levels of triglycerides in the bloodstream. It is estimated that over 40 million adults in the United States have elevated triglyceride levels (TG \geq 200mg/dL) and approximately 4.0 million people in the United States have severely high triglyceride levels (TG \geq 500mg/dL), commonly known as very high triglyceride levels. According to *The American Heart Association Scientific Statement on Triglycerides and Cardiovascular Disease* (2011), triglycerides also provide important information as a marker associated with the risk for heart disease and stroke, especially when an individual also has low high-density lipoprotein cholesterol, or HDL-C (often referred to as “good” cholesterol), and elevated levels of LDL-C (often referred to as “bad” cholesterol). Guidelines for the management of very high triglyceride levels suggest that reducing triglyceride levels is the primary goal in patients to reduce the risk of acute pancreatitis. The effect of Vascepa on cardiovascular mortality and morbidity, or the risk for pancreatitis, in patients with hypertriglyceridemia has not been determined.

The potential efficacy and safety of Vascepa (known in its development stage as AMR 101) was studied in two Phase 3 clinical trials, the MARINE trial and the ANCHOR trial. At a daily dose of 4 grams of Vascepa, the dose at which Vascepa is FDA approved, these trials showed favorable clinical results in their respective patient populations in reducing triglyceride levels without increasing LDL-C levels in the MARINE trial and with a statistically significant decrease in LDL-C levels in the ANCHOR trial, in each case, relative to placebo. These trials also showed favorable results, particularly with the 4-gram dose of Vascepa, in other important lipid and inflammation biomarkers, including apolipoprotein B (apo B), non-high-density lipoprotein cholesterol (non-HDL-C), total-cholesterol (TC), very low-density lipoprotein cholesterol (VLDL-C), lipoprotein-associated phospholipase A2 (Lp-PLA2), and high sensitivity C-reactive protein (hs-CRP). In these trials, the most commonly reported adverse reaction (incidence $>$ 2% and greater than placebo) in Vascepa-treated patients was arthralgia (joint pain) (2.3% for Vascepa vs. 1.0% for placebo).

The Company is also developing Vascepa for the treatment of patients with high (TG \geq 200 mg/dL and $<$ 500 mg/dL) triglyceride levels who are also on statin therapy for elevated low-density lipoprotein cholesterol, or LDL-C, levels which the Company refers to as mixed dyslipidemia. The Company refers to this second proposed indication for Vascepa as the ANCHOR indication. The FDA has stated that it views the proposed ANCHOR indication as ostensibly and impliedly an indication to reduce cardiovascular risk. In addition, in December 2011, Amarin announced commencement of patient dosing in 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.

The Company has a pending supplemental new drug application, or sNDA, with the FDA that seeks marketing approval of Vascepa for use in the ANCHOR indication. On October 16, 2013, the FDA convened an advisory committee to review the sNDA. This advisory committee was not asked by the FDA to evaluate whether Vascepa is effective in lowering triglycerides in the studied population, the ANCHOR indication as specified in the sNDA. Rather, the advisory committee was asked whether Vascepa has been demonstrated to improve cardiovascular outcomes or whether approval of the ANCHOR indication should wait for successful completion of the REDUCE-IT study, the first prospective study of cardiovascular outcomes in patients who have high triglyceride levels despite statin therapy. The advisory committee voted 9 to 2 against recommending approval of the ANCHOR indication based on information presented at the meeting. The FDA considers the recommendation of the advisory committee, but final decisions on the approval of new drug applications are made by the FDA. On October 22, 2013, in an effort to reduce operating expenses following the recommendation of the advisory committee, the Company implemented a worldwide reduction in force of approximately 50% of its staff positions, including sales positions.

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The ANCHOR clinical study was conducted under a special protocol assessment, or SPA, agreement with the FDA. The law governing SPA agreements requires that if the results of the trial conducted under the SPA substantiate the hypothesis of the protocol covered by the SPA, the FDA must use the data from the protocol as part of the primary basis for approval of the product. A SPA agreement is not a guarantee of FDA approval of the related new drug application. A SPA agreement is generally binding upon the FDA, except in limited circumstances, such as if the FDA identifies a substantial scientific issue essential to determining safety or efficacy of the drug after the study begins that rises to the level of a public health concern, or if the study sponsor fails to follow the protocol that was agreed upon with the FDA. On October 29, 2013, the FDA rescinded the ANCHOR study SPA agreement because the FDA determined that a substantial scientific issue essential to determining the effectiveness of Vascepa in the studied population was identified after testing began. As a basis for this determination, the FDA communicated that it determined that the cumulative results from outcome studies of other triglyceride-lowering drugs failed to support the hypothesis that a triglyceride-lowering drug significantly reduces the risk for cardiovascular events among the population studied in the ANCHOR trial. Thus, the FDA stated that while information the Company submitted supports testing the hypothesis that Vascepa 4 grams/day versus placebo reduces major adverse cardiovascular events in statin-treated subjects with residually high triglyceride levels, as is being studied in the Vascepa REDUCE-IT cardiovascular outcomes study, the FDA no longer considers a change in serum triglyceride levels as sufficient to establish the effectiveness of a drug intended to reduce cardiovascular risk in subjects with serum triglyceride levels below 500 mg/dL. In November 2013, the Company submitted to the FDA a request for reconsideration of its decision to rescind the ANCHOR SPA agreement. On January 17, 2014, the Company was notified by the FDA that it does not intend to reinstate the ANCHOR SPA agreement. The Company appealed to the next level within the FDA and was informed in late April 2014 that that level determined to uphold the rescission determination. The Company currently plans to appeal the rescission decision to the next level within the FDA in accordance with FDA dispute resolution guidance.

The FDA did not take action on the ANCHOR sNDA by the Prescription Drug User Fee Act, or PDUFA, goal date for completion of FDA's review, December 20, 2013. Instead, the FDA notified the Company on December 19, 2013 that it would first consider the appeal of the ANCHOR SPA agreement rescission. No new PDUFA goal date for the ANCHOR sNDA was established. Based on information available, the Company does not expect a determination on the ANCHOR sNDA while the Company's appeal of the January 17, 2014 FDA decision to uphold the ANCHOR SPA rescission is pending. The Company is also continuing its efforts toward a positive determination on the pending ANCHOR sNDA. There can be no assurance that the FDA will not communicate the results of its review of the ANCHOR sNDA prior to the timing expected.

Based on the Company's communications with the FDA, the Company currently expects that final positive results from the REDUCE-IT outcomes study will be required for label expansion for Vascepa. There can be no assurance that the Company will be successful in its efforts to reinstate the ANCHOR SPA agreement or obtain a label expansion reflecting the ANCHOR clinical trial. Such label expansion could include FDA approval of the addition of an ANCHOR indication statement and/or the addition of the ANCHOR clinical trial data to the currently approved labeling. If the FDA does not approve the ANCHOR indication, it could have a material impact on the Company's future results of operations and financial condition.

Basis of Presentation

The condensed consolidated financial statements included herein have been prepared by the Company, without audit, in accordance with accounting principles generally accepted in the United States of America (the "U.S." or the "United States") and pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC"). Certain information in the footnote disclosures of the financial statements has been condensed or omitted where it substantially duplicates information provided in the Company's latest audited consolidated financial statements, in accordance with the rules and regulations of the SEC. These condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and notes included in its Annual Report on Form 10-K for the fiscal year ended December 31, 2013, filed with the SEC (the "2013 Form 10-K"). The balance sheet amounts at December 31, 2013 in this report were derived from the Company's audited 2013 consolidated financial statements included in the 2013 Form 10-K.

The condensed consolidated financial statements reflect all adjustments that, in the opinion of management, are necessary to present fairly the Company's financial position, results of operations and cash flows for the periods indicated. The preparation of financial statements in conformity with U.S. Generally Accepted Accounting Principles ("GAAP") requires management to make estimates and assumptions that affect the reported amounts and classifications of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. The results of operations for the three months ended March 31, 2014 and March 31, 2013, respectively, are not necessarily indicative of the results for the entire fiscal year or any future period.

The accompanying consolidated financial statements of the Company and subsidiaries have been prepared on a basis which assumes that the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities and

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commitments in the normal course of business. The Company's business operations are focused on the commercialization and development of Vascepa, which received approval from the FDA in 2012 and for which the Company commenced marketing and sales in 2013.

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

At March 31, 2014, the Company had cash and cash equivalents of \$164.3 million. The Company's consolidated balance sheet also includes derivative liabilities (see Note 5—Warrants and Warrant Derivative Liability) as well as long term debt and exchangeable senior notes (see Note 6—Debt). The warrant derivative liability reflects the fair value of outstanding warrants to purchase shares of the Company's common stock. The long term debt is not puttable except upon a change in control. The Exchangeable Senior Notes may be redeemed on or after January 19, 2017 at the option of the holders. The Notes are exchangeable under certain circumstances into cash, American Depositary Shares, or ADSs, or a combination of cash and ADSs, at the Company's election. Accordingly, the warrant derivative liability, long term debt and Exchangeable Senior Notes do not present a short term claim on the liquid assets of the Company.

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

(2) Significant Accounting Policies

Use of Estimates

The preparation of the Company's consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Accounting estimates are based on historical experience and other factors that are considered reasonable under the circumstances. Actual results could differ from those estimates.

Revenue Recognition

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

The Company commenced its commercial launch in the United States in January 2013. Prior to 2013, the Company recognized no revenue from Vascepa sales. In accordance with GAAP, until the Company had the ability to reliably estimate returns of Vascepa from its Distributors, revenue was recognized based on the resale of Vascepa for the purposes of filling patient prescriptions, and not based on sales from the Company to such Distributors. During the three months ended March 31, 2014, the Company concluded that it had developed sufficient history such that it can reliably estimate returns and as a result, began to recognize revenue based on sales to its Distributors. The change in revenue recognition methodology resulted in the recognition of previously deferred revenue. At December 31, 2013, the Company had deferred approximately \$1.7 million in amounts billed to Distributors that was not recognized as revenue. This change in revenue recognition methodology resulted in the recognition of such deferred revenues during the three months ended March 31, 2014. Revenues for the three months ended March 31, 2014 would have been \$10.0 million if the Company continued to recognize revenues based on the resale of Vascepa for purposes of filling patient prescriptions and not based on sales from the Company to Distributors.

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

Trade Allowances: The Company generally provides invoice discounts on Vascepa sales to its Distributors for prompt payment and pays fees for distribution services, such as fees for certain data that Distributors provide to the Company. The

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payment terms for sales to Distributors generally include a 2% discount for payment within 30 days. Based on the Company's judgment and experience, the Company expects its Distributors to earn these discounts and fees, and deducts the full amount of these discounts and fees from its gross product revenues and accounts receivable at the time such revenues are recognized.

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

Product Returns: The Company's Distributors have the right to return unopened 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 March 31, 2014, the Company had experienced a de minimis quantity of product returns. The Company estimates future product returns on sales of Vascepa based on: (i) data provided to the Company by its Distributors (including weekly reporting of Distributors' sales and inventory held by Distributors that provided the Company with visibility into the distribution channel in order to determine what quantities were sold to retail pharmacies and other providers), (ii) information provided to the Company from retail pharmacies, (iii) data provided to the Company by a third party data provider which collects and publishes prescription data, and other third parties, (iv) historical industry information regarding return rates for similar pharmaceutical products, (v) the estimated remaining shelf life of Vascepa previously shipped and currently being shipped to Distributors and (vi) contractual agreements intended to limit the amount of inventory maintained by the Company's Distributors.

Other Incentives: Other incentives that the Company offers to indirect customers include co-pay mitigation rebates provided by the Company to commercially insured patients who have coverage for Vascepa and who reside in states that permit co-pay mitigation programs. The Company's co-pay mitigation program is intended to reduce each participating patient's portion of the financial responsibility for Vascepa's purchase price to a specified dollar amount. Based upon the terms of the program and information regarding programs provided for similar specialty pharmaceutical products, the Company estimates the average co-pay mitigation amounts and the percentage of patients that it expects to participate in the program in order to establish its accruals for co-pay mitigation rebates and deducts these estimated amounts from its gross product revenues at the time the revenues are recognized. The Company adjusts its accruals for co-pay mitigation rebates based on actual redemption activity and estimates regarding the portion of issued co-pay mitigation rebates that it estimates will be redeemed. In addition, as is customary prior to the launch of new drugs, the Company provided certain of its Distributors with financial incentives to begin stocking Vascepa prior to the Company's commercial launch of Vascepa in order to ensure that Vascepa was readily available to fill patient prescriptions upon launch. Such incentives were only offered on purchases of initial launch quantities of Vascepa stocked by Distributors in January 2013. The amount of these financial incentives was recorded by the Company as a reduction to revenues on a pro-rata basis for each of the bottles subject to such financial incentives. The Company estimates that all of these initial launch quantities stocked by its primary Distributors in January 2013 were resold by such Distributors prior to December 31, 2013.

The following table summarizes activity in each of the product revenue allowance and reserve categories described above for the three months ended March 31, 2014 and 2013 (in thousands):

	Trade Allowances	Rebates, Chargebacks and Discounts	Product Returns	Other Incentives	Total
Balance at January 1, 2014	\$ 1,071	\$ 1,137	\$ 72	\$ 189	\$ 2,469
Provision related to current period sales	1,400	1,930	68	901	4,299
Provision related to prior period sales	—	—	12	—	12
Credits/payments made for current period sales	(411)	(765)	—	(972)	(2,148)
Credits/payments made for prior period sales	(926)	(911)	—	—	(1,837)
Balance at March 31, 2014	<u>\$ 1,134</u>	<u>\$ 1,391</u>	<u>\$ 152</u>	<u>\$ 118</u>	<u>\$ 2,795</u>

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	<u>Trade Allowances</u>	<u>Rebates, Chargebacks and Discounts</u>	<u>Product Returns</u>	<u>Other Incentives</u>	<u>Total</u>
Balance at January 1, 2013	\$ —	\$ —	\$ —	\$ —	\$ —
Provision related to current period and deferred sales	1,073	259	72	830	2,234
Credits/payments made for current period and deferred sales	(566)	(3)	—	(210)	(779)
Balance at March 31, 2013	<u>\$ 507</u>	<u>\$ 256</u>	<u>\$ 72</u>	<u>\$ 620</u>	<u>\$1,455</u>

The following table summarizes product revenue recognized and deferred during the three months ended March 31, 2014 and 2013 (in thousands):

	<u>March 31, 2014</u>	<u>March 31, 2013</u>
Product revenue recognized	\$ 10,967	\$ 2,341
Deferred product revenue	—	2,865
	<u>\$ 10,967</u>	<u>\$ 5,206</u>

In conjunction with the Company's recognition and deferral of product revenues, the Company expensed and capitalized the associated cost of goods, as follows, during the three months ended March 31, 2014 and 2013 (in thousands):

	<u>March 31, 2014</u>	<u>March 31, 2013</u>
Cost of goods sold expensed	\$ 4,246	\$ 1,287
Finished goods inventory held by others	—	1,422
	<u>\$ 4,246</u>	<u>\$ 2,709</u>

Cash and Cash Equivalents

Cash and cash equivalents consist of cash, deposits with banks and short term highly liquid instruments with remaining maturities at the date of purchase of 90 days or less. Restricted cash represents cash and cash equivalents pledged to guarantee repayment of certain expenses which may be incurred for business travel under corporate credit cards held by employees.

Accounts Receivable

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

Inventory

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

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Property, Plant and Equipment

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

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. The Company concluded that use of the straight-line method was appropriate as the majority of cash flows are expected to be generated over the estimated useful life and no degradation of the cash flows over time is currently anticipated.

Deferred Revenue

Deferred revenue represents product shipments to Distributors for which the Company has invoiced the Distributors but not recognized as revenue because the product was not reported to the Company as having been resold for the purpose of filling prescriptions. Commencing on January 1, 2014, the Company recognizes revenue based on product shipments to its Distributors and as a result, no deferred revenue was recorded as of March 31, 2014.

Research and Development Costs

The Company charges research and development costs to operations as incurred. Research and development expenses are comprised of costs incurred by the Company in performing research and development activities, including salary and benefits; stock-based compensation expense; laboratory supplies and other direct expenses; contractual services, including clinical trial and pharmaceutical development costs; commercial supply investment in its drug candidates; and infrastructure costs, including facilities costs and depreciation expense. In addition, research and development costs include the costs of product supply received from suppliers when such receipt by the Company is prior to regulatory approval of the supplier.

Selling, General and Administrative Costs

The Company charges selling, general and administrative costs to operations as incurred. Selling, general and administrative costs include costs of salaries, programs and infrastructure necessary for the general conduct of the Company's business, including the commercial launch of Vascepa in the United States for the MARINE indication. Included as part of selling, general and administrative costs is warrant related expense from non-cash changes in the fair value of a derivative liability associated with warrants issued in October 2009 to former officers of Amarin which is recorded as compensation income (expense).

Income Taxes

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

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

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

Derivative Instruments

Derivative financial liabilities are recorded at fair value, with gains and losses arising for changes in fair value recognized in the statement of operations at each period end while such instruments are outstanding. If the Company issues shares to discharge the liability, the derivative financial liability is derecognized and common stock and additional paid-in capital are recognized on the issuance of those shares. The warrants are valued using a Black-Scholes option pricing model due to the nature of instrument. The long term debt redemption feature is valued using a probability-weighted model incorporating management estimates for potential change in control, and by determining the fair value of the debt with and without the change in control provision included.

If the terms of warrants that initially require the warrant to be classified as a derivative financial liability lapse, the derivative financial liability is reclassified out of financial liabilities into equity at its fair value on that date. At settlement date, if the instruments are settled in shares, the carrying value of the warrants are derecognized and transferred to equity at their fair value at that date. The cash proceeds received from exercises of warrants are recorded in common stock and additional paid-in capital.

Loss per Share

Basic net loss per share is determined by dividing net loss by the weighted average shares of common stock outstanding during the period. Diluted net loss per share is determined by dividing net loss by diluted weighted average shares outstanding. Diluted weighted average shares reflects the dilutive effect, if any, of potentially dilutive common shares, such as common stock options and warrants calculated using the treasury stock method and convertible notes using the "if-converted" method. In periods with reported net operating losses, all common stock options and warrants are deemed anti-dilutive such that basic net loss per share and diluted net loss per share are equal. However, in certain periods in which there is a gain recorded pursuant to the change in fair value of the warrant derivative liability, for diluted earnings per share purposes, the impact of such gains is reversed and the treasury stock method is used to determine diluted earnings per share.

The calculation of net loss and the number of shares used to compute basic and diluted earnings per share for the three months ended March 31, 2014 and 2013 are as follows:

In thousands	March 31, 2014	March 31, 2013
Net loss—basic	\$ (25,980)	\$ (62,158)
Gain on warrant derivative liability	(965)	(5,843)
Net loss—diluted	(26,945)	(68,001)
Net loss per share—basic	(0.15)	(0.41)
Weighted average shares outstanding—basic	172,872	150,430
Effect of dilutive warrants	1,559	6,643
Weighted average shares outstanding—diluted	174,431	157,073
Net income loss per share—diluted	(0.15)	(0.43)

For the three months ended March 31, 2014 and 2013, the following potentially dilutive securities were not included in the computation of net loss per share because the effect would be anti-dilutive:

In thousands	March 31, 2014	March 31, 2013
Stock options	11,577	11,256
Restricted stock and restricted stock units	2,168	913
Warrants	1,685	1,752

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 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.

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

Stock-Based Compensation

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

Concentration of Credit Risk

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

A significant portion of the Company's sales are to wholesalers in the pharmaceutical industry. The Company monitors the creditworthiness of customers to whom it grants credit terms and has not experienced any credit losses. The Company does not require collateral or any other security to support credit sales. The Company's top three customers accounted for 96% and 94% of gross product sales for the quarters ending March 31, 2014 and 2013, respectively and represented 95% and 96% of the gross accounts receivable balance as of March 31, 2014 and March 31, 2013, respectively.

Foreign Currency

All subsidiaries use the United States dollar as the functional currency. Monetary assets and liabilities denominated in a foreign currency are remeasured into United States dollars at period-end exchange rates. Non-monetary assets and liabilities carried in a foreign currency are remeasured into United States dollars using rates of exchange prevailing when such assets or liabilities were obtained or incurred, and expenses are generally remeasured using rates of exchange prevailing when such expenses are incurred. Gains and losses from the remeasurement are included in other income (expense), net in the consolidated statements of operations. For transactions settled during the applicable period, gains and losses are included in other income (expense), net in the consolidated statements of operations. The Company periodically uses foreign exchange forward contracts to hedge against changes in exchange rates for inventory purchases denominated in foreign currency. As of March 31, 2014 and December 31, 2013, there were no outstanding foreign exchange contracts.

Debt Issuance Costs

Debt issuance costs are initially capitalized 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 income (expense), net in the consolidated statements of operations.

Fair Value of Financial Instruments

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

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

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

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

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The following table presents information about the Company's assets and liabilities as of March 31, 2014 and December 31, 2013 that are measured at fair value on a recurring basis and indicates the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value:

<i>In millions</i>	March 31, 2014			
	Total	Level 1	Level 2	Level 3
Asset:				
Cash equivalents—money markets	\$ 93.5	\$ 93.5	\$ —	\$ —
Liabilities:				
Warrant derivative liability	\$ 5.9	\$ —	\$ —	\$ 5.9
Long term debt redemption feature	\$ 7.6	\$ —	\$ —	\$ 7.6

<i>In millions</i>	December 31, 2013			
	Total	Level 1	Level 2	Level 3
Asset:				
Cash equivalents—money markets	\$113.5	\$113.5	\$ —	\$ —
Liabilities:				
Warrant derivative liability	\$ 6.9	\$ —	\$ —	\$ 6.9
Long term debt redemption feature	\$ 11.1	\$ —	\$ —	\$ 11.1

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

Warrant Derivative Liability

At March 31, 2014, the fair value of the warrant derivative liability was determined to be \$5.9 million using the Black-Scholes option valuation model applying the following assumptions: (i) risk-free rate of 0.07%, (ii) remaining term of 0.5 years, (iii) no dividend yield, (iv) volatility of 120% and (v) the stock price on the date of measurement.

As of December 31, 2013, the fair value of the warrant derivative liability was determined to be \$6.9 million using the Black-Scholes option valuation applying the following assumptions: (i) risk-free rate of 0.12%, (ii) remaining term of 0.8 years, (iii) no dividend yield (iv) volatility of 99%, and (v) the stock price on the date of measurement. The \$1.0 million decrease in the fair value of the warrant liability during the three months ended March 31, 2014 was recognized as: (i) a \$0.9 million gain on change in fair value of the remaining derivative liability and (ii) \$0.1 million in compensation income for change in fair value of warrants issued to former employees. Both amounts are included in the consolidated statement of operations for the three months ended March 31, 2014. The fair value of this warrant liability is determined using the Black-Scholes option valuation model and is therefore sensitive to changes in the market price and volatility of our common stock among other factors. In the event of a hypothetical 10% increase in the market price of our common shares (\$1.99 based on the \$1.81 market price of our stock at March 31, 2014) on which the March 31, 2014 valuation was based, the value of the derivative liability would have increased by \$1.1 million. Such increase would have been reflected as additional loss on change in fair value of derivative liabilities within our statement of operations. Significant increases (decreases) in this input in isolation would result in a significantly higher (lower) fair value asset measurement.

Long Term Debt Redemption Feature

The Company's December 2012 financing agreement contains a redemption feature whereby, upon a change of control, the Company would be required to pay \$140 million, less any previously repaid amount, if the change of control occurs on or before December 31, 2013, or required to repay \$150 million, less any previously repaid amount, if the change of control event occurs after December 31, 2013. The Company determined this redemption feature to be an embedded derivative, which is carried at fair value and is classified as Level 3 in the fair value hierarchy due to the use of significant unobservable inputs. The fair value of the embedded derivative was calculated using a probability-weighted model incorporating management estimates for potential change in control, and by determining the fair value of the debt with and without the change in control provision included. The difference between the two was determined to be the fair value of the embedded derivative. At March 31, 2014, the fair value of the derivative was determined to be \$7.6 million, and the debt was valued by comparing debt issues of similar companies with (i) remaining terms of between 3.0 and 4.4 years, (ii) coupon rates of between 9.9% and 12.5% and (iii) market yields of between 10.2% and 30.7%. The Company recognized a \$3.5 million gain on change in fair value of derivative liability for the three months ended March 31, 2014. At March 31, 2013, the

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fair value of the derivative was determined to be \$15.6 million, and the debt was valued by comparing debt issues of similar companies with (i) remaining terms of between 4.0 and 7.4 years, (ii) coupon rates of between 9.9% and 11.9% and (iii) market yields of between 12.3% and 25.6%. The Company recognized a \$1.0 million loss on change in fair value of derivative liability for the three months ended March 31, 2013.

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

	October 2009 Warrants	Debt Redemption Feature	Foreign Exchange Contracts	Totals
Balance at December 31, 2013	\$ 6,894	\$ 11,100	\$ —	\$17,994
Gain on change in fair value of derivative liability	(893)	(3,500)	—	(4,393)
Compensation income for change in fair value of warrants issued to former employees	(72)	—	—	(72)
Transfers to equity	—	—	—	—
Balance at March 31, 2014	\$ 5,929	\$ 7,600	\$ —	\$13,529
	October 2009 Warrants	Debt Redemption Feature	Foreign Exchange Contracts	Totals
Balance at December 31, 2012	\$54,854	\$ 14,576	\$ —	\$69,430
(Gain) loss on change in fair value of derivative liabilities	(5,392)	1,024	748	(3,620)
Compensation income for change in fair value of warrants issued to former employees	(451)	—	—	(451)
Transfers to equity	—	—	—	—
Balance at March 31, 2013	\$49,011	\$ 15,600	\$ 748	\$65,359

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

(3) Intangible Assets

Intangible assets consist of technology rights for Vascepa and have an estimated remaining useful life of 16.3 years. The carrying value as of March 31, 2014 and December 31, 2013 is as follows (in thousands):

	March 31, 2014	December 31, 2013
Technology rights	\$ 11,624	\$ 11,624
Accumulated amortization	(1,076)	(915)
	\$ 10,548	\$ 10,709

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(4) Inventory

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

	<u>March 31, 2014</u>	<u>December 31, 2013</u>
Raw materials, current	\$ 6,614	\$ 4,246
Work in process	11,592	11,310
Finished goods	3,624	5,026
Finished goods inventory held by others	—	627
Total inventory, current	21,830	21,209
Raw materials, long-term	—	5,482
Total inventory	\$ 21,830	\$ 26,691

(5) Warrants and Warrant Derivative Liability

The Company had 9,772,276 warrants to purchase common shares outstanding at March 31, 2014 at a weighted-average exercise price of \$1.41, as summarized in the following table:

<u>Issue Date</u>	<u>Amount</u>	<u>Exercise Price</u>	<u>Expiration Date</u>
7/31/09	1,684,888	1.00	7/30/14
10/16/09	7,487,388	1.50	10/15/14
10/16/09	600,000	1.50	10/15/14
	9,772,276	\$ 1.41	

October 2009 Warrants derivative liability

On October 16, 2009, the Company completed a \$70.0 million private placement with both existing and new investors resulting in \$62.3 million in net proceeds and an additional \$3.6 million from bridge notes converted in conjunction with the private placement. In consideration for the \$62.3 million in net cash proceeds Amarin issued 66.4 million units, each unit consisting of (i) one ADS (representing one ordinary share) at purchase price of \$1.00 and (ii) a warrant with a five year term to purchase 0.5 of an ADS at an exercise price of \$1.50 per ADS. In consideration for the conversion of \$3.6 million of convertible bridge notes, Amarin issued 4.0 million units, each unit consisting of (i) one ADS (representing one ordinary share) at a purchase price of \$0.90 and (ii) a warrant with a five year term to purchase 0.5 of an ADS an exercise price of \$1.50 per ADS. The total number of warrants issued in conjunction with the financing was 35.2 million of which 7.5 million are outstanding at March 31, 2014.

In conjunction with the October 2009 financing, the Company issued an additional 0.9 million warrants to three former officers of which 0.6 million are outstanding as of March 31, 2014. 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.

July 2009 and April 2007 Warrants

The Company issued several warrants in July 2009 and April 2007. As of March 31, 2014 and December 31, 2013 these warrants have been classified as equity instruments and have been included in the Company's consolidated balance sheet within additional paid-in-capital. During the three months ended March 31, 2013, 70,000 of the July 2009 warrants were exercised, resulting in proceeds to the Company of \$0.1 million.

(6) Debt

Long term debt—December 2012 Financing

On December 6, 2012 the Company entered into an agreement with BioPharma Secured Debt Fund II Holdings Cayman LP ("BioPharma"). Under this agreement, the Company granted to BioPharma a security interest in future receivables associated with the Vascepa patent rights, in exchange for \$100 million received at the closing of the agreement which occurred in December 2012. The Company has agreed to repay BioPharma up to \$150 million of future revenue and receivables. The first repayments under the agreement of \$0.8 million and \$1.0 million were paid to BioPharma in November 2013 and February 2014, respectively and an additional \$1.1 million is scheduled to be paid in May 2014. 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 described below, are scheduled to be paid thereafter in accordance with the following schedule: \$8.0 million in the third quarter of 2014 and in each of the next two quarters, \$10.0 million per quarter in each of the next four quarters, \$15.0 million per quarter in each of the next four quarters and a final payment of \$13.0 million scheduled for payment in May 2017. All such payments reduce the remainder of the \$150 million in aggregate payments to BioPharma. The quarterly repayments through the third quarter of September 2014 represent interest only. Quarterly payments do not begin to reduce the principal balance until the fourth quarter of 2014. These quarterly payments are subject to a quarterly threshold amount whereby, if a calculated threshold, based on quarterly Vascepa revenues, is not achieved, the quarterly payment payable in that quarter can at the Company's election be reduced and with the reduction carried forward without interest for payment in a future period. The payment of any carried forward amount is subject to similarly calculated threshold repayment amounts based on Vascepa revenue levels. Except upon a change of control in Amarin, the agreement does not expire until \$150 million has been repaid. Under the agreement, upon a change of control, the Company would be required to pay \$140 million, less any previously repaid amount, if a change of control occurred on or before December 31, 2013, or required to repay \$150 million, less any previously repaid amount, if a change of control event occurs after December 31, 2013. The Company can prepay after October 1, 2013, an amount equal to \$150 million less any previously repaid amount.

The Company determined the redemption feature upon a change of control to be an embedded derivative requiring bifurcation. The fair value of the embedded derivative was calculated by determining the fair value of the debt with the change in control provision included and also without the change in control provision. The difference between the two fair values of the debt was determined to be the fair value of the embedded derivative, and upon closing the Company recorded a derivative liability of \$14.6 million as a reduction to the note payable. The fair value of this derivative liability is remeasured at each reporting period, with changes in fair value recognized in the statement of operations. The Company recognized a gain on change in fair value of derivative liability of \$3.5 million and a loss on change in fair value of derivative liability of \$1.0 million during the three months ended March 31, 2014 and 2013, respectively.

During the three months ended March 31, 2014, the Company recorded \$1.9 million and \$0.5 million of cash and non-cash interest expense, respectively, on the BioPharma debt. During the three months ended March 31, 2013, the Company recorded \$3.4 million and \$0.7 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.

The Company currently estimates that its Vascepa revenue levels will not be high enough in each quarter to support repayment to BioPharma in accordance with the threshold amounts in the repayment schedule. For the quarters ended September 30, 2013, December 31, 2013, and March 31, 2014, revenues were below the contractual threshold amount such that cash payments were calculated for each period reflecting the optional reduction amount as opposed to the contractual threshold payment due for each quarterly period. The payment of \$1.1 million for the first quarter of 2014 is due in May 2014. In accordance with the agreement with BioPharma, quarterly differences between the calculated optional reduction amounts and the repayment schedule amounts are rescheduled for payment beginning in the second quarter of 2017. Any such deferred repayments will remain subject to continued application of the quarterly ceiling in amounts due established by the calculated threshold limitation based on quarterly Vascepa revenues. No additional interest expense or liability is incurred as a result of such deferred repayments. These estimates will be reevaluated each reporting period by the Company and adjusted if necessary.

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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 we have already made).

Exchangeable Senior Notes

In January 2012, the Company issued \$150.0 million in principal amount of 3.5% exchangeable senior notes due 2032 (the "Notes"). The Notes were issued by Corsicanto Limited, an Irish limited company acquired by Amarin in January 2012. Corsicanto Limited is a wholly-owned subsidiary of Amarin. The general, unsecured, senior obligations are fully and unconditionally guaranteed by Amarin but not by any of the Company's subsidiaries. Corsicanto Limited has no assets, operations, revenues or cash flows other than those related to the issuance, administration and repayment of the 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 Notes have a stated interest rate of 3.5% per year, payable semiannually in arrears on January 15 and July 15 of each year beginning on July 15, 2012, and ending upon the Notes' maturity on January 15, 2032. The Notes are subject to repurchase by the Company at the option of the holders on each of January 19, 2017, January 19, 2022, and January 19, 2027, at a price equal to 100% of the principal amount of the Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the repurchase date. The Notes are exchangeable under certain circumstances into cash, ADSs, or a combination of cash and ADSs, at the Company's election, with an initial exchange rate of 113.4752 ADSs per \$1,000 principal amount of Notes. It is the Company's current intention to settle these obligations in cash. If the Company elected physical settlement, the Notes would initially be exchangeable into 17,021,280 ADSs. Based on the closing price of the Company's stock at March 31, 2014, the principal amount of the Notes would exceed the value of the shares if converted on that date by \$119.2 million.

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

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

The Notes are exchangeable under certain circumstances. The Company calculated the fair value of the liability component of the Notes to be \$126.2 million, and the excess of the principal amount of the debt over the liability component of \$23.8 million was allocated to the conversion option resulting in a discount on the debt. The discount created from allocating proceeds to the conversion option is being amortized to interest expense using the effective interest method over the Notes' estimated remaining life, which was calculated to be a period of twenty-four months. The effective interest rate of the Notes is 14.5%. As of March 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 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 is being amortized as interest expense over the estimated remaining life of the Notes of

twenty-four months. As of March 31, 2014, the debt discount was fully amortized and the carrying value of the Notes was \$150.0 million. During the three months ended March 31, 2014, the Company recognized interest expense of \$2.0 million related to the Notes, of which \$0.6 million represents amortization of the debt discount created upon allocation of proceeds to the conversion option, \$1.3 million represents contractual coupon interest, and \$0.1 million represents the amortization of the discount from the underwriter's discounts and offering costs. As of March 31, 2013, the unamortized debt discount was \$2.1 million and the carrying value of the Notes, net of the unamortized discount, was \$137.7 million. During the three months ending March 31, 2013, the Company recognized interest expense of \$4.8 million related to the Notes, of which \$2.9 million represents amortization of the debt discount created upon allocation of proceeds to the conversion option, \$1.3 million represents contractual coupon interest, and \$0.6 million represents the amortization of the discount from the underwriter's discounts and offering costs. At March 31, 2014 and December 31, 2013, and the Company had accrued interest 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 in 2014 and 2013 of \$2.6 million and \$5.3 million, respectively.

(7) Commitments and Contingencies

Litigation

On November 1, 2013, a purported investor of Amarin filed a putative class action lawsuit captioned *Steven Sklar v. Amarin Corporation plc et al.*, No. 13-cv-6954 (D.N.J. Nov. 1, 2013) in the U.S. District Court for the District of New Jersey. Substantially similar lawsuits, captioned *Bove v. Amarin Corporation plc*, Civ. No. 13-07882 (AT) (S.D.N.Y. Nov. 5, 2013), *Bentley v. Amarin Corporation plc*, Civ. No. 13-08283 (AT) (S.D.N.Y. Nov. 20, 2013) and *Siegel v. Amarin Corporation plc*, No. 3:13-cv-07210 (D.N.J. Nov. 27, 2013), were subsequently filed in the U.S. District Court for the District of New Jersey and U.S. District Court for the Southern District of New York. On December 9, 2013 the cases filed in the Southern District of New York were transferred to the District of New Jersey, where the four cases are now proceeding in front of the same judge pending a formal order consolidating the actions.

Each of the complaints asserts claims under the Securities Exchange Act of 1934. The complaints allege that Amarin and certain of its current and former officers and directors made misstatements and omissions regarding the FDA's willingness to approve Vascepa's ANCHOR indication and the potential relevance of data from the ongoing REDUCE-IT trial to that approval. The putative class periods alleged in the complaints vary from the July 9, 2009-October 15, 2013 period alleged in the *Sklar* and *Siegel* complaints, the July 9, 2009-October 16, 2013 period alleged in the *Bentley* complaint, and August 8, 2012-October 16, 2013 period alleged in the *Bove* complaint. The lawsuits seek unspecified monetary damages and attorneys' fees and costs.

On January 3, 2014, ten plaintiffs and their respective counsel moved for appointment as lead plaintiff and lead counsel for the putative class. The plaintiffs also moved for consolidation of the pending actions. The motion for appointment of lead plaintiff was set for February 3, 2014, but has not yet been decided. After the Court appoints a lead plaintiff, and consolidates the actions, the Company expects that the lead plaintiff will file a consolidated amended complaint that will become the operative complaint for the action.

The Company believes that it has valid defenses and will vigorously defend against the claims. The Company is unable to reasonably estimate the loss exposure, if any, associated with these claims.

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

On March 4, 2014, the Company filed a lawsuit for patent infringement in the United States District Court for the District of Delaware of United States Patent No. 8,663,662 against AstraZeneca Pharmaceuticals LP and its subsidiary, Omthera Pharmaceuticals, Inc., over the commercial marketing of Epanova® (omega-3-carboxylic acids) capsules. Epanova was approved by the FDA in May 2014 with substantially the same indication as Vascepa and is expected to compete with Vascepa. The Company is seeking damages and injunctive relief in the litigation. Amarin intends to litigate the case vigorously.

In addition to the above, in the ordinary course of business, the Company is from time to time involved in lawsuits, claims, investigations, proceedings, and threats of litigation relating to intellectual property, commercial arrangements and other matters. While the outcome of these proceedings and claims cannot be predicted with certainty, as of March 31, 2014, the Company was not party to any legal or arbitration proceedings that may have, or have had in the recent past, significant effects on the Company's

financial position or profitability. No governmental proceedings are pending or, to our knowledge, contemplated against the Company. The Company is not a party to any material proceedings in which any director, member of senior management or affiliate of ours is either a party adverse to the Company or its subsidiaries or has a material interest adverse to the Company or its subsidiaries.

Royalty and Milestone Obligations

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

- In 2011, the Company entered into agreements with two additional suppliers, Chemport, Inc. (“Chemport”) and BASF (formerly Equateq Limited) for the supply of API materials for Vascepa. In 2012, the Company agreed to terms with a fourth API supplier, a consortium of companies led by Slanmhor Pharmaceutical, Inc. These agreements include requirements for the suppliers to qualify their materials and facilities with applicable regulatory authorities including the FDA. The Company will incur certain costs associated with the qualification of product produced by these suppliers as described below. In each case, following qualification of the supplier for the manufacture of API for commercial sale, these agreements include annual purchase levels to enable Amarin to maintain certain exclusivity with each respective supplier. Chemport and BASF were approved by the FDA to manufacture API for commercial sale in April 2013. On December 30, 2013, the Company issued a notice of termination of its API agreement to BASF as a result of BASF’s non-compliance with the terms of such agreement. BASF did not remedy within a contractual 60-day cure period and as a result, this agreement terminated on February 28, 2014, though the Company may enter into a new development and supply agreement with BASF and may purchase supply from BASF.

The Company has begun to purchase commercial supply from Chemport. The agreement with Chemport contains a provision requiring the Company to pay Chemport in cash for any shortfall in the minimum purchase obligations. The minimum purchase commitment was achieved in 2013. The agreement with the Slanmhor consortium contains a provision requiring the Company to pay the consortium in cash for any shortfall in the minimum purchase obligations, which will become effective upon the approval for manufacture by the FDA of supply from the consortium. The 2011 supply agreements include commitments for the Company to fund (i) certain development fees (ii) material purchases for initial raw materials, which amount will be credited against future API purchases and (iii) a raw material purchase commitment. The Company made payments of \$3.1 million related to these commitments through March 31, 2014. Under these agreements, during the quarter ended March 31, 2014, the Company made payments of \$1.3 million to Chemport and made no payments to BASF. The agreement with the Slanmhor consortium provides for certain development fees and other commitments, which will be credited against future API material purchases. The Company made payments of \$6.2 million related to these commitments through March 31, 2014. Certain of these commitments are contingent upon the mutually agreed upon expansion of the Slanmhor consortium’s API manufacturing capacity. To date, the parties have not agreed upon such additional expansion. Additionally, certain obligations are subject to sNDA approval. Under this agreement, during the quarter ended March 31, 2014, the Company made payments of \$0.4 million to the Slanmhor consortium related to stability and technical batches and advances on future API purchases.

- Concurrent with its entry into one of the two agreements entered into in 2011 for the supply of API materials for Vascepa, the Company agreed to make a non-controlling minority share equity investment in the supplier of up to \$3.3 million. The Company invested \$1.7 million under this agreement in July 2011 and the remaining \$1.6 million during 2012. In September 2013, the Company entered into an equity sale and purchase agreement between this supplier and a third party in which the Company agreed to sell approximately \$1.3 million of its investment in the supplier to the third party at cost. This transaction closed in the first quarter of 2014. The carrying amount of the investment of \$2.0 million and \$3.3 million as of March 31, 2014 and December 31, 2013, respectively, is included in other long term assets and is accounted for under the cost method.
- Under the 2004 share repurchase agreement with Laxdale Limited, or Laxdale, upon receipt of marketing approval in Europe for the first indication for Vascepa (or first indication of any product containing Amarin Neuroscience intellectual property acquired from Laxdale in 2004), the Company must make an aggregate stock or cash payment to the former shareholders of Laxdale (at the sole option of each of the sellers) of £7.5 million (approximately \$12.5 million at March 31, 2014).

Also under the Laxdale agreement, upon receipt of a marketing approval in the U.S. or Europe for a further indication of Vascepa (or further indication of any other product using Amarin Neuroscience intellectual property), the Company must make an aggregate stock or cash payment (at the sole option of each of the sellers) of £5 million (approximately \$8.3 million at March 31, 2014) for each of the two potential market approvals (i.e. £10 million maximum, or approximately \$16.6 million at March 31, 2014).

The Company has no provision for any of the obligations above since the amounts are either not probable or estimable at March 31, 2014.

(8) Equity*Common stock*

During the three months ended March 31, 2014 and 2013, the Company issued 215,000 and 260,000 shares, respectively, as a result of the exercise of stock options, resulting in gross and net proceeds of \$0.3 million and \$0.4 million, respectively for each period. In addition, during the three months ended March 31, 2013, the Company issued 70,000 shares as a result of the exercise of warrants, resulting in gross and net proceeds of \$0.1 million.

On January 8, 2014, the Company granted a total of 2,082,000 RSUs and 2,605,500 stock options to employees under the Amarin Corporation plc 2011 Stock Incentive Plan (the 2011 Plan). The RSU's vest annually over a three year period and the stock options vest monthly over a four year period.

In January 2013, the Company granted 454,875 RSUs to several employees under the 2011 Plan. These RSUs vest upon the achievement of certain operational milestones. In the year ended December 31, 2013, as a result of the operational milestones not being achieved, all of these RSU's were forfeited and no shares were issued as a result of vesting. The Company recorded no expense during the quarters ended March 31, 2014 and 2013 related to the vesting of these RSUs.

(9) Restructuring

As part of a program to reduce costs and increase operational efficiencies, in October 2013, the Company announced a plan to streamline operations to better align its cost structure with current market conditions by reducing its global workforce by approximately 50%. In connection with this program, the Company recorded \$2.8 million in charges for severance and related benefits during the quarter ended December 31, 2013. The Company does not expect to incur any additional charges related to this program subsequent to 2013 and expects to make all remaining payments in the second quarter of 2014.

The restructuring charges, which are included in accrued expenses and other current liabilities in the accompanying consolidated balance sheet as of March 31, 2014 and December 31, 2013, are summarized as follows:

	Employee Severance and Benefits
Balance as of December 31, 2013	\$ 135
Restructuring charges	—
Cash payments	(120)
Balance as of March 31, 2014	<u>\$ 15</u>

(10) Co-Promotion Agreement

On March 31, 2014, the Company entered into a Co-Promotion Agreement (the Agreement) with Kowa Pharmaceuticals America 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 the right to be the sole co-promoter, together with the Company, of Vascepa in the United States during the term. The initial term of the Agreement extends through 2018.

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

Amarin will continue to recognize all revenue from sales of Vascepa under the Agreement. In exchange for Kowa Pharmaceuticals America's co-promotional services, Kowa Pharmaceuticals America is entitled to a quarterly co-promotion fee based on a percentage of Vascepa gross margins that increases during the Agreement's term, from the high single digits in 2014 to the low twenty percent levels in 2018. The co-promotion fee also varies based on sales levels and whether the FDA has approved an ANCHOR indication labeling expansion for Vascepa or has permitted the use of data generated to support obtaining FDA approval of the ANCHOR indication in the promotion of Vascepa, in which case the co-promotion fee would be decreased if specified requirements are met.

(11) Subsequent Events

The Company has evaluated subsequent events from March 31, 2014 through the date of the issuance of these condensed consolidated financial statements.

In March and April 2014, the Company received paragraph IV certification notices from five companies contending to varying degrees that certain of its patents are invalid, unenforceable and/or will not be infringed by the manufacture, use, sale or offer for sale of a generic form of Vascepa as described in those companies' abbreviated new drug applications, or ANDAs. The Company has filed or is in the process of filing patent infringement lawsuits against each of these ANDA applicants. In each of the lawsuits, Amarin is seeking, among other remedies, an order enjoining the defendants from marketing generic versions of Vascepa before the last to expire of the asserted patents in 2030. In April 2014, Amarin filed lawsuits against Apotex, Inc. and Apotex Corporation (collectively, "Apotex") in the U.S. District Court for the District of New Jersey and the U.S. District Court for the Northern District of Illinois. The cases against Apotex are captioned *Amarin Pharma, Inc. et al. v. Apotex, Inc. et al.*, Civ. A. No. 14-2550 (D.N.J) and *Amarin Pharma, Inc. et al. v. Apotex, Inc. et al.*, Civ. A. No. 14-2958 (N.D. Ill.). In April 2014, Amarin also filed lawsuits against Roxane Laboratories, Inc. ("Roxane") in the U.S. District Court for the District of New Jersey and the U.S. District Court for the Northern District of Ohio. The cases against Roxane are captioned *Amarin Pharma, Inc. et al. v. Roxane Laboratories, Inc.*, Civ. A. No. 14-2551 (D.N.J) and *Amarin Pharma, Inc. et al. v. Roxane Laboratories, Inc.*, Civ. A. No. 14-901 (N.D. Ohio). In April 2014, Amarin also filed a lawsuit against Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. (collectively, "Dr. Reddy's") in the U.S. District Court for the District of New Jersey. The case against Dr. Reddy's is captioned *Amarin Pharma, Inc. et al. v. Dr. Reddy's Laboratories, Inc. et al.*, Civ. A. No. 14-2760 (D.N.J.). In the near future, Amarin plans to file lawsuits against the other two ANDA applicants referenced above, Watson Laboratories, Inc. and Teva Pharmaceuticals USA, Inc. asserting patent infringement in a manner similar to that in the pending suits. As a result of the 30-month stay associated with the filing of these lawsuits under the Hatch-Waxman Act, the FDA cannot grant final approval to any ANDA before September 2016, unless there is an earlier court decision holding that the subject patents are not infringed and/or are invalid. The Company intends to vigorously enforce its intellectual property rights relating to Vascepa, but cannot predict the outcome of these lawsuits.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. These forward-looking statements reflect our plans, estimates and beliefs. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "would" and similar expressions intended to identify forward-looking statements. Forward-looking statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Because of these risks and uncertainties, the forward-looking events and circumstances discussed in this report may not transpire. We discuss many of these risks in Part I, Item 1A under the heading "Risk Factors" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2013 and below under Part II, Item 1A, "Risk Factors".

Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, forward-looking statements represent our estimates and assumptions only as of the date of this document. You should read this document with the understanding that our actual future results may be materially different from what we expect. Except as required by law, we do not undertake any obligation to publicly update or revise any forward-looking statements contained in this report, whether as a result of new information, future events or otherwise.

Overview

We are a biopharmaceutical company with expertise in lipid science focused on the commercialization and development of therapeutics to improve cardiovascular health.

Our lead product, Vascepa® (icosapent ethyl) capsules, is approved by the U.S. Food and Drug Administration, or FDA, for use as an adjunct to diet to reduce triglyceride levels in adult patients with severe (TG \geq 500mg/dL) hypertriglyceridemia. Vascepa is available in the United States by prescription only. We began selling and marketing Vascepa in the United States in January 2013. We sell Vascepa principally to a limited number of major wholesalers, as well as selected regional wholesalers and specialty pharmacy providers, or collectively, its Distributors, that in turn resell Vascepa to retail pharmacies for subsequent resale to patients and health care providers. We market Vascepa through our sales force of approximately 150 sales professionals, including sales representatives and their managers. We also recently entered into a co-promotion agreement with Kowa Pharmaceuticals America, Inc. (Kowa Pharmaceuticals America) under which approximately 250 Kowa Pharmaceuticals America sales representatives are expected to devote a substantial portion of their time to promoting Vascepa starting in May 2014. We operate in one business segment.

Triglycerides are fats in the blood. Hypertriglyceridemia refers to a condition in which patients have high levels of triglycerides in the bloodstream. It is estimated that over 40 million adults in the United States have elevated triglyceride levels (TG \geq 200mg/dL) and approximately 4.0 million people in the United States have severely high triglyceride levels (TG \geq 500mg/dL), commonly known as very high triglyceride levels. According to *The American Heart Association Scientific Statement on Triglycerides and Cardiovascular Disease* (2011), triglycerides also provide important information as a marker associated with the risk for heart disease and stroke, especially when an individual also has low high-density lipoprotein cholesterol, or HDL-C (often referred to as "good" cholesterol), and elevated levels of LDL-C (often referred to as "bad" cholesterol). Guidelines for the management of very high triglyceride levels suggest that reducing triglyceride levels is the primary goal in patients to reduce the risk of acute pancreatitis. The effect of Vascepa on cardiovascular mortality and morbidity, or the risk for pancreatitis, in patients with hypertriglyceridemia has not been determined.

The potential efficacy and safety of Vascepa (known in its development stage as AMR 101) was studied in two Phase 3 clinical trials, the MARINE trial and the ANCHOR trial. At a daily dose of 4 grams of Vascepa, the dose at which Vascepa is FDA approved, these trials showed favorable clinical results in their respective patient populations in reducing triglyceride levels without increasing LDL-C levels in the MARINE trial and with a statistically significant decrease in LDL-C levels in the ANCHOR trial, in each case, relative to placebo. These trials also showed favorable results, particularly with the 4-gram dose of Vascepa, in other important lipid and inflammation biomarkers, including apolipoprotein B (apo B), non-high-density lipoprotein cholesterol (non-HDL-C), total-cholesterol (TC), very low-density lipoprotein cholesterol (VLDL-C), lipoprotein-associated phospholipase A2 (Lp-PLA2), and high sensitivity C-reactive protein (hs-CRP). In these trials, the most commonly reported adverse reaction (incidence $>$ 2% and greater than placebo) in Vascepa-treated patients was arthralgia (joint pain) (2.3% for Vascepa vs. 1.0% for placebo).

We are also developing Vascepa for the treatment of patients with high (TG \geq 200 mg/dL and $<$ 500 mg/dL) triglyceride levels who are also on statin therapy for elevated low-density lipoprotein cholesterol, or LDL-C, levels which we refer to as mixed dyslipidemia. We refer to this second proposed indication for Vascepa as the ANCHOR indication. The FDA has stated that it views the proposed ANCHOR indication as ostensibly and impliedly an indication to reduce cardiovascular risk. In addition, in December 2011, we announced commencement of patient dosing in our cardiovascular outcomes study of Vascepa, titled REDUCE-IT (Reduction of Cardiovascular Events with EPA—Intervention Trial). The REDUCE-IT study is designed to evaluate the efficacy of Vascepa in reducing major cardiovascular events in a high risk patient population on statin therapy.

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

The ANCHOR clinical study was conducted under a special protocol assessment, or SPA, agreement with the FDA. The law governing SPA agreements requires that if the results of the trial conducted under the SPA substantiate the hypothesis of the protocol covered by the SPA, the FDA must use the data from the protocol as part of the primary basis for approval of the product. A SPA agreement is not a guarantee of FDA approval of the related new drug application. A SPA agreement is generally binding upon the FDA except in limited circumstances, such as if the FDA identifies a substantial scientific issue essential to determining safety or efficacy of the drug after the study begins that rises to the level of a public health concern, or if the study sponsor fails to follow the protocol that was agreed upon with the FDA. On October 29, 2013, the FDA rescinded the ANCHOR study SPA agreement because the FDA determined that a substantial scientific issue essential to determining the effectiveness of Vascepa in the studied population was identified after testing began. As a basis for this determination, the FDA communicated that it determined that the cumulative results from outcome studies of other triglyceride-lowering drugs failed to support the hypothesis that a triglyceride-lowering drug significantly reduces the risk for cardiovascular events among the population studied in the ANCHOR trial. Thus, the FDA stated that while information we submitted supports testing the hypothesis that Vascepa 4 grams/day versus placebo reduces major adverse cardiovascular events in statin-treated subjects with residually high triglyceride levels, as is being studied in the Vascepa REDUCE-IT cardiovascular outcomes study, the FDA no longer considers a change in serum triglyceride levels alone as sufficient to establish the effectiveness of a drug intended to reduce cardiovascular risk in subjects with serum triglyceride levels below 500 mg/dL. In November 2013, we submitted to the FDA a request for reconsideration of its decision to rescind the ANCHOR SPA agreement. On January 17, 2014, we were notified by the FDA that it does not intend to reinstate the ANCHOR SPA agreement. We appealed to the next level within the FDA and were informed in late April 2014 that that level determined to uphold the rescission determination. Our plan is to appeal the rescission decision to the next level within the FDA in accordance with FDA dispute resolution guidance.

The FDA did not take action on the ANCHOR sNDA by the Prescription Drug User Fee Act, or PDUFA, goal date for completion of FDA's review, December 20, 2013. Instead, the FDA notified us on December 19, 2013 that it would first consider our appeal of the ANCHOR SPA agreement rescission. No new PDUFA goal date for the ANCHOR sNDA was established. Based on information available to us, we do not expect a determination on the ANCHOR sNDA while our appeal is in process to the next level within FDA. We are also continuing our efforts toward a positive determination on the pending ANCHOR sNDA. There also can be no assurance that the FDA will not communicate the results of its review of the ANCHOR sNDA prior to the timing expected.

In April 2014, we commenced patent litigation against multiple abbreviated new drug applications, or ANDAs, seeking approval for generic versions of Vascepa. Our filing of such patent litigation triggered a 30-month stay of approval of such applications from notice to Amarin of the ANDAs in March 2014.

Based on our communications with the FDA, we currently expect that final positive results from the REDUCE-IT outcomes study will be required for label expansion for Vascepa. There can be no assurance that we will be successful in our effort to reinstate the ANCHOR SPA agreement or obtain a label expansion reflecting the ANCHOR clinical trial. Such label expansion could include FDA approval of the addition of an ANCHOR indication statement and/or the addition of the ANCHOR clinical trial data to our currently approved labeling.

On October 22, 2013, in an effort to reduce operating expenses following the recommendation of the advisory committee to the FDA against approval of the ANCHOR indication, we implemented a worldwide reduction in force of approximately 50% of our staff positions. The majority of affected staff members were sales professionals who supported the initial commercial launch of Vascepa. We incurred approximately \$2.8 million in charges related to the reduction in force, all of which includes cash expenditures for one-time termination benefits and associated costs. The charges were recorded in the fourth quarter of 2013 and the related payments will be made by the first half of 2014. As part of the reduction in force, we retained approximately 130 sales representatives, excluding sales management, in the United States in sales territories that we believe have demonstrated the greatest potential for Vascepa sales growth. We plan to have this team cover the target base of physicians responsible for the majority of Vascepa prescription volume and growth since its launch in early 2013. With these changes and the resulting target base coverage and the upcoming addition of the promotional efforts of 250 sales representatives from Kowa Pharmaceuticals America, we anticipate continued Vascepa revenue growth over time. We also anticipate that such sales growth may be inconsistent from period to period.

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We have over 6,800 patients enrolled in the REDUCE-IT study. We currently estimate that we will complete patient enrollment in this study in the first half of 2015. However, if we do not receive an expansion of Vascepa labeling for the ANCHOR indication, we plan to re-evaluate continuation of the REDUCE-IT study in its present form and re-evaluate whether it is advisable to continue the study. If continued, the REDUCE-IT study will be completed after reaching an aggregate number of cardiovascular events. Based on event rates in other outcomes studies, we estimate completing the REDUCE-IT study in or about 2017 with results expected to be available in 2018. Based on the results of REDUCE-IT, we may seek additional indications for Vascepa beyond the indications studied in the ANCHOR or MARINE trials.

In August 2013, we completed dosing of AMR102, a fixed dose combination of Vascepa and a leading statin product. The study is a randomized, open-label, single-dose, 4-way cross-over study to continue testing of the relative bioavailability of AMR102 capsules, Vascepa capsules with the selected statin taken concomitantly, Vascepa taken alone and the selected statin taken alone. The results of this study support the feasibility of AMR102. We have suspended additional development of AMR102 pending resolution of the ANCHOR sNDA with the FDA. If we do not receive FDA approval for the ANCHOR indication, we may discontinue development of AMR102.

Commercialization Strategy

Vascepa became commercially available in the United States by prescription in January 2013 when we commenced sales and shipments to our network of U.S.-based wholesalers. On January 28, 2013, we commenced our full commercial launch of Vascepa in the United States. In preparation for our commercial launch, we hired and trained a direct sales force of approximately 275 sales representatives. In October 2013, we reduced our number of sales representatives to approximately 130, excluding sales management, in the United States to focus on the sales territories that we believe have demonstrated the greatest potential for Vascepa sales growth. We now market Vascepa in the United States through our sales force of approximately 150 sales professionals and their managers. Commencing in the middle of the second quarter of 2014, in addition to promotion by our sales representatives, approximately 250 Kowa Pharmaceuticals America sales representatives will be promoting Vascepa. We also employ various marketing and medical affairs personnel to support our commercialization of Vascepa. Our clinical and commercial supply is provided to us under agreements with various third-party suppliers. As of May 1, 2014, over 18,000 clinicians had written prescriptions for Vascepa.

Under the co-promotion agreement with Kowa Pharmaceuticals America, 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, and the use of a negotiated number of minimum sales representatives from each party, including no less than 250 Kowa Pharmaceuticals America sales representatives. Kowa Pharmaceuticals America has also agreed to continue to bear the costs incurred for its sales force associated with the commercialization of Vascepa and to pay for certain incremental costs associated with the use of its sales force, such as sample costs and costs for promotional and marketing materials. We will continue to recognize all revenue from sales of Vascepa. In exchange for Kowa Pharmaceuticals America's co-promotional services, Kowa Pharmaceuticals America is entitled to a quarterly co-promotion fee based on a percentage of Vascepa gross margins that increases during the term, from the high single digits in 2014 to the low twenty percent levels in 2018, subject to certain adjustments.

Based on monthly compilations of data provided by a third party, Symphony Health Solutions, the estimated number of normalized total Vascepa prescriptions for the quarter ended March 31, 2014 was approximately 93,000. According to data from another third party, IMS Health, the estimated number of normalized total Vascepa prescriptions for the quarter ended March 31, 2014 was approximately 78,000. Normalized total prescriptions represent the estimated total number of Vascepa prescriptions shipped to patients, calculated on a normalized basis (i.e., total capsules shipped divided by 120 capsules, or one month's supply). The data reported above is based on information made available to us from a third party resource and may be subject to adjustment and may overstate or understate actual prescriptions.

Although we believe these data are prepared on a period-to-period basis in a manner that is generally consistent and that such results are generally indicative of current prescription trends, these data are based on estimates and should not be relied upon as definitive. In addition, because we had limited selling history during the year ended December 31, 2013, we only recognized revenue on product that was resold for purposes of filling prescriptions. Those prescription data may differ from data reported by other third parties.

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

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We secured managed care coverage for over 200 million lives, including as of May 1, 2014 over 100 million lives covered on Tier 2. This level of Tier 2 coverage exceeds 66% of the maximum level of Tier 2 coverage which has been achieved over multiple years by comparable therapies.

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

Commercial Supply Update

During the quarter ended March 31, 2014, we acquired approximately \$1.3 million of Vascepa active pharmaceutical ingredient, or API, which was capitalized to inventory as of March 31, 2014.

In April 2013, the FDA approved our sNDAs covering Chemport, Inc. and BASF (formerly Equateq Limited) as additional Vascepa API suppliers. On December 30, 2013, we issued a notice of termination of our API agreement to BASF as a result of BASF’s non-compliance with the terms of such agreement. BASF did not remedy within a contractual 60-day cure period and as a result, this agreement terminated on February 28, 2014, though we may enter into a new development and supply agreement with BASF and may purchase supply from BASF. We are working with a consortium of companies led by Slanmhor Pharmaceuticals, Inc. to pursue FDA approval for the consortium to manufacture Vascepa API and submitted an sNDA in August 2013. Until an API supplier is approved, all Vascepa API purchased from such supplier is included as a component of research and development expense.

The amount of supply purchases in 2014 and beyond will depend on the level of growth of Vascepa revenues, which will be significantly impacted by the outcome of the FDA’s decision on approval of the ANCHOR indication, and, with certain suppliers, will depend on the timing of their qualification to consistently produce Vascepa to our specification and to minimum purchase commitments. We anticipate that our gross margin from Vascepa sales will be lower in 2014 than in subsequent years due to multiple factors, including API supply pricing with our earliest approved supplier, Nisshin. This is the case particularly as it relates to our earliest volume of purchases from Nisshin being higher than supply pricing later agreed with other suppliers, tiered supply pricing at certain suppliers such that cost per kilogram of supply purchases are scheduled to decline as volume of purchases increase, geographic location of our suppliers, and rebate cards offered to consumers filling prescriptions for Vascepa to reduce the size of the consumer’s co-payment requirements while we work with payors to migrate Vascepa coverage from “tier-3” to “tier-2” in these payors’ drug pricing systems. We anticipate rebate amounts that we will agree to provide payors for tier-2 insurance coverage on sales of Vascepa will ultimately cost us less than our current rebate card program.

Financial Position

We believe that our cash and cash equivalents balance of \$164.3 million at March 31, 2014 is sufficient to fund our projected operations for at least the next twelve months, including the continued commercialization of Vascepa for the MARINE indication, preparations for commercialization of Vascepa for the ANCHOR indication, if approved, and significant advancement of the REDUCE-IT cardiovascular outcomes study.

Financial Operations Overview

Revenue. All of our revenue is derived from product sales of Vascepa, net of allowances, discounts, incentives, rebates, chargebacks and returns. We sell product to a limited number of major wholesalers, as well as selected regional wholesalers and specialty pharmacy providers, or collectively, our Distributors, who resell the product to retail pharmacies for purposes of their reselling the product to fill patient prescriptions. The Company commenced its commercial launch in the United States in January 2013. In accordance with GAAP, until we had the ability to reliably estimate returns of Vascepa from our Distributors, revenue was recognized based on the resale of Vascepa for the purposes of filling patient prescriptions, and not based on our sales to such Distributors. 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 revenue based on sales to our Distributors. Consequently, we recognized revenues of \$11.0 million based on sales to Distributors during the three months ended March 31, 2014, compared to revenues of \$10.0 million that we would have recognized based on the resale of Vascepa for the purposes of filling patient prescriptions during this period. Through March 31, 2014, product returns were de minimis.

Cost of Goods Sold. Cost of goods sold includes the cost of API for Vascepa on which revenue was recognized during the period, as well as the associated costs for encapsulation, packaging, shipment, supply management, insurance and quality assurance.

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The cost of the API included in cost of goods sold reflects the average cost method of inventory valuation and relief. This average cost reflects the actual purchase price of Vascepa API, the majority of which through March 31, 2014 was from Nisshin, our first approved API supplier.

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

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

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

Critical Accounting Policies and Significant Judgments and Estimates

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

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

We began recognizing revenue from the sale of Vascepa following our commercial launch in the United States in January 2013. Prior to 2013, we recognized no revenue from Vascepa sales. We sell Vascepa to Distributors. In accordance with GAAP, until we had the ability to reliably estimate returns of Vascepa from our Distributors, revenue was recognized based on the resale of Vascepa for the purposes of filling patient prescriptions, and not based on our sales to such Distributors. 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 revenue based on sales to our Distributors. Consequently, we recognized revenues of \$11.0 million based on sales to Distributors during the three months ended March 31, 2014, compared to revenues of \$10.0 million that we would have recognized based on the resale of Vascepa for the purposes of filling patient prescriptions during the period. Through March 31, 2014, product returns were de minimis.

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

Derivative Financial Liabilities—Derivative financial liabilities are initially recorded at fair value. They are subsequently held at fair value, with gains and losses arising for changes in fair value recognized in the statement of operations. The fair value of derivative financial liabilities is determined using valuation techniques; typically we use the Black-Scholes option pricing model. We use our judgment to select a variety of methods and make assumptions that are mainly based on market conditions existing at each balance sheet date. Fluctuations in the assumptions used in the valuation model would result in adjustments to the fair value of the warrant derivative liability reflected on our balance sheet and, therefore, our statement of operations. If we issue shares to discharge the liability, the derivative financial liability is derecognized and common stock and additional paid-in capital are recognized on the issuance of those shares. For options and warrants treated as derivative financial liabilities, at settlement date the carrying value of the options and warrants are transferred to equity. The cash proceeds received from shareholders for additional shares are recorded in common stock and additional paid-in capital. We have recorded a financial derivative related to the change in control provision associated with our December 2012 debt financing. During 2013, we recorded a derivative liability related to our forward foreign exchange contracts, which was extinguished prior to December 31, 2013. The fair value of these derivatives could fluctuate based on changes in the assumptions used in the valuation models.

Inventory—Prior to July 26, 2012, when we received approval from the FDA to market and sell Vascepa in the United States for the MARINE indication, Vascepa was considered a product candidate under development. All supply of Vascepa purchased prior to July 26, 2012 was not capitalized and instead charged as a component of research and development expense in the period received. After Vascepa was approved, we began to capitalize inventory purchased from Nisshin, the API supplier approved in the NDA. Prior to April 2013, only Nisshin was an FDA-approved supplier of API for Vascepa. In April 2013, the FDA approved our sNDAs covering Chemport and BASF as additional Vascepa API suppliers. All supply from Chemport and BASF prior to FDA approval of these API suppliers was not capitalized and instead charged as a component of research and development expense in the period received. Subsequent to the approval of these suppliers, we capitalize API purchases from them. We are working with the Slanmhor consortium to pursue FDA approval for the consortium to manufacture Vascepa API and submitted an sNDA in August 2013. Until an API supplier is approved, all Vascepa API purchased from such supplier is included as a component of research and development expense. Upon sNDA approval of each additional supplier, we capitalize subsequent Vascepa API purchases from such supplier as inventory. Purchases of Vascepa API received and expensed before such regulatory approvals are not subsequently capitalized, and all such purchases are quarantined and not used for commercial supply until such time as the sNDA for the supplier that produced the API is approved. Additionally, the determination of the classification of our inventory requires the use of estimates in order to determine the portion of inventories anticipated to be utilized within twelve months of the balance sheet date.

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

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

We assess the realizability of deferred tax assets at each reporting period. The realization of deferred tax assets depends on generating future taxable income during the periods in which the tax benefits are deductible or creditable. The Company has been historically profitable in the U.S. When making its assessment about the realization of its U.S. deferred tax assets at March 31, 2014, the Company considered all available evidence, placing particular weight on evidence that could be objectively verified. The evidence considered included the (i) historical profitability of the Company's U.S. operations, (ii) sources of future taxable income, giving weight to sources according to the extent to which they can be objectively verified, and (iii) the risks to our business related to the commercialization and development of Vascepa. Based on its assessment, the Company concluded that the U.S. deferred tax assets are more likely than not realizable as of March 31, 2014. Changes in historical earnings performance and future earnings projections, among other factors, may cause us to adjust our valuation allowance on deferred tax assets, which would impact our income tax expense in the period in which we determine that these factors have changed. In the event sufficient taxable income is not generated in future periods, additional valuation allowances could be required relating to these U.S. deferred tax assets.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by FASB and are adopted by us as of the specified effective date. Unless otherwise discussed, we believe that the impact of recently issued accounting pronouncements will not have a material impact on consolidated financial position, results of operations, and cash flows, or do not apply to our operations.

Results of Operations

Comparison of Three Months Ended March 31, 2014 and March 31, 2013

Revenue. We recorded revenue of \$11.0 million and \$2.3 million during the three months ended March 31, 2014 and 2013, respectively, an increase of \$8.7 million or 378%. We commenced our full commercial launch of Vascepa in the United States for use in the MARINE indication in January, 2013. All of our revenue in the three months ended March 31, 2014 and 2013 was derived from product sales of Vascepa, net of allowances, discounts, incentives, rebates, chargebacks and returns.

We sell Vascepa to Distributors. In accordance with GAAP, until we had the ability to reliably estimate returns of Vascepa from our Distributors, revenue was recognized based on the resale of Vascepa for the purposes of filling patient prescriptions, and not based on our sales to such Distributors. 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 revenue based on sales to our Distributors. Consequently, we recognized revenues of \$11.0 million based on sales to Distributors during the three months ended March 31, 2014, compared to revenues of \$10.0 million that we would have recognized based on the resale of Vascepa for the purposes of filling patient prescriptions during the period. Through March 31, 2014, product returns were de minimis.

During the quarters ended March 31, 2014 and 2013, our net product revenues included an adjustment for co-pay mitigation rebates provided by us to commercially insured patients. Such rebates are intended to offset the cost differential for patients of Vascepa not covered by commercial insurers at the time of launch on tier 2, resulting in higher co-pay amounts for such patients. Our cost for these co-payment mitigation rebates was up to \$75 per prescription filled prior to February 20, 2014 and is up to \$70 per prescription filled after February 20, 2014. Commencing in March 2013, certain third-party payors added Vascepa to their tier 2 coverage, which results in lower co-payments for patients covered by these third-party payors. The number of lives covered by these payors increased throughout 2013 and continued to increase in 2014. As of May 1, 2014, over 100 million lives covered by medical insurance were under insurance plans that have added Vascepa to their tier 2 coverage. In connection with the start of such tier 2 coverage, we have agreed to pay customary rebates to these third-party payors on the resale of Vascepa to patients covered by these third-party payors.

As is typical in the pharmaceutical industry, the majority of Vascepa sales are to major commercial wholesalers which then resell Vascepa to retail pharmacies. As of May 1, 2014, over 18,000 clinicians had written prescriptions for Vascepa. As of May 1, 2014, we are not aware of any clinician who is responsible for 10% or more of the aggregate prescriptions written for Vascepa.

On October 22, 2013, in an effort to reduce operating expenses following the recommendation of the advisory committee to the FDA, we implemented a worldwide reduction in force including a reduction of approximately 50% of our sales representatives. Following the reduction in force, we retained approximately 130 sales representatives in the United States in sales territories which have demonstrated what we believe is the greatest potential for Vascepa sales growth. This team will cover the target base of physicians responsible for the majority of Vascepa prescription volume and growth since its launch in early 2013. With these changes and the resulting target base coverage and the addition of the promotional efforts of 250 sales representatives from Kowa Pharmaceuticals America, we anticipate continued Vascepa revenue growth over time. We further anticipate that such revenue growth may be inconsistent from period to period.

Cost of Goods Sold. Cost of goods sold during the three months ended March 31, 2014 and 2013 was \$4.2 million and \$1.3 million, respectively, an increase of \$2.9 million or 223%. These amounts include the cost of API for Vascepa on which revenue was recognized during the period, as well as the associated costs for encapsulation, packaging, shipment, supply management, insurance and quality assurance. The cost of the API included in cost of goods sold reflects the average cost of API included in inventory. This average cost reflects the actual purchase price of Vascepa API, as well as a portion of API carried at zero cost for material which was purchased prior to FDA approval of Vascepa on July 26, 2012 or was purchased prior to the sNDA approval of our suppliers. Additionally, cost of goods sold for the three months ended March 31, 2014 includes \$0.6 million of expense for inventories that were classified as inventory held by others as of December 31, 2013 but were recognized as sales in the three months ended March 31, 2014 in conjunction with the change in revenue recognition methodology.

The majority of API included in the calculation of the average cost of goods sold during the three months ended March 31, 2014 and 2013 was sourced from one API supplier. The contracted cost of supply from this API supplier for initial purchase volumes is higher than the contracted cost from our other API suppliers. Contracted purchase costs from this initial API supplier reflect that they were working with Amarin prior to commencement of the MARINE and ANCHOR clinical trials and are anticipated to decline as additional API volume is purchased. In the future, we anticipate making continued purchases from this initial supplier at substantially lower unit pricing than the pricing of the initial purchases from this supplier and to make additional lower unit cost purchases of Vascepa API from other API suppliers. We began purchasing lower unit cost API from Chemport, which was approved by the FDA in April 2013 to produce Vascepa, in the second quarter of 2013. During the three months ended March 31, 2014 and 2013, the cost basis of product sold that had a carrying value of zero was zero and \$1.7 million, respectively. Had such inventories been valued at acquisition cost, it would have resulted in a corresponding increase in cost of goods sold and a decrease in gross margin during such

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periods. We expect current inventories with a carrying value of zero to be utilized in 2014. We may have additional zero cost inventories in the future to the extent that we receive approval of the sNDA for our fourth commercial supplier. As of March 31, 2014, we maintained inventory with a carrying value of zero and an acquisition cost of approximately \$0.6 million, which has an estimated net realizable value of \$2.7 million based on our average net selling price for the quarter ended March 31, 2014.

Our gross margin for the three months ended March 31, 2014 and 2013 was 61% and 45%, 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 tiered supply pricing at certain suppliers such that cost per kilogram of supply purchases are scheduled to decline as volume of purchases increase and potential advantages derived from the geographical 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 March 31, 2014 and 2013 was \$20.6 million and \$39.3 million, respectively, a decrease of \$18.7 million, or 48%. Selling, general and administrative expenses for the three months ended March 31, 2014 and 2013 are summarized in the table below (in thousands):

	Three Months Ended March, 31	
	2014	2013
Selling, general and administrative expenses, excluding non-cash expenses (1)	\$19,338	\$35,658
Non-cash stock based compensation expense (2)	1,319	4,060
Non-cash warrant related compensation income (3)	(72)	(451)
	<u>\$20,585</u>	<u>\$39,267</u>

- (1) Selling, general and administrative expense, excluding non-cash compensation charges for stock compensation and warrants, for the three months ended March 31, 2014 and 2013 was \$19.3 million and \$35.7 million, respectively, a decrease of \$16.4 million, or 46%. The decrease was due primarily to cost decreases in 2014 for sales force staffing, marketing program spending and costs for other general and administrative costs incurred in connection with the commercialization of Vascepa. The three months ended March 31, 2013 was the first quarter in which we were selling Vascepa and costs during this period included certain launch-related costs.
- (2) Stock-based compensation expense for the three months ended March 31, 2014 and 2013 was \$1.3 million and \$4.1 million, respectively, a decrease of \$2.8 million, or 68%, primarily due to a decrease in the fair value of new stock option and restricted stock awards granted to attract and retain qualified employees as a result of a decrease in our stock price.
- (3) Warrant-related compensation income for the three months ended March 31, 2014 and 2013 was \$0.1 million and \$0.5 million, respectively. Warrant related compensation income for the periods ended March 31, 2014 and 2013 reflects a non-cash change in fair value of the warrant derivative liability associated with warrants issued in October 2009 to three of our former employees, net of warrants exercised. The decrease in the fair value of the warrants is due primarily to a decrease in our stock price during each period. We anticipate that the value of this warrant derivative liability may increase or decrease from period to period based upon changes in the price of our common stock. Such non-cash changes in valuation could be significant as the history of our stock price has been volatile. The gain or loss resulting from such non-cash changes in valuation could have a material impact on our reported net income or loss from period to period. In particular, if the price of our stock increases, the change in valuation of this warrant derivative liability will add to our history of operating losses.

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

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Research and Development Expense. Research and development expense for the three months ended March 31, 2014 and 2013 was \$11.7 million and \$21.8 million, respectively, a decrease of \$10.1 million, or 46%. Research and development expenses for the three months ended March 31, 2014 and 2013 are summarized in the table below (in thousands):

	Three Months Ended March 31,	
	2014	2013
REDUCE-IT study (1)	\$ 7,504	\$10,925
Pre-approval commercial supply (2)	308	2,994
Regulatory filing fees and expenses (3)	643	1,141
Internal staffing, overhead and other (4)	2,614	5,964
Research and development expense, excluding non-cash expense	11,069	21,024
Non-cash stock-based compensation (5)	638	814
Total research and development expense	\$11,707	\$21,838

The decrease in research and development expenses for the quarter ended March 31, 2014, as compared to the prior year period, is primarily due to a decrease in costs associated with the REDUCE-IT study, a decrease in expenses associated with pre-commercial inventory supply, and a decrease in staffing and overhead costs, as further described below.

- (1) In December 2011, we announced commencement of patient dosing in our cardiovascular outcomes study of Vascepa, titled REDUCE-IT, which is designed to evaluate the efficacy of Vascepa in reducing major cardiovascular events in a high risk patient population on statin therapy. The study duration is dependent on the rate of clinical events in the study, which rate may be affected by the number of patients enrolled in the study and the epidemiology of the patients enrolled in the study. We manage the study through a contract research organization (CRO) through which all costs for this outcomes study are incurred with the exception of costs for clinical trial material (CTM) and costs for internal management. Our internal personnel are responsible for managing multiple projects and their costs are not specifically allocated to REDUCE-IT or any other individual project. We currently have over 6,800 patients enrolled in REDUCE-IT. We estimate that we will complete patient enrollment in this study in the first half of 2015. The REDUCE-IT study will be completed after reaching an aggregate number of cardiovascular events. Based on event rates in other outcomes studies, we estimate completing the REDUCE-IT study in or about 2017 with results expected to be available in 2018. For the three months ended March 31, 2014 and 2013, we incurred expenses through our CRO in connection with this trial of approximately \$5.1 million and \$9.3 million, respectively. Inclusive of CTM costs, the combined CRO and CTM costs in the three months ended March 31, 2014 and 2013 for REDUCE-IT were approximately \$7.5 million and \$10.9 million, respectively. We expense costs for CTM upon receipt. The aggregate cost of this outcomes study will depend on the rate of clinical events in the study. We currently estimate that costs incurred for this study in 2014 will continue at approximately the same levels as we have incurred in 2013 but may vary from quarter to quarter. Based on our current assumptions of CRO and CTM costs, we estimate that aggregate remaining costs to complete the REDUCE-IT study and evaluate its results to likely exceed \$100 million. We anticipate that our costs for this outcomes study will continue to represent the most significant component of our research and development expenditures. However, if we do not receive FDA approval of the ANCHOR indication, we plan to re-evaluate the REDUCE-IT study, including the likelihood of REDUCE-IT providing clinically and commercially useful results, the likelihood of FDA approval for an expanded indication for Vascepa based on these results and whether it is advisable to continue or discontinue the study. We anticipate that in any such re-evaluation we will seek further feedback from the FDA.
- (2) Until an API supplier is approved by the FDA to manufacture commercial supply of Vascepa, all Vascepa purchased from such supplier is included as a component of research and development expense. Upon approval of the supplier, we capitalize subsequent Vascepa API purchases from such supplier as inventory. Purchases of Vascepa API received and expensed before such regulatory approvals are not subsequently capitalized, and all such purchases are quarantined and not used for commercial supply until such time as the supplier that produced the API is approved. The commercial supply expense for the periods shown above represents inventory received from Nisshin prior to NDA approval of Vascepa on July 26, 2012 or received from our other suppliers prior to their sNDA approvals. In April 2013, sNDAs were approved for two of our additional suppliers, BASF and Chemport. A sNDA was submitted in August 2013 for Novasep as part of the Slanmhor consortium. The amount of commercial supply that we receive from Novasep prior to sNDA approval depends upon production schedules at Novasep and the timing of regulatory approval, and we are unable to estimate these amounts at this time. We will continue to expense inventory received from the unapproved supplier until such time as FDA approval is obtained.
- (3) The regulatory filing fees in each of the three months ended March 31, 2014 and 2013 included annual FDA fees for maintaining manufacturing sites. In addition, during the three months ended March 31, 2013, these fees included regulatory filings associated with the sNDA for the ANCHOR indication.
- (4) Internal staffing, overhead and other research and development expenses primarily relate to the costs of our personnel employed to managed research, development and regulatory affairs activities and related overhead costs including consulting and other professional fees that are not allocated to specific projects. Such costs also include costs related to qualifying suppliers and legal

costs. We anticipate a reduction in such costs in 2014 compared to 2013 levels as a result of a company-wide reduction in force announced in October 2013. Other research and development costs also include costs related to testing of the relative bioavailability of AMR102 capsules, Vascepa capsules with a selected statin taken concomitantly. We have suspended additional development of AMR102 pending resolution of the ANCHOR sNDA with the FDA.

- (5) Non-cash stock-based compensation expense represents the costs associated with equity awards issued to internal staff supporting our research and development and regulatory functions.

Gain on Change in Fair Value of Derivative Liabilities. Gain on change in fair value of derivative liabilities for the three months ended March 31, 2014 and 2013 was \$4.4 million and \$3.6 million, respectively. Gain on change in change in fair value of derivative liabilities is comprised of (i) the change in fair value of the warrant derivative liability, (ii) the change in fair value of the derivative liability related to the change in control provision associated with the December 2012 BioPharma financing and (iii) an unrealized loss on foreign exchange contracts of \$0.7 million for the three months ended March 31, 2013.

The warrant derivative liability is related to the change in fair value of warrants issued in conjunction with the October 2009 private placement. In October 2009 we issued 36.1 million warrants at an exercise price of \$1.50 and recorded a \$48.3 million warrant derivative liability, representing the fair value of the warrants issued. As these warrants have been classified as a derivative liability, they are revalued at each reporting period, with changes in fair value recognized in the statement of operations. The fair value of the warrant derivative liability at December 31, 2013 was \$6.9 million and we recognized a \$0.9 million gain on change in fair value of derivative liability for the period ended March 31, 2014 for these warrants. The fair value of the warrant derivative liability at December 31, 2012 was \$54.9 million and we recognized a \$5.4 million gain on change in fair value of derivative liability for the period ended March 31, 2013 for these warrants. The decrease or increase in the fair value of the warrant derivative liability is due primarily to the decrease or increase in the price of our common stock on the date of valuation.

Our December 2012 financing agreement contains a redemption feature whereby, upon a change of control, we would be required to pay \$140 million, less any previously repaid amount, if the change of control occurs on or before December 31, 2013, or required to repay \$150 million, less any previously repaid amount, if the change of control event occurs after December 31, 2013. The fair value of the derivative liability is recalculated at each reporting period using a probability-weighted model incorporating management estimates for potential change in control, and by determining the fair value of the debt with and without the change in control provision included. The difference between the two fair values of the debt was determined to be the fair value of the embedded derivative. At December 31, 2013, the fair value of the derivative was determined to be \$11.1 million, and at March 31, 2014, the fair value of the derivative was determined to be \$7.6 million. We recognized a \$3.5 million gain on change in fair value of derivative liability for the three months ended March 31, 2014. At December 31, 2012, the fair value of the derivative was determined to be \$14.6 million, and at March 31, 2013, the fair value of the derivative was determined to be \$15.6 million. We recognized a \$1.0 million loss on change in fair value of derivative liability for the three months ended March 31, 2013.

We periodically use foreign exchange forward contracts to hedge against changes in exchange rates for inventory purchases denominated in foreign currency. As of March 31, 2014, there were no such outstanding contracts. As of March 31, 2013 we held foreign exchange forward contracts with notional amounts totaling \$15.0 million. For the period ended March 31, 2013, we recognized expense of \$0.7 million for a foreign exchange forward contract derivative liability, which was included as a component of change in fair value of derivative liabilities and in other current liabilities at March 31, 2013.

Interest Expense, net. Net interest expense for the three months ended March 31, 2014 and 2013 was \$4.4 million and \$8.9 million, respectively, a decrease of \$4.5 million, or 51%. Net interest expense for the three months ended March 31, 2014 and 2013 is summarized in the table below (in thousands):

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	Three Months Ended March 31,	
	2014	2013
Exchangeable senior notes (1):		
Amortization of debt discount created upon allocation of proceeds to the conversion option	\$ 569	\$ 2,901
Contractual coupon interest	1,312	1,312
Amortization of the discount from the underwriter's discounts and offering costs	114	583
Total exchangeable senior notes interest expense	1,995	4,796
Long-term debt—BioPharma financing (2):		
Cash interest—current	1,097	—
Cash interest—deferred	821	3,439
Non-cash interest	489	720
Total long-term debt interest expense	2,407	4,159
Other interest expense	1	2
Total interest expense	4,403	8,957
Interest income (3)	(10)	(97)
Total interest expense, net	\$ 4,393	\$ 8,860

- (1) Cash and non-cash interest expenses related to the exchangeable senior notes for the three months ended March 31, 2014 and 2013 was \$2.0 million and \$4.8 million, respectively. The decrease in interest expense of \$2.8 million is the result of the debt discount associated with the exchangeable notes having been fully amortized as of January 2014.
- (2) Cash and non-cash interest expenses related to the BioPharma financing for three months ended March 31, 2014 and 2013 was \$2.4 million and \$4.2 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. For the quarters ended September 30, 2013, December 31, 2013 and March 31, 2014, our revenues were below the contractual threshold amount such that we made cash payments of \$0.8 million in November 2013 and \$1.0 million in February 2014 and will make a payment of \$1.1 million in May 2014, each such payment reflecting the calculated optional reduction amount as opposed to the contractual threshold payments for each quarterly period.
- (3) Interest income for the three months ended March 31, 2014 and 2013 was \$0.01 million and \$0.1 million, respectively. Interest income represents income earned on cash balances.

Other Income (Expense), net. Other income (expense), net for the three months ended March 31, 2014 and 2013 was \$0.02 million and \$(0.1) million, respectively. Other income (expense), net primarily consists of losses and gains on foreign exchange transactions, including realized gains and losses on foreign exchange forward contracts. We periodically use foreign exchange forward contracts to hedge against changes in exchange rates for inventory purchases denominated in foreign currency.

(Provision for) Benefit from Income Taxes. (Provision for) benefit from income taxes for the three months ended March 31, 2014 was a \$0.4 million provision versus a \$3.3 million benefit in the prior year. The current provision relates entirely to the United States subsidiary operations. We are profitable in the United States as a result of intercompany transactions between our United States subsidiary and our other companies.

Liquidity and Capital Resources

Our sources of liquidity as of March 31, 2014 include cash and cash equivalents of \$164.3 million. Our projected uses of cash include commercialization of Vascepa for the MARINE indication, preparations for commercialization of Vascepa for the ANCHOR indication, if approved, the continued funding of the REDUCE-IT cardiovascular outcomes study, working capital and other general corporate activities. Our cash flows from operating, investing and financing activities, as reflected in the consolidated statements of cash flows, are summarized in the following table (in millions):

	Three Months Ended March 31,	
	2014	2013
Cash (used in) provided by continuing operations:		
Operating activities	\$ (27.5)	\$ (59.6)
Investing activities	—	—
Financing activities	0.3	1.1
Decrease in cash and cash equivalents	\$ (27.2)	\$ (58.5)

On December 6, 2012 we entered into a financing agreement with BioPharma. Under this agreement, we granted to BioPharma a security interest in future receivables and all related rights to Vascepa, in exchange for \$100 million received at the closing of the agreement which closing occurred in December 2012. We have agreed to repay BioPharma up to \$150 million of future revenue and receivables. For the quarters ended September 30, 2013, December 31, 2013 and March 31, 2014, our revenues were below the contractual threshold amount such that we made a cash payment of \$0.8 million in November 2013 and \$1.0 million in February 2014 and will make a payment of \$1.1 million in May 2014, each such payment reflecting the calculated optional reduction amount as

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opposed to the contractual threshold payments for each quarterly period. Additional quarterly repayments are due thereafter in accordance with the following schedule: \$8.0 million per quarter in the third quarter of 2014 and each of the next two quarters, \$10.0 million per quarter in each of the next four quarters, \$15.0 million per quarter in each of the next four quarters and a final payment of \$13.0 million due in May 2017. The quarterly repayments through the third quarter of September 2014 represented interest only. Quarterly payments did not begin to reduce the principal balance until the fourth quarter of 2014. In accordance with the agreement with BioPharma, quarterly differences between the calculated optional reduction amounts and the repayment schedule amounts are rescheduled for payment beginning in the second quarter of 2017. 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. Except upon a change of control in Amarin, the agreement does not expire until \$150 million has been repaid. Under the agreement, upon a change of control, we would be required to pay \$140 million, less any previously repaid amount, if the change of control occurs on or before December 31, 2013, or required to repay \$150 million, less any previously repaid amount, if the change of control event occurs after December 31, 2013. We can prepay after October 1, 2013, an amount equal to \$150 million less any previously repaid amount. We currently estimate that Vascepa revenue levels will not be high enough in each quarter to support repayment to BioPharma in accordance with threshold amounts in the repayment schedule.

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

As of March 31, 2014, we had cash and cash equivalents of \$164.3 million, a decrease of \$27.2 million from December 31, 2013. The decrease is primarily due to net cash used in operating activities in support of the commercial launch of Vascepa, net of proceeds from financing activities. We have incurred annual operating losses since our inception and, as a result, we had an accumulated deficit of \$939.9 million as of March 31, 2014. We believe that our cash and cash equivalents balance of \$164.3 million at March 31, 2014 will be sufficient to fund our projected operations for at least the next twelve months. We anticipate that net cash outflows in 2014 will be significantly lower than net cash outflows in 2013 as a result of a reduction in expenses associated with the commercialization of Vascepa, lower headcount and lower supply purchases.

On March 29, 2014, the universal shelf registration statement on Form S-3 (Registration No. 333-173132) that we had filed with the SEC on March 29, 2011, expired. We currently intend to file a new registration statement.

Contractual Obligations

The following table summarizes our contractual obligations at March 31, 2014 and the effects such obligations are expected to have on our liquidity and cash flows in future periods (in millions):

Payments Due by Period

(in millions)

	Total	2014	2015 to 2016	2017 to 2018	After 2018
Purchase Obligations (1)	\$ 57.7	\$ 8.8	\$ 27.3	\$ 17.8	\$ 3.8
Operating Lease Obligations (2)	2.6	0.6	1.2	0.8	—
Interest Payment Obligations—Exchangeable Debt (3)	23.6	2.6	10.5	10.5	—
BioPharma Repayment—Principal & Interest (4)	148.2	17.1	93.0	38.1	—
Total Contractual Cash Obligations	\$232.1	\$29.1	\$132.0	\$ 67.2	\$ 3.8

- (1) We have agreements with API suppliers which include minimum purchase levels to enable us to maintain certain exclusivity with each respective supplier. The amounts in the table above reflect amounts potentially payable to our suppliers based on our minimum purchase obligations. These amounts reflect the assumption that the sNDA for the Slanmhor consortium is approved and that the Slanmhor consortium completes construction and validation of its manufacturing facility.
- (2) Represents operating lease costs, primarily consisting of leases for facilities in Dublin, Ireland, Bedminster, NJ and Groton, CT.
- (3) Represents scheduled interest payments due under the terms of our 3.5% exchangeable senior notes ("notes") due 2032, assuming they remain outstanding through 2018 and they have not been exchanged for ADRs. The above table does not reflect the repayment of the \$150.0 million notes as they may be exchanged for ADRs.
- (4) Represents principal and interest payments which we anticipate paying under the terms of the agreement entered into with BioPharma Secured Debt Fund II Holdings Cayman LP (BioPharma) reflecting full payment based on the quarterly repayment schedule under that agreement, without regard to our potential to elect quarterly reductions in such payment amounts in the event that Vascepa revenue levels result in calculation under the agreement of lower quarterly repayment amounts. Under this agreement, the Company granted to BioPharma a security interest in future receivables and all rights to Vascepa, in exchange for \$100 million received at the closing of the agreement which closing occurred in December 2012. The Company has agreed to repay BioPharma up to \$150 million of future revenue and receivables. We made cash payments of \$0.8 million in November 2013 and \$1.0 million in February 2014 and will make a payment of \$1.1 million in May 2014, each such payment reflecting the calculated optional reduction amount as opposed to the contractual threshold payments for each quarterly period. Additional quarterly repayments are due thereafter in accordance with the following schedule: \$8.0 million per quarter in the third quarter of 2014 and in each of the next two quarters, \$10.0 million per quarter in each of the next four quarters, \$15.0 million per quarter in each of the next four quarters and a final payment of \$13.0 million due in May 2017. All such payments reduce the remainder of the \$150 million in aggregate payments to BioPharma. For accounting purposes, the quarterly repayments through the third quarter of September 2014 represent interest only. Quarterly payments do not begin to reduce the principal balance until the fourth quarter of 2014. These quarterly payments are subject to a quarterly threshold amount whereby, if a calculated threshold, based on quarterly Vascepa revenues, is not achieved, the quarterly payment payable in that quarter can at our election be reduced and with the reduction carried forward without interest for payment in a future period. The table above reflects payment in full of the scheduled quarterly amounts without regard to such potential elected reductions.

We do not enter into financial instruments for trading or speculative purposes. At March 31, 2014, we had no outstanding forward exchange contracts. At March 31, 2013, we had three forward exchange contracts with a nominal amount of \$15.0 million to hedge payments made in foreign currency for API supply and we recorded an unrealized loss of \$0.7 million under these contracts.

In April 2013, we announced the approval by the FDA of the sNDAs covering two of our API suppliers, Chemport, Inc. and BASF (formerly Equateq Limited). On December 30, 2013, we issued a notice of termination of our API agreement to BASF as a result of BASF's non-compliance with the terms of such agreement. BASF did not remedy within a contractual 60-day cure period and as a result, this agreement terminated on February 28, 2014 and as such, no future purchase obligations for BASF are reflected in the table above. However, we may enter into a new development and supply agreement with BASF and may purchase supply from BASF. The Chemport supply agreement provides access to additional API supply that is incremental to supply from Nisshin, our other existing FDA-approved API supplier. The Chemport agreement includes minimum annual purchase levels enabling us to maintain certain supply exclusivity with each respective supplier. The Chemport agreement also includes a provision that any shortfall in the minimum purchase commitments is payable in cash, and the maximum amounts payable pursuant to this provision are reflected in the table above. The sNDA for the Slanmhor consortium, our intended incremental API supplier, is not yet approved and the construction and validation of their facility has not been completed for the manufacture of Vascepa API, however, the minimum purchase commitments that could result in a future cash obligation have been included in the above table.

The two supply agreements entered into in 2011 with BASF, which has since terminated, and Chemport also include commitments for: (i) certain development fees, (ii) material purchase commitments million for initial raw materials, which will be credited against future API purchases, and is refundable to us if a supplier does not successfully develop and qualify the API by a certain date, and (iii) raw material purchase commitments. We have paid \$3.1 million related to these commitments through March 31, 2014. The agreement with the Slanmhor consortium, when all contingencies are eliminated by the supplier, provides for certain development fees and other commitments of, which will be credited against future API material purchases. We have paid \$6.2 million related to these commitments through March 31, 2014. Certain of these commitment fees are contingent upon the mutually agreed upon expansion of the Slanmhor consortium's API manufacturing capacity beyond the facility which has already been constructed and is in the process of being qualified by the consortium. To date, the parties have not agreed upon such additional expansion. Under this agreement, during the three months ended March 31, 2014 and 2013, we made payments of \$0.4 million and \$3.9 million, respectively, to the Slanmhor consortium related to stability and technical batches and advances on future API purchases. Under all of our supply agreements, during the three months ended March 31, 2014 we purchased approximately \$1.3 million of Vascepa API.

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

Under the 2004 share repurchase agreement with Laxdale Limited, or Laxdale, upon approval of Vascepa by the FDA on July 26, 2012, we were required to make a milestone payment to Laxdale of £7.5 million. We made this payment in 2012 and capitalized this Laxdale milestone payment of \$11.6 million as a component of other long term assets. This long-term asset is being amortized over the estimated useful life of the intellectual property we acquired from Laxdale and we recognized amortization expense of \$0.2 million for the quarters ended March 31, 2014 and 2013. Also under the Laxdale agreement, upon receipt of marketing approval in Europe for the first indication for Vascepa (or first indication of any product containing Amarin Neuroscience intellectual property acquired from Laxdale in 2004), we must make an aggregate stock or cash payment to the former shareholders of Laxdale (at the sole option of each of the sellers) of £7.5 million (approximately \$12.5 million at March 31, 2014). Additionally, upon receipt of a marketing approval in the U.S. or Europe for a further indication of Vascepa (or further indication of any other product using Amarin Neuroscience intellectual property), we must make an aggregate stock or cash payment (at the sole option of each of the sellers) of £5 million (approximately \$8.3 million at March 31, 2014) for each of the two potential market approvals (i.e. £10 million maximum, or approximately \$16.6 million at March 31, 2014).

In addition to the obligations in the table above, we have recorded a liability of \$0.6 million for uncertain tax positions that have been recorded in long-term liabilities at March 31, 2014. We are not able to reasonably estimate in which future periods these amounts will ultimately be settled.

Off-Balance Sheet Arrangements

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

Item 3. *Quantitative and Qualitative Disclosures about Market Risk*

There have been no material changes with respect to the information appearing in PART II, Item 7A “Quantitative and Qualitative Disclosures about Market Risk” of our Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 27, 2014.

Item 4. *Controls and Procedures*

Evaluation of Disclosure Controls and Procedures

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

As of March 31, 2014, our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities and Exchange Act of 1934). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer have concluded, based upon the evaluation described above that, as of March 31, 2014, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

During the quarter ended March 31, 2014, there have been no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15(d)-15(f) promulgated under the Securities Exchange Act of 1934, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II

Item 1. Legal Proceedings

We are in the process of appealing the October 2013 rescission of the Special Protocol Assessment, or SPA, agreement related to our ANCHOR clinical trial within the FDA in accordance with FDA dispute resolution guidance. A SPA agreement is an agreement with the FDA that Phase 3 trial protocol design, clinical endpoints, and planned statistical analyses are acceptable to support regulatory approval. A SPA is generally binding upon the FDA except in limited circumstances, such as if the FDA identifies a substantial scientific issue essential to determining safety or efficacy after the study begins, or if the study sponsor fails to follow the protocol that was agreed upon with the FDA. On October 29, 2013, the FDA notified us that it rescinded the SPA agreement we entered into for the ANCHOR trial protocol because the FDA determined that a substantial scientific issue essential to determining the effectiveness of Vascepa in the studied population was identified after testing began. As a basis for this determination, the FDA communicated that, consistent with discussion at the related, public October 16, 2013 advisory committee meeting, it determined that results from outcome studies of other triglyceride-lowering drugs failed to support the hypothesis that a triglyceride-lowering drug significantly reduces the risk for cardiovascular events among the population studied in the ANCHOR trial. Thus, the FDA stated that it no longer considers a change in serum triglyceride levels as sufficient to establish the effectiveness of a drug intended to reduce cardiovascular risk in subjects with serum triglyceride levels below 500 mg/dL.

On November 7, 2013, we submitted to the FDA a formal appeal of its decision to rescind the SPA agreement including documents outlining why we believe the SPA was wrongfully rescinded. On November 21, 2013, we received notification from the dispute resolution group of the Office of New Drugs at the FDA that it had not accepted for review, on procedural grounds, our appeal regarding the rescission of the SPA. We were also notified by the FDA that our request for a meeting at a high level within the FDA regarding the appeal was not granted and that we would first need to address the matter at the division level within the FDA. On December 19, 2013, the FDA notified us it did not expect to take action on our underlying sNDA on December 20, 2013 because our request to re-instate the ANCHOR SPA agreement remained under consideration with the FDA. The FDA also communicated to us that, as of December 19, 2013, it viewed our appeal of the ANCHOR SPA agreement rescission and the ANCHOR sNDA as separate administrative decisions worthy of separate consideration and that it FDA planned to complete its review of our request to re-instate the ANCHOR SPA agreement. The FDA provided no additional information on when it expects to complete its review of the ANCHOR sNDA.

On January 17, 2014, the Division of Metabolism and Endocrinology Products, or DMEP, within the FDA notified Amarin in connection with Amarin's request for reconsideration of the October 2013 decision to rescind the ANCHOR SPA agreement that the DMEP "does not plan to re-instate the ANCHOR SPA agreement." We appealed the DMEP decision to the next level within the FDA, the Office of Drug Evaluation II, or ODE II, and were informed in late April 2014, that ODE II determined to uphold the DMEP rescission determination. Our plan is to appeal the rescission decision to the next level within the FDA, the Director of the Office of New Drugs, Dr. John Jenkins, in accordance with FDA dispute resolution guidance. There can be no assurance that we will be successful in the reinstatement of the ANCHOR SPA agreement or in approval of the ANCHOR indication sNDA.

On November 1, 2013, a purported investor of Amarin filed a putative class action lawsuit captioned *Steven Sklar v. Amarin Corporation plc et al.*, No. 13-cv-6954 (D.N.J. Nov. 1, 2013) in the U.S. District Court for the District of New Jersey. Substantially similar lawsuits, captioned *Bove v. Amarin Corporation plc*, Civ. No. 13-07882 (AT) (S.D.N.Y. Nov. 5, 2013), *Bentley v. Amarin Corporation plc*, Civ. No. 13-08283 (AT) (S.D.N.Y. Nov. 20, 2013) and *Siegel v. Amarin Corporation plc*, No. 3:13-cv-07210 (D.N.J. Nov. 27, 2013), were subsequently filed in the U.S. District Court for the District of New Jersey and U.S. District Court for the Southern District of New York. On December 9, 2013 the cases filed in the Southern District of New York were transferred to the District of New Jersey, where the four cases are now proceeding in front of the same judge pending a formal order consolidating the actions.

Each of the complaints asserts claims under the Securities Exchange Act of 1934. The complaints allege that Amarin and certain of its current and former officers and directors made misstatements and omissions regarding the FDA's willingness to approve Vascepa's ANCHOR indication and the potential relevance of data from the ongoing REDUCE-IT trial to that approval. The putative class periods alleged in the complaints vary from the July 9, 2009-October 15, 2013 period alleged in the *Sklar* and *Siegel* complaints, the July 9, 2009-October 16, 2013 period alleged in the *Bentley* complaint, and August 8, 2012-October 16, 2013 period alleged in the *Bove* complaint. The lawsuits seek unspecified monetary damages and attorneys' fees and costs.

On January 3, 2014, ten plaintiffs and their respective counsel moved for appointment as lead plaintiff and lead counsel for the putative class. The plaintiffs also moved for consolidation of the pending actions. The motion for appointment of lead plaintiff was set for February 3, 2014, but has not yet been decided. After the court appoints a lead plaintiff, and consolidates the actions, we expect that the lead plaintiff will file a consolidated amended complaint that will become the operative complaint for the action.

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We believe that we have valid defenses and we will vigorously defend against the claims, but cannot predict the outcome. We are unable to reasonably estimate the loss exposure, if any, associated with these claims. We have insurance coverage that is anticipated to cover any significant loss exposure that may arise from this action after payment by us of the associated deductible obligation under such insurance coverage.

On February 27, 2014, we commenced a lawsuit against the FDA in the U.S. District Court for the District of Columbia captioned *Amarin Pharmaceuticals Ireland Ltd. v. Food & Drug Administration, et al.*, Civ. A. No. 14-0324 (D.D.C.) that challenges FDA's denial of our request for five-year NCE exclusivity for Vascepa based on our reading of the relevant statute, our view of FDA's inconsistency with its past actions in this area and the retroactive effect of what we believe is a new policy at FDA as it relates to our situation. Our complaint requests that the court vacate FDA's decision, declare that Vascepa is entitled to the benefits of five-year statutory exclusivity, bar the FDA from accepting any ANDA or similar application for which Vascepa is the reference-listed drug until after the statutory exclusivity period and set aside what we contend are—due to the denial of five-year exclusivity to Vascepa—prematurely accepted pending ANDA applications. We intend to litigate the case vigorously, but we cannot predict the outcome of this lawsuit.

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

In March and April 2014, we received paragraph IV certification notices from five companies contending to varying degrees that certain of our patents are invalid, unenforceable and/or will not be infringed by the manufacture, use, sale or offer for sale of a generic form of Vascepa as described in those companies' abbreviated new drug applications, or ANDAs. We have filed or are in the process of filing patent infringement lawsuits against each of these ANDA applicants. In each of the lawsuits, Amarin is seeking, among other remedies, an order enjoining the defendants from marketing generic versions of Vascepa before the last to expire of the asserted patents in 2030. In April 2014, Amarin filed lawsuits against Apotex, Inc. and Apotex Corporation (collectively, "Apotex") in the U.S. District Court for the District of New Jersey and the U.S. District Court for the Northern District of Illinois. The cases against Apotex are captioned *Amarin Pharma, Inc. et al. v. Apotex, Inc. et al.*, Civ. A. No. 14-2550 (D.N.J.) and *Amarin Pharma, Inc. et al. v. Apotex, Inc. et al.*, Civ. A. No. 14-2958 (N.D. Ill.). In April 2014, Amarin also filed lawsuits against Roxane Laboratories, Inc. ("Roxane") in the U.S. District Court for the District of New Jersey and the U.S. District Court for the Northern District of Ohio. The cases against Roxane are captioned *Amarin Pharma, Inc. et al. v. Roxane Laboratories, Inc.*, Civ. A. No. 14-2551 (D.N.J.) and *Amarin Pharma, Inc. et al. v. Roxane Laboratories, Inc.*, Civ. A. No. 14-901 (N.D. Ohio). In April 2014, Amarin also filed a lawsuit against Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. (collectively, "Dr. Reddy's") in the U.S. District Court for the District of New Jersey. The case against Dr. Reddy's is captioned *Amarin Pharma, Inc. et al. v. Dr. Reddy's Laboratories, Inc. et al.*, Civ. A. No. 14-2760 (D.N.J.). In the near future, Amarin plans to file lawsuits against the other two ANDA applicants referenced above, Watson Laboratories, Inc. and Teva Pharmaceuticals USA, Inc. asserting patent infringement in a manner similar to that in the pending suits. As a result of the 30-month stay associated with the filing of these lawsuits under the Hatch-Waxman Act, the FDA cannot grant final approval to any ANDA before September 2016, unless there is an earlier court decision holding that the subject patents are not infringed and/or are invalid. We intend to vigorously enforce our intellectual property rights relating to Vascepa, but we cannot predict the outcome of these lawsuits.

In addition to the above, in the ordinary course of business, we are from time to time involved in lawsuits, claims, investigations, proceedings, and threats of litigation relating to intellectual property, commercial arrangements and other matters.

Item 1A. Risk Factors

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

Those risk factors below denoted with a "" are newly added or have been materially updated from our Annual Report on 10-K filed with the SEC on February 27, 2014.*

Risks Related to the Commercialization and Development of Vascepa

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

While we are currently marketing Vascepa for use in the MARINE indication in the United States, our ability to commercialize Vascepa in the ANCHOR indication in the United States or market Vascepa for either indication outside of the United States is dependent upon receiving additional regulatory approvals. In April 2013, the FDA accepted our Supplemental New Drug Application, or sNDA, which seeks approval for the use of Vascepa in patients with high triglyceride levels (TG \geq 200 mg/dL and <500 mg/dL) who are also on statin therapy for elevated LDL-C levels, which we refer to as the ANCHOR indication. The FDA originally assigned the sNDA a Prescription Drug User Fee Act, or PDUFA, date of December 20, 2013 for the completion of its review. The PDUFA date is the goal date for the FDA to complete its review of the sNDA. On December 19, 2013, the FDA notified us it did not expect to take action on our sNDA on December 20, 2013 because our request to re-instate the ANCHOR special protocol assessment, or SPA, agreement remained under consideration with the FDA. Our request to reinstate the ANCHOR SPA was denied twice and we are in the process of appealing that decision within the FDA. No new PDUFA date has been established.

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

Taking into account the described efficacy and safety data for Vascepa, do you believe that its effects on the described lipid/lipoprotein parameters are sufficient to grant approval for co-administration with statin therapy for the treatment of patients with mixed dyslipidemia and CHD or CHD risk equivalent prior to the completion of REDUCE-IT?

During the advisory committee meeting, based in part on the briefing materials prepared by the FDA for the meeting, the advisory committee reviewed the safety and efficacy data observed in the ANCHOR trial. This included a discussion regarding observed nominally statistically significant changes from baseline in an adverse direction, while on background statin therapy, in certain lipid parameters, including TGs, in the placebo group, raising the possibility that the mineral oil placebo used in the ANCHOR trial (and in the REDUCE-IT trial) was not biologically inert and might be viewed as artificially exaggerating the clinical effect of Vascepa when measured against placebo in the ANCHOR trial. Because no strong evidence for biological activity of mineral oil was identified by the FDA in the MARINE trial, ultimately it was concluded that the between-group differences likely provided the most appropriate descriptions of the treatment effect of Vascepa and that whatever factor(s) led to the within-group changes over time in the placebo group were likely randomly distributed to all treatment groups. Thus, the FDA approved Vascepa for use in the MARINE indication in July 2012. Following this discussion at the advisory committee meeting, while no formal vote was taken related to the inert nature of the placebo, we believe that the consensus of the advisory committee, although not unanimous, and the FDA was that, based on the information made available to the advisory committee and FDA at the meeting, Vascepa appeared to be safe and effective for the reduction of TGs in patients with mixed dyslipidemia on statin therapy.

However, there was also extensive discussion during the advisory committee meeting regarding the expected clinical benefit of a reduction in TGs in this patient population. That is, whether the clinical data derived from the ANCHOR trial was a sufficient basis for approval. In particular, the advisory committee and FDA noted the lack of prospective, controlled clinical trial data demonstrating that pharmacological reduction of TGs in patients with mixed dyslipidemia on statin therapy significantly reduces residual cardiovascular risk in these patients. The FDA noted that prior clinical outcomes studies conducted by others, albeit in different patient populations, evaluating different drugs with different mechanisms of action, failed to demonstrate a statistically significant reduction in cardiovascular events following concomitant use of drug therapy in patients on statin therapy. We believe that the negative vote of the advisory committee was principally due to the lack of recent conclusive data in these clinical outcomes studies in favor of the hypothesis that TG reduction will result in reduced cardiovascular risk. The FDA is not bound by the recommendations of the advisory committee, but it generally follows such recommendations.

A Special Protocol Assessment, or SPA, agreement is an agreement with the FDA that Phase 3 trial protocol design, clinical endpoints, and planned statistical analyses are acceptable to support regulatory approval. A SPA is generally binding upon the FDA except in limited circumstances, such as if the FDA identifies a substantial scientific issue essential to determining safety or efficacy after the study begins, or if the study sponsor fails to follow the protocol that was agreed upon with the FDA. On October 29, 2013, the FDA notified us that it rescinded the SPA agreement we entered into for the ANCHOR trial protocol because the FDA determined that a substantial scientific issue essential to determining the effectiveness of Vascepa in the studied population was identified after testing began. As a basis for this determination, the FDA communicated that, consistent with discussion at the advisory committee meeting, it determined that results from outcome studies of other triglyceride-lowering drugs failed to support the hypothesis that a triglyceride-lowering drug significantly reduces the risk for cardiovascular events among the population studied in the ANCHOR trial. Thus, the FDA stated that it no longer considers a change in serum triglyceride levels as sufficient to establish the effectiveness of a

drug intended to reduce cardiovascular risk in subjects with serum triglyceride levels below 500 mg/dL. On November 7, 2013, we submitted to the FDA a formal appeal of its decision to rescind the SPA including documents outlining why we believe the SPA was wrongfully rescinded.

On November 21, 2013, we received notification from the dispute resolution group of the Office of New Drugs at the FDA that it had not accepted for review, on procedural grounds, our appeal regarding the rescission of the SPA. We were also notified by the FDA that our request for a meeting at a high level within the FDA regarding the appeal was not granted and that we would first need to address the matter at the division level within the FDA. On December 19, 2013, the FDA notified us it did not expect to take action on our sNDA on December 20, 2013 because our request to re-instate the ANCHOR SPA agreement remained under consideration with the FDA. The FDA also communicated to us that, as of December 19, 2013, it viewed our appeal of the ANCHOR SPA agreement rescission and the ANCHOR sNDA as separate administrative decisions worthy of separate consideration and that it FDA planned to complete its review of our request to re-instate the ANCHOR SPA agreement. The FDA provided no additional information on when it expects to complete its review of the ANCHOR sNDA. On January 17, 2014, the Division of Metabolism and Endocrinology Products, or DMEP, within the FDA notified Amarin in connection with Amarin's request for reconsideration of the October 2013 decision to rescind the ANCHOR SPA agreement that the DMEP "does not plan to re-instate the ANCHOR SPA agreement." We appealed the DMEP decision to the next level within the FDA, the Office of Drug Evaluation II, or ODE II, and were informed in late April 2014, that ODE II determined to uphold the DMEP rescission determination. Our plan is to appeal the rescission decision to the next level within the FDA in accordance with FDA dispute resolution guidance. There can be no assurance that we will be successful in the reinstatement of the ANCHOR SPA agreement or in approval of the ANCHOR indication sNDA.

Based on our communications with the FDA, we currently expect that final positive results from the REDUCE-IT outcomes study will be required for FDA approval of label expansion for Vascepa. If we do not receive FDA approval of the ANCHOR indication, we plan to re-evaluate the REDUCE-IT study, including the likelihood of REDUCE-IT providing clinically and commercially useful results, the likelihood of FDA approval for an expanded indication for Vascepa based on these results and whether it is best to continue or discontinue the study. We anticipate that in any such re-evaluation we will seek further feedback from the FDA. The aggregate cost to complete REDUCE-IT, excluding amounts previously expensed, is estimated to exceed \$100 million, which is a significant financial burden given our current financial position. To the extent the FDA conditions approval of Vascepa for the ANCHOR indication on its review of the data from the REDUCE-IT trial, Vascepa may never be approved for this indication. Any delay in obtaining, or an inability to obtain, marketing approval in this indication could prevent us from growing revenue significantly and could have a material adverse effect on our operations and financial condition, including our ability to reach profitability.

Even if we obtain additional regulatory approvals for Vascepa, the timing or scope of any approvals may prohibit or reduce our ability to commercialize the product successfully. For example, if the approval process for the ANCHOR indication takes too long, we may miss market opportunities and give other companies the ability to develop competing products or establish market dominance. Additionally, the terms of any approvals, including the approval received from the FDA in July 2012 for the MARINE indication, may prove to not have the scope or breadth needed for us to successfully commercialize Vascepa or become profitable.

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

A SPA is an evaluation by the FDA of a protocol with the goal of reaching an agreement that the Phase 3 trial protocol design, clinical endpoints, and statistical analyses are acceptable to support regulatory approval of the drug product candidate with respect to effectiveness for the indication studied. The ANCHOR trial was, and the REDUCE-IT trial is, being conducted under an SPA agreement with the FDA. In each case, the FDA agreed that, based on the information we submitted to the agency, the design and planned analysis of the trial is adequate to support use of the conducted study as the primary basis for approval with respect to effectiveness. A SPA agreement is generally binding upon the FDA except in limited circumstances, such as if the FDA identifies a substantial scientific issue essential to determining safety or efficacy after the study begins, or if the study sponsor fails to follow the protocol that was agreed upon with the FDA.

On October 29, 2013, the FDA notified us that it rescinded the ANCHOR study SPA agreement because the FDA determined that a substantial scientific issue essential to determining the effectiveness of Vascepa in the studied population was identified after testing began. Specifically, consistent with discussion at the advisory committee meeting, the FDA determined that results from outcome studies of other drugs failed to support the hypothesis that a triglyceride-lowering drug significantly reduces the risk for cardiovascular events among the population studied in the ANCHOR trial. In response to our appeal of the decision to rescind the ANCHOR SPA agreement, on January 17, 2014, the DMEP within the FDA notified Amarin in connection with Amarin's request for reconsideration of the October 2013 decision to rescind the ANCHOR SPA agreement that the DMEP "does not plan to re-instate the ANCHOR SPA agreement." The DMEP also stated that it no longer considers a change in serum triglyceride levels as sufficient to establish the effectiveness of a drug intended to reduce cardiovascular risk in subjects with serum triglyceride levels below 500 mg/dL. We appealed this decision within FDA and were denied again. We plan to appeal this decision to the next level within the FDA.

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 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.

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

Our ongoing REDUCE-IT cardiovascular outcome study was designed to determine whether Vascepa, when added to statin therapy, would reduce the risk of major cardiovascular events in an at-risk patient population. We expect the ongoing incremental cost of the REDUCE-IT study to us over the next several years will exceed \$100 million as the study currently involves over 450 clinical trial sites in eleven countries. The timing of completion of the REDUCE-IT study is based on the rate of cardiovascular events for patients in the study. If it takes longer for such events to accrue than we expect, the trial could take longer to complete and cost more than we currently expect. AMR102, a fixed dose combination of Vascepa and a leading statin product, is in early stage development with relatively minimal current expenses associated with ongoing development, but significant expense associated with development over the next several years. We have not been profitable in any of the last five fiscal years. Our cash and cash equivalents at March 31, 2014 was \$164.3 million. For the fiscal year ended December 31, 2013, we reported a loss of approximately \$166.2 million. For the three months ended March 31, 2014, we reported a loss of approximately \$26.0 million and we had an accumulated deficit at March 31, 2014 of \$939.9 million. For the three months ended March 31, 2014, net revenue from the sale of Vascepa based on the MARINE indication was \$11.0 million. Given the substantial ongoing cost of the REDUCE-IT cardiovascular outcome study, our current capital resources and the current sales of Vascepa resulting from FDA approval of Vascepa for use in the MARINE indication, we may not be able to continue the study with our current financial resources and anticipated revenues from Vascepa without the additional revenues that may be available to us from the sale of Vascepa following an FDA approval of the ANCHOR indication. If we do not receive FDA approval of the ANCHOR indication, we plan to re-evaluate the REDUCE-IT study, including the likelihood of REDUCE-IT providing clinically and commercially useful results, the likelihood of FDA approval for an expanded indication for Vascepa based on these results and whether it is advisable to continue or discontinue the study. We anticipate that in any such re-evaluation we will seek further feedback from the FDA. If we do not receive FDA approval of the ANCHOR indication and do not continue the ongoing REDUCE-IT trial or our development of AMR102, our ability to generate revenue now and over the next several years will be substantially dependent on sales of Vascepa resulting from FDA approval of Vascepa for use in the MARINE indication. Accordingly, our prospects for substantially increasing future revenue from sales of Vascepa beyond what might be expected from the MARINE indication labeling alone will be substantially diminished.

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

As a result of our reliance on a single product and our primary focus on the U.S. market in the near-term, much of our near-term results and value as a company depends on our ability to execute our commercial strategy for Vascepa in the United States, which we launched in January 2013. If commercialization efforts for Vascepa in the MARINE indication are not successful, our business will be materially and adversely affected. Even if we are able to develop additional products from our research and development efforts, the development time cycle for products typically takes several years. This restricts our ability to respond to adverse business conditions for Vascepa. If we are not successful in developing any future product or products, or if there is not adequate demand for Vascepa or the market for such product develops less rapidly than we anticipate, we may not have the ability to effectively shift our resources to the development of alternative products or do so in a timely manner without suffering material adverse effects on our business. As a result, the lack of alternative products we develop could constrain our ability to generate revenues and achieve profitability.

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

In January 2013, we began selling and marketing Vascepa in the United States through our own, newly established sales and marketing teams and through a newly established third-party commercial distribution infrastructure. We hired key personnel in these areas over the last several years and hired and trained a professional sales force in early January 2013. In October 2013, following an FDA advisory committee recommendation against approval for the ANCHOR indication, we implemented a plan to reduce our workforce and our team of sales professionals in half. In May 2014 we plan to begin co-promoting Vascepa in the United States with Kowa Pharmaceuticals America, Inc., or Kowa Pharmaceuticals America, under a co-promotion agreement we entered into in March 2014. Under the agreement, approximately 250 Kowa Pharmaceuticals America sales representatives are expected to devote a substantial portion of their time to promoting Vascepa with Amarin's approximately 130 sales representatives based on a plan designed to substantially increase both the number of sales targets reached and the frequency of sales calls on existing sales targets. However, the commercialization of a new pharmaceutical product is a complex undertaking for a company to manage, and we have very limited experience as a company operating in this area and co-promoting a pharmaceutical product with a partner.

Factors related to building and managing a sales and marketing organization that can inhibit our efforts to successfully commercialize Vascepa include:

- our inability to attract and retain adequate numbers of effective sales and marketing personnel;
- our inability to adequately train our sales and marketing personnel, in particular as it relates to various healthcare regulatory requirements applicable to the marketing and sale of pharmaceutical products, and our inability to adequately monitor compliance with these requirements;
- the inability of our new sales personnel, working for us as a new market entrant, to obtain access to or persuade adequate numbers of physicians to prescribe Vascepa;
- the effect of our recent reduction in force and regulatory events on our ability to contact potential purchasers of Vascepa in an efficient manner;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with operating a new independent sales and marketing organization.

In addition, we believe that investors should view with caution both the results for the twelve months ended December 31, 2013 and the results for quarterly periods for the foreseeable future, as data for this limited period may not be representative of a trend consistent with the results presented or otherwise predictive of future results, especially in light of the recent negative advisory committee vote, the October 2013, approximately 50% reduction in our sales force and the March 2014 co-promotion Agreement with Kowa Pharmaceuticals America. We commenced our commercial launch of Vascepa on January 28, 2013. Accordingly, there is a very limited amount of information available at this time to determine the actual number of total prescriptions for Vascepa. We believe investors should consider our results for the twelve months ended December 31, 2013 together with results over several future quarters, or longer, before making an assessment about potential future performance.

In addition to the factors identified above, seasonal fluctuations in pharmaceutical sales, for example, may affect future prescription trends of Vascepa. Prior to 2013, we recognized no revenue from Vascepa sales. In accordance with GAAP, until we 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 us to such 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 revenue based on sales to our Distributors. The change in revenue recognition methodology resulted in the recognition of previously deferred revenue. At December 31, 2013, the Company had deferred approximately \$1.7 million in amounts billed to Distributors that was not recognized as revenue. This change in revenue recognition methodology resulted in the recognition of such deferred revenues during the three months ended March 31, 2014. Revenues for the three months ended March 31, 2014 based on the resale of Vascepa for the purposes of filling patient prescriptions during the period would have been \$10.0 million. We cannot assure that our revenue recognition process will consistently result in accurate financial results or that future adjustments, possibly material in scope or amount, will not occur.

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

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

We began marketing and selling Vascepa for use in the MARINE indication in January 2013. Vascepa may fail to gain sufficient market acceptance by physicians, patients, healthcare payors and others in the medical community. If Vascepa does not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of Vascepa for the MARINE indication and any future approved indications will depend on a number of factors, including:

- the perceived efficacy, safety and potential advantages of Vascepa, as compared to alternative treatments;
- our ability to offer Vascepa for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the scope, effectiveness and strength of product education, marketing and distribution support, including our sales and marketing team (which was affected by our recent reduction in force);
- publicity concerning Vascepa or competing products;

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- perception that we will continue to market and sell Vascepa in the MARINE indications and any future approved indications;
- sufficient third-party coverage or reimbursement; and
- the actual efficacy of the product and the prevalence and severity of any side effects, including any limitations or warnings contained in Vascepa's approved labeling.

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

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

Our competitors both in the United States and Europe include large, well-established pharmaceutical companies, specialty pharmaceutical sales and marketing companies, and specialized cardiovascular treatment companies. GlaxoSmithKline plc, which currently markets Lovaza®, a prescription-only omega-3 fatty acid indicated for patients with severe hypertriglyceridemia has been on the market since 2004. As described below, a generic version of Lovaza is now available in the United States. Other large companies with competitive products include AbbVie, Inc., which currently markets Tricor® and Trilipix® for the treatment of severe hypertriglyceridemia and mixed dyslipidemia and Niaspan, which is primarily used to raise HDL-C, but is also used to lower triglycerides. Generic versions of Tricor and Trilipix 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. 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. Pronova/BASF has appealed to the U.S. Supreme Court to challenge its loss in the Lovaza patent litigation against Teva and Par Pharmaceutical Inc., or Par, which, if Pronova/BASF wins, could lead to an injunction against Teva and Par from selling generic versions of Lovaza in the United States. In addition, in March 2011, Pronova/BASF entered into an agreement with Apotex Corp. and Apotex Inc., or Apotex, to settle its patent litigation in the United States related to Lovaza. Pursuant to the terms of the settlement agreement, Pronova/BASF granted Apotex a license to enter the United States market with a generic version of Lovaza in the first quarter of 2015, or earlier depending on circumstances. Apotex and Par must obtain FDA approval of generic versions of Lovaza before they are permitted to sell such products in the United States.

In addition, we are aware of other pharmaceutical companies that are developing products that, if approved and marketed, would compete with Vascepa. We understand that Acasti Pharma, a subsidiary of Neptune Technologies & Bioresources Inc., announced in late 2012 that it intends to conduct a Phase 3 clinical program to assess the safety and efficacy of its omega-3 prescription drug candidate derived from krill oil for the treatment of hypertriglyceridemia. We believe Catabasis Pharmaceuticals, or Catabasis, Resolvix Pharmaceuticals, or Resolvix, and Sancilio & Company are also developing potential treatments for hypertriglyceridemia based on omega-3 fatty acids. To our knowledge, Catabasis initiated a Phase 2 clinical trial of its product in December 2013; Resolvix's compound remains in Phase 1 clinical testing; and Sancilio is preparing to commence Phase 3 clinical testing. In addition, we are aware that Matinas BioPharma, Inc. is developing an omega-3-based therapeutic for the treatment of severe hypertriglyceridemia and mixed dyslipidemia. Matinas BioPharma, Inc. has reported that it is preparing to file an Investigational New Drug Application with the FDA and to conduct a human study in the first half of 2014. 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.

**** 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."

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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 have received five paragraph IV notices notifying us of submitted ANDAs to Vascepa under the Hatch-Waxman Amendments. We are now engaged in costly litigation with the ANDA applicants to protect our patent rights. If an ANDA filer is ultimately successful in patent litigation against us, it meets the requirements for a generic version of Vascepa to the satisfaction of the FDA under its ANDA (after any applicable regulatory exclusivity period and the litigation-related 30-month stay period expires), and is able to supply the product in significant commercial quantities, the generic company could, with the market introduction of a generic version of Vascepa. Such a market entry would likely limit our U.S. sales, which would have an adverse impact on our business and results of operations. In addition, even if a competitor's effort to introduce a generic product is ultimately unsuccessful, the perception that such development is in progress and/or news related to such progress could materially affect the perceived value of our company and our stock price.

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

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

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

NCE marketing exclusivity, not granted to Vascepa, precludes approval during the five-year exclusivity period of certain 505(b)(2) applications and ANDAs submitted by another company for another version of the drug. However, an application may be

submitted after four years if it contains a certification of patent invalidity or non-infringement. In this case, the pioneer drug company may be afforded the benefit of a 30-month stay against the launch of such a competitive product that would extend from the end of the 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 afforded the benefit of a 30-month stay against the launch of such a competitive product that would extend from the period that Amarin receives notice of the patent challenge (the paragraph IV notice), assuming Amarin responds to the patent challenge with 45 days, and Amarin may also be afforded a judicial extension if applicable requirements are met. This three-year form of exclusivity may also not prevent the FDA from approving an NDA that relies only on its own data to support the change or innovation.

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

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

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

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

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

In March 2014, we entered into a co-promotion agreement with Kowa Pharmaceuticals America to co-promote Vascepa in the United States under which approximately 250 Kowa Pharmaceuticals America sales representatives are expected to devote a substantial portion of their time to promoting Vascepa with Amarin's approximately 130 sales representatives. Co-promotion under the agreement is expected to commence during May 2014 based on a plan designed to substantially increase both the number of sales targets reached and the frequency of sales calls on existing sales targets. While our agreement provides for minimum performance

criteria, we have little control over Kowa Pharmaceuticals America, and it may fail to devote the necessary resources and attention to promote Vascepa effectively. If that were to occur, depending on Vascepa revenues, we may have to curtail the continued development of Vascepa for approval for additional indications or increase our planned expenditures and undertake additional development or commercialization activities at our own expense. Or, we may seek to terminate the agreement and search for another commercialization partner. If we elect to increase our expenditures to fund development or commercialization activities on our own, depending on Vascepa's revenues, we may need to obtain additional capital, which may not be available to us on acceptable terms, or at all, or which may not be possible due to our other financing arrangements. If we do not generate sufficient funds from the sale of Vascepa or, to the extent needed to supplement funds generated from product revenue, cannot raise sufficient funds, we may not be able to devote resources sufficient to market and sell Vascepa on our own in a manner required to realize the full market potential of Vascepa.

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

There can be no assurance as to the adequacy for commercial success of the scope and breadth of the MARINE indication or, if approved, the ANCHOR indication. Even if we obtain marketing approval for additional indications, the FDA may impose restrictions on the product's conditions for use, distribution or marketing and in some cases may impose ongoing requirements for post-market surveillance, post-approval studies or clinical trials. Also, with regard to the MARINE indication and any other indications for which we may gain approval, the number of actual patients with the condition included in such approved indication may be smaller than we anticipate. If any such approved indication is narrower than we anticipate, the market potential for our product would suffer.

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

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

With respect to sales and marketing activities including direct-to-consumer advertising and promotional activities involving the internet, advertising and promotional materials must comply with FDA rules in addition to other applicable federal and local laws in the United States and in other countries. Industry-sponsored scientific and educational activities also must comply with FDA and other requirements. In the United States, the distribution of product samples to physicians must comply with the requirements of the U.S. Prescription Drug Marketing Act. Manufacturing facilities remain subject to FDA inspection and must continue to adhere to the FDA's current good manufacturing practice requirements, or cGMPs. Application holders must obtain FDA approval for product and manufacturing changes, depending on the nature of the change. We also are subject to the new federal transparency requirements under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, which require manufacturers of certain drugs, devices, biologics, and medical supplies to report to the Centers for Medicare & Medicaid Services, or CMS, information related to payments and other transfers of value to physicians and teaching hospitals and physician ownership and investment interests. We may also be subject, directly or indirectly through our customers and partners, to various fraud and abuse laws, including, without limitation, the U.S. Anti-Kickback Statute, U.S. False Claims Act, and similar state laws, which impact, among other things, our proposed sales, marketing, and scientific/educational grant programs. If we participate in the U.S. Medicaid Drug Rebate Program, the Federal Supply Schedule of the U.S. Department of Veterans Affairs, or other government drug programs, we will be subject to complex laws and regulations regarding reporting and payment obligations. All of these activities are also potentially subject to U.S. federal and state consumer protection and unfair competition laws. Similar requirements exist in many of these areas in other countries.

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

The commercial value of Vascepa may be negatively affected by the advisory committee recommendation against approval of Vascepa in the ANCHOR indication, the rescission of the ANCHOR SPA agreement or any subsequent rejection of the pending FDA application with the FDA for the use of Vascepa in the ANCHOR indication.

Though we are restricted from promoting Vascepa under applicable regulations for any indication other than the FDA-approved MARINE indication, healthcare professionals are not restricted from prescribing Vascepa for such so-called off-labeled uses. A

significant amount of the sales of Vascepa may, in fact, be attributable to so-called off-labeled uses of the drug. We expect that among the off-labeled uses of Vascepa are uses that would fall into, or be closely related to, the proposed ANCHOR indication. The recent negative recommendation of the advisory committee meeting against approval of Vascepa in the ANCHOR indication, the recent rescission by the FDA of the ANCHOR SPA, and/or a subsequent decision by the FDA to not approve Vascepa in the ANCHOR indication may negatively and materially affect the perception of the utility of Vascepa for use in the ANCHOR indication or for other purposes and thus negatively and materially affect sales of Vascepa.

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products. If we or Kowa Pharmaceuticals America are found to have improperly promoted off-label uses of Vascepa, we may become subject to significant fines and other liability.

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. Even though we received FDA marketing approval for Vascepa for the MARINE indication, physicians may still prescribe Vascepa to their patients for use in the treatment of conditions that are not included as part of the indication statement in our FDA-approved Vascepa label. If we are found to have promoted such off-label uses, we may become subject to significant government fines and other related liability. We may also be held responsible for the non-compliance of our co-promotion partner, Kowa Pharmaceuticals America. For example, the Federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

In addition, incentives exist under applicable laws that encourage competitors, employees and physicians to report violations of rules governing promotional activities for pharmaceutical products. These incentives could lead to so-called whistleblower lawsuits as part of which such persons seek to collect a portion of moneys allegedly overbilled to government agencies due to, for example, promotion of pharmaceutical products beyond labeled claims. These incentives could also lead to suits that we have mischaracterized a competitor's product in the marketplace and may, as a result, be sued for alleged damages to our competitors. Such lawsuits, whether with or without merit, are typically time-consuming and costly to defend. Such suits may also result in related shareholder lawsuits, which are also costly to defend.

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

In accordance with the SPA for our MARINE and ANCHOR trials, efficacy was evaluated in these trials compared to placebo at twelve weeks. No placebo-controlled studies have been conducted regarding the long-term effect of Vascepa on lipids, and no outcomes study has been conducted evaluating Vascepa. The REDUCE-IT study is designed to evaluate the efficacy of Vascepa in reducing major cardiovascular events in an at-risk patient population on statin therapy.

Outcomes studies of certain other lipid-modifying therapies have failed to achieve the endpoints of such studies. For example, in 2010, the results of the ACCORD-Lipid trial were published. This trial studied the effect of adding fenofibrate onto open-label simvastatin therapy on cardiovascular outcomes. The addition of fenofibrate did not show any treatment benefit on cardiovascular outcomes over simvastatin monotherapy in this study. In 2011, the results of the AIM-HIGH trial were published. This trial studied the effect of adding a second lipid-altering agent, extended-release niacin, to simvastatin therapy on cardiovascular outcomes in people at high risk for cardiovascular events. No significant incremental treatment benefit with extended-release niacin was observed. In addition, in September 2012, researchers published in the *Journal of the American Medical Association*, or *JAMA*, the results of a retrospective meta-analysis of twenty previously conducted studies regarding the use of omega-3 supplements across various patient populations. This meta-analysis suggested that the use of such supplements was not associated with a lower risk of all-cause death, cardiac death, sudden death, heart attack, or stroke. We believe the results of these studies may not be directly applicable to the use of Vascepa over time. For instance, the outcomes studies for fenofibrates and niacin were conducted in patient populations in which the majority of patients studied had triglycerides below 200 mg/dL and fenofibrates and niacin are believed to work differently than Vascepa in the body and do not have as favorable a side-effect profile, and nineteen of the twenty studies included in the JAMA meta-analysis involved the use of omega-3 supplements containing a mixture of EPA and DHA, and most were evaluated at relatively lower doses. In addition, in May 2013, *The New England Journal of Medicine* published the results of an outcome study of 1 gram per day of an omega-3 acid ethyl ester composition. In that study, the composition failed to show a benefit in reducing the rate of death from cardiovascular causes or hospitalization for cardiovascular causes when administered to patients with cardiovascular risk factors under different study conditions than in the REDUCE-IT study. Vascepa is comprised of highly-pure ethyl-EPA, and has been approved by the FDA for use in patients with severe hypertriglyceridemia at a dose of 4 grams per day.

The only other outcomes study involving the use of a highly-pure formulation of ethyl-EPA, called the Japan EPA Lipid Intervention Study (JELIS), suggested that use of a highly-pure formulation of ethyl-EPA in Japan, when used in conjunction with

statins, reduced cardiovascular events by 19% compared to the use of statins alone. However, there are several limitations to the JELIS study. First, the patient population was exclusively Japanese, the majority of the participants were women, and at baseline patients had a much higher LDL, limiting its generalizability to the intended target population. Second, a low dose of statins was used. It is unknown whether the positive treatment effects would have persisted if these patients had been optimally treated with statins using contemporary LDL targets in the United States. Third, JELIS was an open-label trial, which could influence patient and physician behavior and reporting of symptoms, decisions regarding hospitalization, and referral of events for adjudication. This may be particularly relevant since hospitalizations for unstable angina was a primary contributor of the overall positive result, and is considered a softer endpoint than fatal cardiovascular events.

Although we believe the results of the JAMA meta-analysis and other studies are not directly applicable to the potential long-term clinical experience with Vascepa, there can be no assurance that the endpoints of the REDUCE-IT cardiovascular outcomes study will be achieved or that the lipid-modifying effects of Vascepa in REDUCE-IT or any other study of Vascepa will not be subject to variation beyond twelve weeks. If the REDUCE-IT trial fails to achieve its clinical endpoints or if the results of these long-term studies are not consistent with the 12-week clinical results, it could prevent us from expanding the label of any approved product or even call into question the efficacy of any approved product.

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

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

- the lack of efficacy during clinical trials;
- the inability to manufacture sufficient quantities of qualified materials under cGMPs for use in clinical trials;
- slower than expected rates of patient recruitment;
- the inability to observe patients adequately after treatment;
- changes in regulatory requirements for clinical or preclinical studies;
- the emergence of unforeseen safety issues in clinical or preclinical studies;
- delay, suspension, or termination of a trial by the institutional review board responsible for overseeing the study at a particular study site;
- unanticipated changes to the requirements imposed by regulatory authorities on the extent, nature or timing of studies to be conducted on quality, safety and efficacy;
- government or regulatory delays or “clinical holds” requiring suspension or termination of a trial; and
- political instability affecting our clinical trial sites, such as the potential for political unrest affecting our REDUCE-IT clinical trial sites in the Ukraine and Russia.

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

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

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

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

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

- An annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents;
- A new Medicare Part D coverage gap discount program, in which pharmaceutical manufacturers who wish to have their drugs covered under Part D must offer discounts to eligible beneficiaries during their coverage gap period; and
- A new formula that increases the rebates a manufacturer must pay under the Medicaid Drug Rebate Program.

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

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

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

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

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

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

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

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

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

We initially purchased all of our supply of the bulk compound (ethyl-EPA), which constitutes the only active pharmaceutical ingredient, or API, of Vascepa, from a single supplier, Nisshin Pharma, or Nisshin, located in Japan. Nisshin was approved by the FDA as a Vascepa API supplier as part of our FDA marketing approval for the MARINE indication in July 2012. In April 2013, we announced the approval by the FDA of Chemport, Inc. and BASF (formerly Equateq Limited) as additional Vascepa API suppliers. We purchase and use commercial supply from Chemport in addition to Nisshin. We recently terminated our agreement with BASF due to its inability to meet the agreement requirements and may enter into a new development and supply agreement with BASF and may purchase API from BASF. Each of the API manufacturers obtains supply of the key raw material to manufacture API from other third party sources of supply.

While we have contractual freedom to source the API for Vascepa and have entered into supply agreements with multiple suppliers who also rely on other third party suppliers of the key raw material to manufacture the API for Vascepa, Nisshin and Chemport currently supply all of our API for Vascepa. Our strategy in adding API suppliers beyond Nisshin has been to expand manufacturing capacity and to partially mitigate the risk of reliance on one supplier.

Also, in December 2012 we announced the addition of an exclusive consortium of companies led by Slanmhor Pharmaceutical, Inc. to our planned API global supply chain for Vascepa. Slanmhor Pharmaceutical, Inc. was spun-out from Ocean Nutrition Canada, or ONC, prior to the May 2012 acquisition of ONC by Royal DSM N.V., a global leader in life sciences and materials sciences. Once the Slanmhor consortium's application is approved by the FDA, Amarin will have a total of four suppliers of qualified API to utilize in supporting the global commercialization of Vascepa, subject to appropriate regulatory approval of the consortium, for which we submitted a sNDA in August 2013. The Slanmhor consortium is working to complete construction and validation of its facility for the manufacture of Vascepa.

Expanding manufacturing capacity and qualifying such capacity is difficult and subject to numerous regulations and other operational challenges. The resources of our suppliers vary and are limited; costs associated with projected expansion and qualification can be significant. For example, Chemport, which was approved as one of our API suppliers in April 2013, is a privately-held company and their commitment to Vascepa supply has required them to seek additional resources. There can be no assurance that the expansion plans of any of our suppliers will be successful. Our aggregate capacity to produce API is dependent upon the qualification of our API suppliers. Each of our API suppliers has outlined plans for potential further capacity expansion. If no additional API supplier is approved by the FDA, our API supply will be limited to the API we purchase from previously approved suppliers. If our third party manufacturing capacity is not expanded and compliant with application regulatory requirements, we may not be able to supply sufficient quantities of Vascepa to meet anticipated demand. We cannot assure you that we can contract with any future manufacturer on acceptable terms or that any such alternative supplier will not require capital investment from us in order for them to meet our requirements. Alternatively, our purchase of supply may exceed actual demand for Vascepa.

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We currently rely exclusively on Patheon (formerly Banner Pharmacaps) for the encapsulation of Vascepa. We have encapsulation agreements with two other commercial API encapsulators. These companies are working to qualify their processes and to prove that the Vascepa capsules they produce meet the same quality standards as the capsules produced by Patheon. There can be no guarantee that additional other suppliers with which we have contracted to encapsulate API will be qualified to manufacture the product to our specifications or that these and any future suppliers will have the manufacturing capacity to meeting anticipated demand for Vascepa. We cannot assure you that we can contract with any future manufacturer on acceptable terms or that any such alternative supplier will not require capital investment from us in order for them to meet our requirements.

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

Certain of our agreements with our suppliers include minimum purchase obligations and limited exclusivity provisions based on such minimum purchase obligations. If we do not meet the respective minimum purchase obligations in our supply agreements, our suppliers, in certain cases, will be free to sell the active pharmaceutical ingredient of Vascepa to potential competitors of Vascepa. Similarly if we terminate certain of our supply agreements, such suppliers may be free to sell the active pharmaceutical ingredient of Vascepa to potential competitors of Vascepa. On December 30, 2013, we issued a notice of termination in connection with our active pharmaceutical ingredient supply agreement with BASF as a result of BASF's non-compliance with the terms of such agreement. Our agreement with BASF is now terminated and though we may enter into another agreement with BASF, it is now free to sell active pharmaceutical ingredient to our competitors. 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. For example, we have filed a supplemental NDA to add the Slanmhor consortium as an additional API supplier for Vascepa. If the Slanmhor consortium cannot establish, to the satisfaction of the FDA, that it is in substantial compliance with cGMPs, and that the product manufactured at its site meets FDA requirements, we may not be able to manufacture API from that site, our supply of API for Vascepa may be delayed, and our anticipated future revenues and financial results may be materially adversely affected if such supply cannot be satisfied by our other three API suppliers.

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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.

Risks Related to our Intellectual Property

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

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

- obtain, defend and maintain patent protection and market exclusivity for our current and future products;
- preserve any trade secrets relating to our current and future products;
- acquire patented or patentable products and technologies; and
- operate without infringing the proprietary rights of third parties.

Amarin has prosecuted, and is currently prosecuting, multiple patent applications to protect the intellectual property developed during the Vascepa cardiovascular program. As of the date of this report, we had 40 patent applications in the United States that have been either issued or allowed and more than 30 additional patent applications are pending in the United States. Of such 40 allowed and issued applications, we currently have:

- 2 issued U.S. patents directed to a pharmaceutical composition of Vascepa in a capsule that have terms that expire in 2020 and 2030, respectively,
- 1 issued U.S. patent covering a composition containing highly pure EPA that expires in 2021,
- 35 U.S. patents covering the use of Vascepa in either the MARINE or anticipated ANCHOR indication that have terms that expire in 2030,
- 1 additional patent related to the use of a pharmaceutical composition comprised of free fatty acids to treat the ANCHOR patient population with a term that expires in 2030, and
- 1 additional patent related to the use of a pharmaceutical composition comprised of free fatty acids to treat the MARINE patient population with a term that expires in 2030.

A Notice of Allowance is issued after the USPTO makes a determination that a patent can be granted from an application. A Notice of Allowance does not afford patent protection until the underlying patent is issued by the USPTO. No assurance can be given that applications with issued notices of allowance will be issued as patents or that any of our pending patent applications will issue as

patents. No assurance can be given that, if and when issued, our patents will prevent competitors from competing with Vascepa. We are also pursuing patent applications related to Vascepa in multiple jurisdictions outside the United States. We may be dependent in some cases upon third party licensors to pursue filing, prosecution and maintenance of patent rights or applications owned or controlled by those parties. It is possible that third parties will obtain patents or other proprietary rights that might be necessary or useful to us. In cases where third parties are first to invent a particular product or technology, or first to file after various provisions of the America Invents Act of 2011 went into effect on March 16, 2013, it is possible that those parties will obtain patents that will be sufficiently broad so as to prevent us from utilizing such technology or commercializing our current and future products.

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

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

We anticipate that competitors may from time to time oppose our efforts to obtain patent protection for new technologies or to submit patented technologies for regulatory approvals. Competitors may seek to oppose our patent applications to delay the approval process or to challenge our granted patents, for example, by requesting a reexamination of our patent at the USPTO, or by filing an opposition in a foreign patent office, even if the opposition or challenge has little or no merit. Such proceedings are generally highly technical, expensive, and time consuming, and there can be no assurance that such a challenge would not result in the narrowing or complete revocation of any patent of ours that was so challenged.

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

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

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

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

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

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

Securing patent protection for a product is a complex process involving many legal and factual questions. The patent applications we have filed in the United States and internationally are at varying stages of examination, the timing of which is outside

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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

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

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

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

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

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

We are subject to potential product liability.

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

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

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

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

In June 2009, in keeping with our decision to re-focus our efforts on developing improved treatments for cardiovascular disease and cease development of all product candidates outside of our cardiovascular disease focus, we amended the terms of our acquisition agreement with the original shareholders of Ester. Under the terms of this amendment, Amarin was released from all research and development diligence obligations contained in the original agreement and was authorized to seek a partner for EN101. The amendment agreement also provided that any future payment obligations payable by us to the former shareholders of Ester would be made only out of income received from potential partners. In connection with this amendment agreement, in August 2009 we issued 1,315,789 ordinary shares to the former Ester shareholders. Under the terms of this amendment agreement, the former Ester shareholders have the option of reacquiring the original share capital of Ester if we are unable to successfully partner EN101.

Following our decision to cease development of EN101, Yisum terminated its license agreement with us. In June 2011, Yisum announced that it had entered into a license agreement with BiolineRX Ltd for the development of EN101 in a different indication, inflammatory bowel disease.

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

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

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

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

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

We are highly dependent upon the efforts of our senior management. The loss of the services of one or more members of senior management could have a material adverse effect on us. As a small company with a streamlined management structure, the departure of any key person could have a significant impact and would be potentially disruptive to our business until such time as a suitable replacement is hired. Furthermore, because of the specialized nature of our business, as our business plan progresses we will be highly dependent upon our ability to attract and retain qualified scientific, technical and key management personnel. As we evolve from a development stage company to a commercial stage company we may experience turnover among members of our senior management team. We may have difficulty identifying and integrating new executives to replace any such losses. There is intense competition for qualified personnel in the areas of our activities. In this environment, we may not be able to attract and retain the personnel necessary for the development of our business, particularly if we do not achieve profitability. Furthermore, the lessened probability that we will obtain FDA approval for the ANCHOR indication could have an adverse impact on our ability to retain and recruit qualified personnel. In addition, in October 2013, we eliminated approximately fifty percent of our staff positions worldwide as part of a restructuring following the FDA advisory committee's recommendation against the potential Vascepa label expansion. Even though all employees were offered severance pay in exchange for signing a comprehensive release of claims, this restructuring could lead to claims by former employees related to their termination. The restructuring could also have an adverse impact on our ability to retain and recruit qualified personnel. The failure to recruit key scientific, technical and management personnel would be detrimental to our ability to implement our business plan.

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

A significant portion of our sales are to wholesalers in the pharmaceutical industry. Our top three customers accounted for 96% and 94% of gross product sales for the quarters ended March 31, 2014 and 2013, respectively and represented 95% and 96% of the gross accounts receivable balance as of March 31, 2014 and March 31, 2013, respectively. There can be no guarantee that we will be able to sustain our accounts receivable or gross sales levels from our key customers. If, for any reason, we were to lose, or experience a decrease in the amount of business with our largest customers, whether directly or through our distributor relationships, our financial condition and results of operations could be negatively affected.

Risks Related to our Financial Position and Capital Requirements

We have a history of operating losses and anticipate that we will incur continued losses for an indefinite period of time.

We have not been profitable in any of the last five fiscal years. For the fiscal years ended December 31, 2013, 2012, and 2011, we reported losses of approximately \$166.2 million, \$179.2 million, and \$69.1 million, respectively, and we had an accumulated deficit at December 31, 2013 of \$913.9 million. For the three months ended March 31, 2014 and 2013, we reported losses of approximately \$26.0 million and \$62.2 million, respectively, and we had an accumulated deficit at March 31, 2014 of \$939.9 million. Substantially all of our operating losses resulted from costs incurred in connection with our research and development programs, from general and administrative costs associated with our operations, costs related to the commercialization of Vascepa, and from non-cash losses on changes in the fair value of warrant derivative liabilities. Additionally, as a result of our significant expenses relating to research and development and to commercialization, we expect to continue to incur significant operating losses for an indefinite period. Because of the numerous risks and uncertainties associated with developing and commercializing pharmaceutical products, we are unable to predict the magnitude of these future losses. Our historic losses, combined with expected future losses, have had and will continue to have an adverse effect on our cash resources, shareholders' deficit and working capital.

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

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

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

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

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

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

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

- the level of demand for Vascepa;

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- the extent to which coverage and reimbursement for Vascepa is available from government and health administration authorities, private health insurers, managed care programs and other third-party payers;
- the timing, cost and level of investment in our sales and marketing efforts to support Vascepa sales and the resulting effectiveness of those efforts with our new co-promotion partner, Kowa Pharmaceuticals America;
- additional developments regarding our intellectual property portfolio and regulatory exclusivity protections, if any;
- the results of our sNDA application for the ANCHOR indication and the results of the REDUCE-IT study or post-approval studies for Vascepa;
- outcomes of litigation and other legal proceedings, including recently initiated shareholder litigation, regulatory matters and tax matters; and
- whether we continue the REDUCE-IT study.

We may require substantial additional resources to fund our operations. If we cannot find additional capital resources, we will have difficulty in operating as a going concern and growing our business.

We currently operate with limited resources. We believe that our cash and cash equivalents balance of \$164.3 million at March 31, 2014 will be sufficient to fund our projected operations for at least the next twelve months.

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

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

- revenue generated from the commercial sale of Vascepa in the MARINE indication and, subject to FDA approval, the ANCHOR indication;
- the costs associated with commercializing Vascepa for the MARINE indication in the United States and for additional indications in the United States and in jurisdictions in which we receive regulatory approval, if any, including the cost of sales and marketing capabilities with our new co-promotion partner, Kowa Pharmaceuticals America, and the cost and timing of securing commercial supply of Vascepa and the timing of entering into any new strategic collaboration with others relating to the commercialization of Vascepa, if at all, and the terms of any such collaboration;
- the continued cost associated with our REDUCE-IT cardiovascular outcomes study, if we continue that study;
- continued cost associated with litigation and other legal proceedings, including recently initiated shareholder litigation and patent litigation; and
- the time and costs involved in obtaining additional regulatory approvals for Vascepa;
- the extent to which we continue to develop internally, acquire or in-license new products, technologies or businesses; and
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

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

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

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

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

While we may seek additional funding through public or private financings, we may not be able to obtain financing on acceptable terms, or at all. There can be no assurance that we will be able to access equity or credit markets in order to finance our

current operations or expand development programs for Vascepa, or that there will not be a further deterioration in financial markets and confidence in economies. We may also have to scale back or further restructure our operations. If we are unable to obtain additional funding on a timely basis, we may be required to curtail or terminate some or all of our research or development programs or our commercialization strategies.

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

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

As of March 31, 2014, there were warrants outstanding for the purchase of up to 9,772,276 ADSs each representing one of our ordinary shares, with a weighted average exercise price of \$1.41 per share. We may issue additional warrants to purchase ADSs or ordinary shares in connection with any future financing we may conduct. In addition, on January 9, 2012, we issued \$150 million in aggregate principal amount of 3.50% exchangeable senior notes due 2032, or the notes. The notes are exchangeable under certain circumstances into cash, our ADS, or a combination of cash and ADS, at our election, with a current exchange rate of 113.4752 ADS per \$1,000 principal amount of notes. Although we intend to settle these notes in cash, if we elected physical settlement, the notes would initially be exchangeable into 17,021,280 ADS.

Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration, strategic alliance and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, Vascepa or product candidates beyond the rights we have already relinquished, or grant licenses on terms that are not favorable to us.

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

On a regular basis, we explore potential business combination transactions, including an acquisition of us by a third party, exclusive licenses of Vascepa or other strategic transactions or collaborations with third parties. For example, in March 2014, we entered into a co-promotion agreement with Kowa Pharmaceuticals America related to the commercialization of Vascepa in the United States. The consummation and performance of any such future transactions or collaborations will involve risks, such as:

- diversion of managerial resources from day-to-day operations;
- exposure to litigation from the counterparties to any such transaction, other third parties or our shareholders;
- misjudgment with respect to the value;
- higher than expected transaction costs; or
- an inability to successfully consummate any such transaction or collaboration.

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

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 May 1, 2014 we had 172,906,063 common shares outstanding including 172,440,450 shares held as ADSs and 465,613 held as common shares (which are not held in the form of ADSs). In our October 2009 private placement we issued 66.4 million ADSs and warrants to purchase an additional 33.2 million ADSs. There is a risk that there may not be sufficient liquidity in the market to accommodate significant increases in selling activity or the sale of a large block of our securities. Our ADSs have historically had limited trading volume, which may also result in volatility. If any of our large investors, such as the participants in our October 2009 private placement, seek to sell substantial amounts of our ADSs, particularly if these sales are in a rapid or disorderly manner, or other investors perceive that these sales could occur, the market price of our ADSs could decrease significantly.

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

- developments or disputes concerning ongoing patent prosecution efforts and any future patent or proprietary rights;
- regulatory developments in the United States, the European Union or other countries;
- actual or potential medical results relating to our products or our competitors' products;
- interim failures or setbacks in product development;
- innovation by us or our competitors;
- currency exchange rate fluctuations; and
- period-to-period variations in our results of operations.

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

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

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

In accordance with the guidelines specified under Rule 10b5-1 of the Securities and Exchange Act of 1934 and our policies regarding stock transactions, a number of our directors and employees, including members of our senior management team, have adopted and may continue to adopt pre-arranged stock trading plans to sell a portion of our common stock. Generally, sales under such plans by members of our senior management team and directors require public filings. Actual or potential sales of our ADSs by such persons could cause the price of our ADSs to fall or prevent it from increasing for numerous reasons. For example, a substantial amount of our ADSs becoming available (or being perceived to become available) for sale in the public market could cause the market price of our ADSs to fall or prevent it from increasing. Also, actual or potential sales by such persons could be viewed negatively by other investors.

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

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

We believe it prudent to assume that we were classified as a PFIC in 2012. We do not believe that we were classified as a PFIC in 2013. Our status as a PFIC is subject to change in future years.

If we are a PFIC, U.S. holders of notes, ordinary shares or ADSs would be subject to adverse U.S. federal income tax consequences, such as ineligibility for any preferred tax rates on capital gains or on actual or deemed dividends, interest charges on certain taxes treated as deferred, and additional reporting requirements under U.S. federal income tax laws and regulations. Whether or not U.S. holders of our ADSs make a timely “QEF election” or “mark-to-market election” may affect the U.S. federal income tax consequences to U.S. holders with respect to the acquisition, ownership and disposition of Amarin ADSs and any distributions such U.S. Holders may receive. A QEF election and other elections that may mitigate the effect of our being classified as a PFIC are unavailable with respect to the notes. Investors should consult their own tax advisors regarding all aspects of the application of the PFIC rules to the notes, ordinary shares and ADSs.

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

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

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

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

To secure our obligations under the agreement, we granted BioPharma a security interest in our rights in patents, trademarks, trade names, domain names, copyrights, know-how and regulatory approvals related to the covered products, all books and records relating to the foregoing and all proceeds of the foregoing, which we refer to as the collateral. If we (i) fail to deliver a payment when due and do not remedy that failure within specific notice period, (ii) fail to maintain a first-priority perfected security interest in the collateral in the United States and do not remedy that failure after receiving notice of such failure or (iii) become subject to an event of bankruptcy, then BioPharma may attempt to collect the maximum amount payable by us under this agreement (after deducting any payments we have already made).

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

Our existing indebtedness could adversely affect our financial condition.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- Under English law and our Articles of Association, each shareholder present at a meeting has only one vote unless demand is made for a vote on a poll, in which case each holder gets one vote per share owned. Under U.S. law, each shareholder typically is entitled to one vote per share at all meetings.

Under English law, it is only on a poll that the number of shares determines the number of votes a holder may cast. You should be aware, however, that the voting rights of ADSs are also governed by the provisions of a deposit agreement with our depositary bank.

- Under English law, subject to certain exceptions and disapplications, each shareholder generally has preemptive rights to subscribe on a proportionate basis to any issuance of ordinary shares or rights to subscribe for, or to convert securities into, ordinary shares for cash. Under U.S. law, shareholders generally do not have preemptive rights unless specifically granted in the certificate of incorporation or otherwise.
- Under English law and our Articles of Association, certain matters require the approval of 75% of the shareholders who vote (in person or by proxy) on the relevant resolution (or on a poll shareholders representing 75% of the ordinary shares voting (in person or by proxy)), including amendments to the Articles of Association. This may make it more difficult for us to complete corporate transactions deemed advisable by our board of directors. Under U.S. law, generally only majority shareholder approval is required to amend the certificate of incorporation or to approve other significant transactions.

- In the United Kingdom, takeovers may be structured as takeover offers or as schemes of arrangement. Under English law, a bidder seeking to acquire us by means of a takeover offer would need to make an offer for all of our outstanding ordinary shares/ADSs. If acceptances are not received for 90% or more of the ordinary shares/ADSs under the offer, under English law, the bidder cannot complete a “squeeze out” to obtain 100% control of us. Accordingly, acceptances of 90% of our outstanding ordinary shares/ADSs will likely be a condition in any takeover offer to acquire us, not 50% as is more common in tender offers for corporations organized under Delaware law. By contrast, a scheme of arrangement, the successful completion of which would result in a bidder obtaining 100% control of us, requires the approval of a majority of shareholders voting at the meeting and representing 75% of the ordinary shares voting for approval.
- Under English law and our Articles of Association, shareholders and other persons whom we know or have reasonable cause to believe are, or have been, interested in our shares may be required to disclose information regarding their interests in our shares upon our request, and the failure to provide the required information could result in the loss or restriction of rights attaching to the shares, including prohibitions on certain transfers of the shares, withholding of dividends and loss of voting rights. Comparable provisions generally do not exist under U.S. law.
- The quorum requirement for a shareholders’ meeting is a minimum of two shareholders entitled to vote at the meeting and present in person or by proxy or, in the case of a shareholder which is a corporation, represented by a duly authorized officer. Under U.S. law, a majority of the shares eligible to vote must generally be present (in person or by proxy) at a shareholders’ meeting in order to constitute a quorum. The minimum number of shares required for a quorum can be reduced pursuant to a provision in a company’s certificate of incorporation or bylaws, but typically not below one-third of the shares entitled to vote at the meeting.

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

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 6. Exhibits

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

<u>Exhibit Number</u>	<u>Description</u>
10.1	Co-Promotion Agreement dated March 31, 2014, by and among the Company and Kowa Pharmaceuticals America, Inc. †
31.1	Certification of Chief Executive Officer (Principal Executive Officer) pursuant to Section 302 of Sarbanes-Oxley Act of 2002
31.2	Certification of President (Principal Financial Officer) pursuant to Section 302 of Sarbanes-Oxley Act of 2002
32.1	Certification of Chief Executive Officer (Principal Executive Officer) and President (Principal Financial Officer) pursuant to Section 906 of Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

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

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: May 9, 2014

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH “[***]”. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT UNDER RULE 24b-2 OF THE SECURITIES EXCHANGE ACT OF 1934.

Exhibit 10.1

**EXECUTION VERSION
CONFIDENTIAL**

CO-PROMOTION AGREEMENT

by and among

AMARIN PHARMACEUTICALS IRELAND LIMITED, AMARIN PHARMA, INC.

and

KOWA PHARMACEUTICALS AMERICA, INC.

MARCH 31, 2014

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CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH “[***]”. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT UNDER RULE 24b-2 OF THE SECURITIES EXCHANGE ACT OF 1934.

CO-PROMOTION AGREEMENT

This Co-Promotion Agreement (this “**Agreement**”) is entered into as of March 31, 2014 (the “**Effective Date**”) by and among Amarin Pharmaceuticals Ireland Limited, a company incorporated under the laws of Ireland (registered number 408912) with offices at 2 Pembroke House Upper Pembroke Street 28-32, Dublin 2, Ireland (“**Amarin Ireland**”), and Amarin Pharma, Inc., a Delaware corporation with offices at 1430 Route 206 North, Suite 101, Bedminster, NJ 07921 (“**Amarin Pharma**”, and collectively with Amarin Ireland, “**Amarin**”), on the one hand, and Kowa Pharmaceuticals America, Inc., a Delaware corporation with offices at 530 Industrial Park Blvd, Montgomery, AL 36117 (“**Kowa**”), on the other hand.

RECITALS

WHEREAS, Amarin Ireland owns certain intellectual property and regulatory rights relating to a drug known as Vascepa® (icosapent ethyl) capsules giving it the right to market and sell Vascepa in the Territory;

WHEREAS, Amarin Ireland has granted to Amarin Pharma the right to market and sell Vascepa in the Territory;

WHEREAS, Kowa possesses expertise in the commercialization of pharmaceutical products in the Territory and Amarin desires to engage the services of Kowa to co-promote, and Kowa desires to co-promote, Vascepa in the Territory together with Amarin Pharma to the extent set forth herein; and

WHEREAS, the Parties’ goal under this Agreement is to increase the sales of the Product in the Field in the Territory.

NOW, THEREFORE, in consideration of the following mutual promises and obligations, and for other good and valuable consideration the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

ARTICLE 1

DEFINITIONS

1.1 “Act” means the United States Federal Food, Drug and Cosmetic Act, 21 U.S.C. 301 et seq, as it may be amended from time to time, and relevant regulations and guidelines promulgated thereunder.

1.2 “Active Moiety” means the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds) or other noncovalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance.

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1.3 “Adverse Event” means any adverse event associated with the use of a drug/product in humans, whether or not considered drug related, including the following: (a) an adverse event occurring in the course of the use of a drug/product in professional practice, (b) an adverse event occurring from drug overdose whether accidental or intentional, (c) an adverse event occurring from drug abuse, (d) an adverse event occurring from drug withdrawal, or (e) any failure of expected pharmacological action.

1.4 “Affiliate” means, in relation to a Party, any person, corporation, firm or partnership or other entity, whether *de jure* or *de facto*, which directly or indirectly through one or more intermediaries controls, is controlled by or is under common control with such Party. An entity shall be deemed to control another entity if it: (a) owns, directly or indirectly, more than fifty percent (50%) of the outstanding voting securities or capital stock (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) of such other entity, or has other comparable ownership interest with respect to any entity other than a corporation, or (b) has the power, whether pursuant to contract, ownership of securities or otherwise, to direct the management and policies of such other entity.

1.5 “Agreement” has the meaning set forth in the Preamble to this Agreement.

1.6 “Amarin” has the meaning set forth in the Preamble to this Agreement.

1.7 “Amarin Ireland” has the meaning set forth in the Preamble to this Agreement.

1.8 “Amarin Indemnitees” has the meaning set forth in Section 11.5.

1.9 “Amarin Intellectual Property” means Amarin Patents and Amarin Know-How.

1.10 “Amarin Know-How” means Know-How Controlled by Amarin during the Term that (a) is relevant to this Agreement, and (b) relates to the Product in the Field in the Territory.

1.11 “Amarin Patents” means any patents or patent applications (including any substitutions, divisions, continuations, continuations-in-part, patents of addition, substitutions, registrations, reissues, re-examinations, extensions, renewals, and confirmations, and any patent issued with respect to any such patent application) Controlled by Amarin during the Term that (a) are relevant to this Agreement, and (b) claim inventions directed to the manufacture, composition, formulation or use of the Product in the Field in the Territory.

1.12 “Amarin Pharma” has the meaning set forth in the Preamble to this Agreement.

1.13 “Amarin Sales Representative” means an individual employed or utilized by Amarin (for clarity, other than a Kowa Sales Representative) who (a) engages in Detailing and other activities as a commercial pharmaceutical sales representative that are in compliance with Applicable Laws, and who is trained with respect to the Product, including the Product Labeling and the legal use of said Product Labeling, to engage in such activities with respect to the Product in the Field in the Territory, and (b) has not been threatened with or excluded or debarred by any Regulatory Authority.

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1.14 “Amarin Trademarks” means the registered and unregistered trademarks, trade names, logos and housemarks of Amarin and any of its Affiliates set forth on Schedule 1.14, and intellectual property rights residing in such trademarks or trade names, including copyrights and design rights.

1.15 “ANCHOR Data” means data generated through conducting clinical trials that are intended to support obtaining Regulatory Approval for the Product in the ANCHOR Indication.

1.16 “ANCHOR Indication” means (a) the use of the Product as an adjunct to diet and exercise for adult patients on statin therapy with mixed dyslipidemia (one or more lipid disorders) and triglyceride levels between 200 and 499 mg/dL, or (b) such similar indication covering the range of triglyceride levels between 200 and 499 mg/dL as it may be described in the final FDA approved Product Labeling for the Product based primarily on the ANCHOR Data.

1.17 “Annual PDE Requirements” has the meaning set forth in Section 4.4.1(a).

1.18 “Applicable Laws” means any and all statutes, ordinances, regulations, rules, or guidance of any kind whatsoever and any and all requirements under permits, orders, decrees, judgments or directives and requirements of applicable Governmental Authorities, in each case pertaining to any of the activities contemplated by this Agreement, including any regulations and guidelines promulgated by any Regulatory Authority in the Territory, all as amended from time to time.

1.19 “Audit” has the meaning set forth in Section 7.5.5.

1.20 “Benefit Plans” has the meaning set forth in Section 4.3.5(f).

1.21 “Board” has the meaning set forth in Section 1.23.

1.22 “Business Day” means a day other than a Saturday, Sunday, or a day on which banking institutions in New York, New York are closed.

1.23 “Change of Control” means, with respect to a Party, any of the following events: (a) any Third Party acquires directly or indirectly the beneficial ownership of any voting security of such Party or its controlling Affiliate representing more than fifty percent (50%) of the total voting power of the then-outstanding voting securities of such Party or its controlling Affiliate, (b) the consummation of a merger, consolidation, recapitalization, or reorganization of such Party or its controlling Affiliate with or by a Third Party which would result in more than fifty percent (50%) of the total voting power of the capital stock being transferred to a Third Party, or (c) a change in the composition of such Party’s, or its controlling Affiliate’s, board of directors (the “**Board**”) over a period of twelve (12) consecutive months or less such that a majority of such Board’s members cease by reason of one or more contested elections for Board membership to be comprised of individuals whose election is endorsed by a majority of the members of such Board immediately before the date of election.

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1.24 “Claims” means all charges, complaints, actions, suits, proceedings, hearings, investigations, claims, demands, judgments, orders, decrees, stipulations or injunctions.

1.25 “Codes” mean the Code on Interactions with Healthcare Professionals promulgated by the Pharmaceutical Research and Manufacturers of America (PhRMA) and the American Medical Association Guidelines on Gifts to Physicians, as either of the foregoing may be amended from time to time, and relevant regulations and guidelines promulgated thereunder.

1.26 “Commercially Reasonable Efforts” means, with respect to a Party’s obligation to perform or achieve a specified obligation for the Product or generally under this Agreement, the efforts, expertise, degree of skill, and resources that are comparable in quality and scope to those efforts, expertise, degree of skill and resources that are generally used by such Party to perform or achieve a comparable obligation for a pharmaceutical product Controlled by such Party, which has the same regulatory requirements or status (for example, requires a prescription or is available over-the-counter), is at a comparable stage of development or product life as the Product, and that has similar market potential as the Product, taking into account relative safety and efficacy, product profile, the competitiveness of the marketplace, relevant regulatory circumstances, and other relevant factors, including technical, legal, scientific and/or medical factors, but, in any event, a Party’s effort shall be no less than the effort that a comparable pharmaceutical company would expend with respect to a comparable pharmaceutical product controlled by such company taking into consideration the factors outlined above.

1.27 “Competing Product” means any product (other than the Product) (i) with the same Active Moiety (including drugs with the same Active Moiety included within such product as part of a drug mixture or a fixed dose combination), or in the same class of drug (i.e., Omega-3) as the Product, or (ii) [***]. For clarity, [***] shall not be “Competing Products” for purposes of this Agreement.

1.28 “Confidential Information” has the meaning set forth in Section 10.2.

1.29 “Confidentiality Agreement” has the meaning set forth in Section 10.2.

1.30 “Control” means, with respect to any Know-How, physical material, patent right, or other intellectual property right, possession by a Party or its Affiliates (whether by ownership, license grant or other means) of the legal right to grant the right to access or use, or to grant a license or a sublicense to, such Know-How, physical material, patent right, or other intellectual property right as provided for herein without violating the proprietary rights of any Third Party or any terms of any agreement or other arrangement between such Party (or any of its Affiliates) and any Third Party.

1.31 “Co-Promote Fee Tail Payment” has the meaning set forth in Section 5.3.1.

1.32 “Co-Promotion Fee” has the meaning set forth in Section 5.1.

1.33 “Cost of Goods” means, for Product manufactured by Amarin or a Third Party, Amarin’s actual costs of manufacturing, packaging, and testing the Product and amounts paid to a Third Party for such activities, calculated in accordance with GAAP, including: (a) the costs and expenses associated with components, such as raw materials, drugs and chemicals, encapsulation, packaging materials and components, (b) any applicable net sales taxes, customs duties and similar import fees or costs and freight actually paid by Amarin, (c) direct production labor, (d) Third Party logistics fees and pass-through expenses, and (e) allocated indirect and overhead charges, including insurance and internal staffing, but for clarity, excluding amortization, depreciation and other non-cash charges. Notwithstanding the foregoing, Cost of Goods will exclude the related cost of inventory related to deferred revenue recognized for Products sold in the Territory prior to the Effective Date.

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1.34 “Detail(s)” means an in-person, face to face sales call between a Target and a Kowa Sales Representative or an Amarin Sales Representative, during which the Product’s attributes, benefits, prescribing information, and fairly balanced Safety Information are orally presented in compliance with all Applicable Laws and with or without Promotional Materials. For clarity, (a) presentations made at conventions, exhibit booths, educational programs or speaker meetings, or similar gatherings, and (b) Sample drops (if applicable) and reminders, shall not, in each case of clause (a) or (b), constitute a Detail. Any Details performed in a group situation or in a dinner meeting shall only be considered a single Detail regardless of the number of participants, unless there occur in conjunction therewith one-on-one Details, in which case each such additional one-on-one Detail shall be counted each as a Detail. When used as a verb, ‘**Detail**’ means to engage in a Detail.

1.35 “Dollars” means United States Dollars.

1.36 “Effective Date” has the meaning set forth in the Preamble to this Agreement.

1.37 “Federal Arbitration Act” has the meaning set forth in Section 14.3.

1.38 “Field” means (a) an adjunct treatment to diet to reduce triglyceride (TG) levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia, and (b) any other indications for which the Product is approved by the FDA for sale in the United States, including, to the extent approved by the FDA, the ANCHOR Indication.

1.39 “FDA” means the United States Food and Drug Administration or any successor agency performing comparable functions.

1.40 “Force Majeure” means circumstances beyond the reasonable control of either Party, including acts of God, fires, explosions, earthquakes, floods, droughts, riots, acts of terrorism, wars, civil disturbances, sabotage, accidents, strikes or other labor disputes, unforeseen material shortages or supplier failures or any other event or circumstance of the like of different character to the foregoing beyond the reasonable control and without the fault or negligence of a Party.

1.41 “GAAP” means generally accepted accounting principles in the United States.

1.42 “Governmental Authority” means any multi-national, federal, state, county, local, municipal or other governmental authority or self-regulating organization of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal), including the FDA, the SEC and The NASDAQ Stock Market, Inc.

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1.43 “Gross Margin” means [***]. Gross Margin shall be calculated [***].

1.44 “Gross Sales” means the [***]. For the avoidance of doubt[***]. Notwithstanding the foregoing, Gross Sales will exclude [***].

1.45 “Indemnitee” has the meaning set forth in Section 11.6.

1.46 “Initial Term” has the meaning set forth in Section 12.1.

1.47 “Inventions” has the meaning set forth in Section 9.1.

1.48 “JAMS Rules” has the meaning set forth in Section 14.3.

1.49 “Joint Steering Committee” or “JSC” means the committee established in accordance with the procedures set forth in Section 3.1.

1.50 “Know-How” of a Party means all present and future information, whether or not in written form, whether or not in the public domain and shall include biological, chemical, pharmacological, toxicological, medical or clinical, analytical, quality, manufacturing, research, or sales and marketing information, including processes, methods, procedures, techniques, plans, programs and data.

1.51 “Kowa” has the meaning set forth in the Preamble to this Agreement.

1.52 “Kowa Indemnitees” has the meaning set forth Section 11.4.

1.53 “Kowa Sales Representative” means an individual employed by Kowa who (a) engages in Detailing and other activities as a commercial pharmaceutical sales representative that are in compliance with Applicable Laws, and who is trained with respect to the Product, including the Product Labeling and the legal use of said Product Labeling, to engage in such activities with respect to the Product in the Field in the Territory, and (b) has not been threatened with or excluded or debarred by any Regulatory Authority. Kowa Sales Representatives shall not engage in medical affairs activities (including receiving, approving or delivering grants) nor will they attend formulary committee meetings and no MSL shall serve as a Kowa Sales Representative.

1.54 “Kowa Trademarks” means the registered and unregistered trademarks, trade names, logos and housemarks of Kowa and any of its Affiliates set forth on Schedule 1.54, and intellectual property rights residing in such trademarks or trade names, including copyrights and design rights.

1.55 “Losses” means any and all amounts paid or payable to Third Parties with respect to a Claim of a Third Party, together with all documented Out-of-Pocket Expenses, including attorney’s fees, reasonably incurred in complying with any judgments, orders, decrees, stipulations and injunctions that arise out of a Claim of a Third Party.

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1.56 “Major Market Event” means an event occurring after the Effective Date that materially adversely affects the market or profitability for the Product in the Territory including: [***]. For purposes of this Section 1.56, [***] means [***].

1.57 “Marketing Expenses” means, [***].

1.58 “MSL” means a medical scientific liaison who (a) conducts service based medical activities including providing input and assistance with consultancy meetings, recommending investigators for clinical trials and providing input in the design of such trials and other research related activities, and (b) delivers non-promotional communications and conducts non-promotional activities including reactively responding to enquiries of medical professionals for off-label information and presenting new clinical trial and other scientific information.

1.59 “Net Sales” means [***].

1.60 “Net Sales Tail Payment” has the meaning set forth in Section 5.3.2, as applicable.

1.61 “OIG” means the United States Department of Health and Human Services Office of the Inspector General.

1.62 “OIG Guidance” has the meaning set forth in Section 7.5.2.

1.63 “Out-of-Pocket Expenses” means expenses actually paid by a Party or its Affiliate to any Third Party.

1.64 “Party” means Amarin or Kowa.

1.65 “Performance Standards” has the meaning set forth in Section 4.7.

1.66 “PDMA” means the Prescription Drug Marketing Act, and relevant regulations and guidelines promulgated thereunder.

1.67 “Primary Detail” means a Detail where [***].

1.68 “Primary Detail Equivalent” or **“PDE”** means a numerical amount that scores the value of Details performed by Kowa Sales Representatives or Amarin Sales Representatives: [***].

1.69 “Product” means (a) icosapent ethyl capsules or (b) any other preparations Controlled by Amarin containing icosapent ethyl or ethyl eicosapentaenoic acid as the only active pharmaceutical ingredient and only Active Moiety, in each case of clauses (a) and (b), as approved by the FDA for sale in the United States and sold under either the Vascepa® trademark or another trademark Controlled by Amarin. For clarity, “Product” does not include any product that combines icosapent ethyl or ethyl eicosapentaenoic acid with any other active pharmaceutical ingredient or Active Moiety.

1.70 “Product Invention” has the meaning set forth in Section 9.1.

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1.71 “Product Labeling” means all materials considered labeling of a Product by the FDA from time to time, including labels and other written, printed or graphic matter located on or in (a) any container or wrapper utilized with the Product (even if not physically attached thereto), or (b) any written material accompanying the Product, including, in each case, Product package inserts, invitations, signage, videotapes, CDs, DVDs, any other forms of electronic media, and any other format included in 21 C.F.R. 202.1(l)(2) (as may be supplemented or amended). For purposes of this Agreement, advertising as defined in 21 C.F.R. 202.1(l)(1) (as may be supplemented or amended) is considered Product Labeling.

1.72 “Product Launch” has the meaning set forth in Section 4.4.1.

1.73 “Promote” means any communications or persuasive activities by or on behalf of a Party intended to increase sales of the Product. Promotion includes activities such as distribution of Promotional Materials, Product sampling, advertising, the use of sales aids, and oral or electronic discussions with customers for the purpose of selling the Product. [***].

1.74 “Promotion Plan” means an annual plan that sets forth: (a) the manner in which the Parties shall deploy their respective efforts to Promote and Detail the Product in the Field in the Territory, (b) annual brand objectives, (c) tactical activities, (d) a call plan (including selection of Targets and Detailing frequency per Target), and (e) other matters relevant to Promotion and Detailing of the Product.

1.75 “Promotional Activity Data” has the meaning set forth in Section 4.5.1.

1.76 “Promotional Materials” means Product Labeling that is approved by Amarin for use in connection with the Promotion and Detailing of the Product in the Field in the Territory.

1.77 “Quarter” means, with respect to any given Year, the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 or December 31; provided, however, that (a) the first calendar quarter of the Term shall extend from the Effective Date to the end of the first full calendar quarter thereafter, and (b) the last calendar quarter of the Term shall end upon the effective date of termination or expiration of this Agreement.

1.78 “Regulatory Approval” means all approvals or licenses necessary for the manufacture, marketing, importation, storage and sale of the Product or a product for one or more indications in a country or regulatory jurisdiction, which may include satisfaction of all applicable regulatory and notification requirements, but which shall exclude any pricing and reimbursement approvals.

1.79 “Regulatory Authority” means, in a particular country or regulatory jurisdiction, any applicable Governmental Authority involved in granting Regulatory Approval and/or, to the extent required in such country or regulatory jurisdiction, governmental pricing or reimbursement approval of a Product in such country or regulatory jurisdiction, including the FDA.

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1.80 “Safety Information” means an Adverse Event from any source, where the product is known and at least one demographic is known for the reporter and the patient, including: (a) an Adverse Event related to a quality defect, (b) an event during pregnancy and lactation, without an associated Adverse Event, (c) a drug exposure via parent, (d) lack of efficacy, without an associated Adverse Event, (e) overdose (symptomatic or not), (f) interaction (symptomatic or not), (g) misuse and medication error (symptomatic or not), (h) drug abuse, (i) unintended beneficial effects, (j) serious reports from interventional clinical trials, (k) aggregate safety reports, or (l) administration via incorrect route.

1.81 “Sales Force SOPs” has the meaning set forth in Section 4.3.5(a).

1.82 “Sales Quarter” has the meaning set forth in Section 4.4.1(b).

1.83 “Sales Year” has the meaning set forth in Section 4.4.1(a).

1.84 “Sales Representative” means a Kowa Sales Representative or an Amarin Sales Representative.

1.85 “Sample” means a unit of prescription drug that is not intended to be sold and is intended to be distributed to a licensed practitioner to promote the sale of the Product in the Field in the Territory in accordance with this Agreement and all Applicable Laws.

1.86 “Sample Costs” means, for Samples manufactured by Amarin or a Third Party, Amarin’s actual costs of manufacturing, packaging, and testing the Samples and amounts paid to a Third Party, including: (a) the costs and expenses associated with components, such as raw materials, drugs and chemicals, encapsulation, packaging materials and components, (b) any applicable net sales taxes, customs duties and similar import fees or costs and freight actually paid by Amarin, and (c) direct production labor, all of the foregoing calculated in accordance with GAAP. Schedule 1.86 sets forth an example of the calculation of Sample Costs.

1.87 “SEC” means the United States Securities and Exchange Commission or any successor.

1.88 “Secondary Detail” means [***].

1.89 “Tail Period” shall mean the period commencing on the effective date of the expiration or termination of this Agreement and continuing until no further Tail Period Payments are due from Amarin to Kowa. The Parties acknowledge and agree that, depending on the basis for termination of this Agreement, there may be no Tail Period.

1.90 “Tail Period Payments” means the Co-Promote Fee Tail Payment or the Net Sales Fee Tail Payment, as applicable. The Parties acknowledge and agree that, depending on the basis for termination of this Agreement, there may be no Tail Period Payments.

1.91 “Target” means a healthcare professional with prescribing authority in the Territory to whom a Sales Representative Promotes the Product within applicable policy constraints and in compliance with Applicable Laws.

1.92 “Term” has the meaning set forth in Section 12.1.

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1.93 “Territory” means the fifty (50) United States of America, the District of Columbia and Puerto Rico.

1.94 “Third Party” means any person or entity other than Amarin and Kowa or their respective Affiliates.

1.95 “Transition Point” means such date and time during Year 2014 when annual Net Sales of the Product in the Field in the Territory [***], as such amount is calculated beginning on the date of Product Launch. The Parties acknowledge and agree that the Transition Point may not occur.

1.96 “Year” means (a) for the first calendar year, the period commencing on the Effective Date and ending on December 31, 2014, (b) for each successive period beginning on January 1 and ending twelve (12) consecutive calendar months later on December 31, and (c) for the calendar year in which this Agreement is terminated, the period beginning on January 1 of such calendar year and ending on the effective date of the termination of this Agreement.

ARTICLE 2

RIGHTS AND OBLIGATIONS

2.1 Grant of Right; Retention of Rights. During the Term, subject to the terms and conditions of this Agreement, Amarin Ireland hereby grants Kowa the exclusive right in the Territory to be the sole co-promoter of the Product, along with Amarin Pharma (and any contract sales force retained by Amarin in accordance with Section 15.1.2). In connection with the foregoing, Amarin Ireland hereby covenants and agrees that it will not enforce against Kowa any of Amarin Ireland’s rights to regulatory exclusivity or under the Amarin Intellectual Property in connection with Kowa’s performance of its obligations under this Agreement in accordance with the terms of this Agreement. Kowa shall not, and shall have no obligation or right under this Agreement to (a) Promote or Detail the Product (x) in the Territory outside of the Field or (y) outside of the Territory or (b) sell or offer to sell the Product; provided, however, Promotion shall not be deemed to be the act of selling or offering to sell. Subject to the terms and conditions of this Agreement, Amarin retains all other rights in and to the Product, including the right to Promote and Detail the Product in the Territory during the Term, to Promote the Product outside the Territory, and to sell and offer to sell the Product. Subject to the terms and conditions of this Agreement, Amarin specifically retains the following rights, obligations and responsibilities with respect to the Product:

(a) responsibility for the specifications for the Product, for the manufacture and distribution of the Product, and any future development of the Product (including all studies and clinical trials related thereto, and related regulatory filings);

(b) responsibility for all decisions regarding, and submission of, regulatory submissions, or notices of any kind, and for interactions with Governmental Authorities, including interactions arising from Kowa’s Promotion and Detailing of the Product, subject to meaningful consultation with, and opportunity for comment by, Kowa in circumstances where such submission, notice or interaction relates directly to Kowa’s Promotion or Detailing of the Product;

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(c) responsibility for creation, subsequent modification, internal approval, and filing of all Product Labeling, Promotional Material and medical/scientific material and content (including submission of Promotional Materials to the FDA’s Office of Prescription Drug Promotion);

(d) determining all Product pricing and positioning, including the timing of pricing changes, requests for reimbursement and the offering of any discounts (including cash discounts with wholesalers) or rebates;

(e) determining the Product sampling budget, subject to meaningful consultation with, and opportunity for comment by, Kowa (provided, that such sampling budget with respect to Samples to be distributed by Kowa shall not exceed the amount set forth in Section 4.4.1(b) without Kowa’s prior consent);

(f) booking all Product sales; and

(g) subject to Kowa’s obligations hereunder (or in any separate applicable agreement between the Parties), responsibility for (A) handling all safety-related activities (including receiving all safety related complaints), (B) submitting all safety reports and interacting with Regulatory Authorities with respect thereto), (C) initiating and managing any Product recalls, withdrawals or safety alerts, and (D) as of January 1, 2015, any investigations and notifications of “suspect or illegitimate product” (as such product is defined by the Drug Quality and Security Act (DQSA)).

For the avoidance of doubt, Amarin retains the exclusive right to make, sell and offer to sell the Product.

2.2 Non-compete.

2.2.1 Obligations. Subject to Section 2.2.2, during the Term and through the end of the [***] following the effective date of expiration or termination of this Agreement, Kowa and its Affiliates shall not, itself or with a Third Party, [***].

2.2.2 [*].**

2.2.3 Confirmation. As a condition to receiving the Tail Period Payments, if applicable, Kowa shall submit to Amarin on a Quarterly basis during the Tail Period a written confirmation of compliance with the terms of Section 2.2.1.

2.3 Amarin Trademarks. Kowa shall have the right to use the Amarin Trademarks (i) on the Promotional Materials, training materials, Samples, or any other item provided to Kowa by Amarin in connection with Kowa’s Promotion and Detailing of the Product in the Field in the Territory during the Term in accordance with the terms and conditions contained herein, and (ii) on Kowa’s website, or in Kowa’s promotional materials, in a manner solely intended to describe the relationship created under this Agreement, and in all cases subject to Amarin’s prior

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review and approval of such use(s) in each new circumstance, which shall not be unreasonably withheld, conditioned or delayed. In addition, subject to Section 10.4, Kowa shall have the right to use Amarin Trademarks otherwise only with the prior written consent of Amarin, which consent shall not be unreasonably withheld. Kowa shall not at any time during the Term do any act or thing which will in any way impair or diminish the rights of Amarin in or to the Amarin Trademarks. All goodwill and improved reputation generated by Kowa’s use of the Amarin Trademarks shall inure to the benefit of the appropriate Amarin entity (at Amarin’s discretion), and any use of the Amarin Trademarks by Kowa shall cease at the end of the Term. Kowa shall have no rights under this Agreement in or to the Amarin Trademarks or the goodwill pertaining thereto except as specifically provided herein. Kowa will not contest the ownership of the Amarin Trademarks, their validity, or the validity of any registration therefor during the Term or the Tail Period. Kowa undertakes during the Term and the Tail Period not to have registered and/or not to use any marks that are confusingly similar to the Amarin Trademarks.

2.4 Kowa Trademarks. Amarin shall have the right to use the Kowa Trademarks (i) on the Promotional Materials, training materials, Samples, or any other item used Amarin by in connection with Amarin’s Promotion and Detailing of the Product in the Field in the Territory during the Term, and thereafter until such materials run out of stock, in accordance with the terms and conditions contained herein, and (ii) on Amarin’s website, or in Amarin’s promotional materials, in a manner solely intended to describe the relationship created under this Agreement, and in all cases subject to Kowa’s prior review and approval of such use(s) in each new circumstance, which shall not be unreasonably withheld, conditioned or delayed. In addition, subject to Section 10.4, Amarin shall have the right to use the Kowa Trademarks otherwise only with the prior written consent of Kowa, which consent shall not be unreasonably withheld. Amarin shall not at any time during the Term do any act or thing which will in any way impair or diminish the rights of Kowa in or to the Kowa Trademarks. All goodwill and improved reputation generated by Amarin’s use of the Kowa Trademarks shall inure to the benefit of Kowa, and any use of the Kowa Trademarks by Amarin shall cease at the end of the Term. Amarin shall have no rights under this Agreement in or to the Kowa Trademarks or the goodwill pertaining thereto except as specifically provided herein. Amarin will not contest the ownership of the Kowa Trademarks, their validity, or the validity of any registration therefor during the Term or the Tail Period. Amarin undertakes during the Term or the Tail Period not to have registered and/or not to use any marks that are confusingly similar to the Kowa Trademarks.

2.5 Supply Assurance. Amarin shall use Commercially Reasonable Efforts to maintain approximately [***] of inventory of the Product based on Amarin’s commercially reasonable forecasted demand for the Product in the Field in the Territory. In the event that Amarin’s inventory of the Product falls below such threshold, Amarin shall notify Kowa accordingly. If Amarin subsequently experiences [***], then [***]; provided, that during the period of such stock-out, either (a) the Parties may mutually agree to terminate this Agreement in accordance with Section 12.2[***].

ARTICLE 3

GOVERNANCE

3.1 JSC.

3.1.1 Organization. Within twenty (20) days following the Effective Date, the Parties shall form a JSC whose responsibility shall be to manage the day-to-day Promoting and Detailing and compliance activities of the Parties under this Agreement during the Term. The JSC shall consist of an equal number of representatives from each Party, with at least three (3) representatives appointed by each Party. A Party may change any of its representatives on the JSC at any time with a new person (with appropriate expertise to replace the outgoing member) by giving written notice to the other Party; provided, however, that, without limiting the generality of the foregoing, a key objective with respect to membership in the JSC shall be preserving continuity.

3.1.2 Meetings. For the [***] following the Effective Date, the JSC shall meet on at least [***] basis (with the first meeting being held within twenty (20) days following the Effective Date), and thereafter the JSC shall meet at least [***] every Year on a [***] basis, in each case unless a particular meeting is waived by mutual consent. In addition, each Party shall have the right to call a meeting of the JSC on reasonable notice to the other Party. Subject to the foregoing, the JSC shall meet on such dates and at such times as agreed by the JSC and shall meet via teleconference or videoconference or, if mutually agreed by the Parties, at a location determined by the JSC. Each Party may permit visitors with particular insights regarding the subject matter of a given JSC meeting to attend such meeting; provided, that any such visitor shall be subject to written confidentiality and non-use obligations no less stringent than the terms of ARTICLE 10. Each Party shall be responsible for its own expenses for participating in the JSC. Meetings of the JSC will be chaired by a representative from Amarin. Meetings of the JSC shall be effective only if at least one (1) representative of each Party is present or participating, unless otherwise agreed in writing.

3.1.3 Minutes. Minutes of each JSC meeting will be transcribed and issued by a designee of the JSC within ten (10) Business Days after each meeting. The minutes, if accurate, shall be approved by each Party not later than the first order of business at the immediately succeeding JSC meeting; provided, that if there is a disagreement regarding accuracy, the Parties shall work together in good faith to resolve such disagreement and finalize such minutes as expeditiously as possible.

3.1.4 Decisions. The representatives of each Party serving on the JSC shall collectively have one (1) vote on all matters considered by the JSC. In the event that the JSC is unable to agree on any matter properly brought before it pursuant to Section 3.2, such matter shall be submitted to the Chief Executive Officer of each Party, who shall attempt to reach a mutually agreed upon resolution. If no resolution is possible after a good faith effort, then Amarin shall have final decision-making authority with respect to such dispute; provided, that Amarin shall not have the right to exercise its decision-making authority to amend this Agreement (e.g., to alter the Annual PDE Requirements under Section 4.4.1(a)).

3.2 Responsibilities of the JSC. Except as may be otherwise expressly set forth herein, Amarin will have final planning, oversight, performance evaluation and decision-making authority and responsibility for all sales, marketing and Promotional activities and attendant compliance activities related to the Product and Product Labeling. Notwithstanding the foregoing, Kowa will have the opportunity, through the JSC to confer with, or recommend ideas or Promotional Materials to, Amarin regarding such sales, marketing and Promotional matters. Without limiting the rights, obligations and responsibilities expressly reserved by Amarin under Section 2.1 (and Amarin’s decision-making authority with respect thereto), matters to come before the JSC shall be limited to the following:

- (a) Reviewing available Gross Sales, Net Sales, and other Territory-specific Product performance data as determined by the JSC;

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(b) Making recommendation for new materials for commercial support and Promotional Materials such as product detail aids, advertising, educational give-aways, speaker meetings, speaker kits and direct mail;

(c) Reviewing Sample demand forecast;

(d) Coordinating joint activities undertaken by the Parties in accordance with Section 4.11;

(e) Reviewing and discussing any market research conducted by either Party with respect to the Product in the Field in the Territory;

(f) Reviewing monthly activities of Sales Representatives;

(g) Reviewing the efforts of Sales Representatives who engage in Detailing and other Promotional efforts with respect to the Product to maintain desired frequency of Details and to avoid unintended duplication of Details;

(h) Reviewing, commenting on, and approving the annual Promotion Plan for the Product in accordance with Section 4.2 and monitoring the implementation of the Promotion Plan;

(i) Reviewing and auditing training needs and schedule, including corrective training;

(j) Discussing whether a Major Market Event has occurred and making recommendations with respect thereto;

(k) Establishing subcommittees on an as-needed and as-appropriate basis (e.g., a compliance subcommittee and/or a medical activities subcommittee to oversee medical / scientific matters), overseeing the activities of all subcommittees so established, and addressing disputes or disagreements arising in all such subcommittees;

(l) Considering and making recommendations on such other matters as are stipulated in this Agreement (e.g., non-commercial matters); and

(m) Performing such other responsibilities as may be assigned to the JSC pursuant to this Agreement or as may be mutually agreed upon by the Parties in writing from time to time;

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provided, however, that the JSC shall have no authority to amend any provision of this Agreement, make any binding interpretation of this Agreement, or determine whether or not a breach of this Agreement has occurred or to otherwise increase the devotion of financial or human resources of Kowa under this Agreement.

3.3 Major Market Events. In the event of facts that may amount to a Major Market Event either Party may request that the JSC meet within fifteen (15) days of the occurrence of such an event to discuss, in accordance with Section 3.2(j), whether a Major Market Event has occurred, to consider whether any adjustments to this Agreement should be undertaken to address such Major Market Event (subject to amendments to this Agreement to account for any such adjustments being subject to each Party’s sole discretion and Section 15.8), and to make recommendations with respect thereto.

ARTICLE 4

PROMOTION AND DETAILING OF PRODUCT

4.1 Generally. Amarin hereby engages Kowa, and Kowa hereby accepts such engagement, to Promote and Detail the Product in the Territory, subject to the terms and conditions of this Agreement. Kowa shall have no other rights relating to the Product except as specifically set forth in this Agreement. Commencing no later than [***] after the Effective Date, in order to permit completion of Kowa’s training of Kowa Sales Representatives and other employees engaged in Promoting the Product and subject to Amarin providing such Promotional Materials (and the conversion of such Promotional Materials from Amarin’s Apple format to Kowa’s Windows format) and training materials as Kowa reasonably requires in order to train and supply the Kowa Sales Representatives, Kowa shall deploy Kowa Sales Representatives and such other employees to Promote and Detail the Product in the Territory in accordance with the terms of this Agreement, the Promotion Plan and the instructions of the JSC. In conducting its activities hereunder, Kowa will use Commercially Reasonable Efforts to Promote and Detail the Product and to optimize sales of the Product in the Field during the Term. Amarin also will use Commercially Reasonable Efforts to Detail the Product and to optimize sales of the Product during the Term. The Parties shall cooperate, including taking such actions as are reasonably requested by the other Party, in performing their obligations hereunder.

4.2 Promotion Plan. Appropriate representatives from each Party will jointly prepare the initial Promotion Plan and provide it to the JSC for review, comment, and approval prior to Kowa initiating its Promotion and Detailing activities hereunder. By no later than December 15 of the first Year, the JSC shall review, comment on (if applicable), and approve any modifications to the initial Promotion Plan for the second Year of the Term, and shall thereafter update such Promotion Plan in accordance with Section 3.2(h) each Year thereafter that Kowa is Promoting and Detailing the Product. For clarity, the Promotion Plan will include a plan for Detailing of the Product by the Kowa Sales Representatives and Amarin Sales Representatives to Targets that will permit the Parties to satisfy their minimum PDE obligations under Section 4.4.1(a) or 4.4.2(a), as applicable.

4.3 Sales Representatives.

4.3.1 Generally. Kowa and Amarin shall at all times during the Term maintain a properly qualified and trained sales force containing [***] of Sales Representatives in order to satisfy their respective obligations under this Agreement (including Kowa’s and Amarin’s express obligations under Section 4.4.1 and Section 4.4.2, respectively).

4.3.2 Training.

(a) Amarin shall be responsible for providing initial Product and sales training materials for all Kowa Sales Representatives and members of Kowa’s sales management. In connection therewith, promptly after the Effective Date, Amarin will provide to Kowa sufficient copies of training materials and will make trainers reasonably available to train Kowa directly regarding compliance related matters (including (A) Detailing in compliance with Applicable Laws, Product Labeling and applicable Kowa policies and (B) maintaining Samples and records related thereto in accordance the PDMA, other Applicable Laws, Product Labeling and applicable Kowa policies) and to train Kowa trainers generally regarding the Product so that such Kowa trainers can train the Kowa Sales Representatives. Following Amarin’s initial direct training regarding compliance related matters (which may be done together with Kowa trainers), Kowa trainers shall be responsible for the further training and retraining of Kowa Sales Representatives regarding such matters. Kowa’s trainers and Product marketers shall have the right, with respect to the Product, to monitor and observe Amarin’s sales training programs and have ongoing access to new training materials developed by Amarin; provided, that (1) Amarin shall be entitled to exclude any person from such training for competitive reasons or to protect its confidential information or trade secrets pertaining to matters other than the Product and (2) such monitoring or observation is not disruptive to the training.

(b) Amarin’s training of Kowa personnel shall be conducted at places and times to be mutually agreed upon by the Parties promptly after the Effective Date; provided, that such training shall be consistent with Amarin’s regularly scheduled training programs. Amarin shall provide such training using a training program that relates to the Product (including training materials) and that is provided to Amarin’s sales force (with respect to Kowa Sales Representative level training and materials) or to Amarin’s district managers (with respect to Kowa’s sales management level training and materials). After the initial training, Amarin shall periodically provide additional training and continuing education materials to Kowa and Kowa’s trainers (as applicable), at Kowa’s expense except for Amarin’s travel and personnel expenses, on a regular basis so that Kowa may align on-going training of the Kowa Sales Representatives to the content training provided to Amarin Sales Representatives. Amarin agrees to provide such initial and additional training at Kowa’s cost, except for Amarin’s travel and personnel expenses, consistent with and on a schedule no less frequent than that provided to Amarin Sales Representatives by Amarin. The Parties shall work in good faith to arrange a mutually satisfactory training schedule for the Kowa Sales Representatives and Kowa’s sales management.

(c) No Kowa Sales Representative shall Promote or Detail the Product without having undergone training. Amarin shall have the right to monitor or observe all such Kowa training and training materials. The Parties acknowledge and agree that in order for a Kowa Sales Representative to be deemed to have successfully completed the training, such Kowa Sales Representative must demonstrate thorough knowledge of the medical and technical

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aspects of the Product and applicable commercial practices policies and must achieve scores on Product certifications of at least [***] percent ([***]%) on original testing or, if required, on re-testing on Product certifications. Kowa covenants that it shall use only training materials provided by, or approved by, Amarin in the performance of its responsibilities under this Agreement, and such materials shall not then be modified, changed, misbranded, or altered by Kowa or any Kowa Sales Representative at any time.

(d) Kowa shall bear all incremental costs and expenses of the trainers (except for Amarin’s travel and personnel expenses), training facility and training materials to train the Kowa Sales Representatives and Kowa’s sales management, and Kowa shall be responsible for all travel expenses and Out-of-Pocket Expenses incurred by the Kowa Sales Representatives and Kowa’s sales management in connection with such training.

4.3.3 Incentive Bonus. During the Term, at least [***] percent ([***]%) of the annual sales incentive bonus payable to a Kowa Sales Representative shall be allocated to the Product. The bonus shall not be capped.

4.3.4 Background Checks. Prior to assignment to Promote or Detail the Product, Kowa shall be responsible for performing background checks of all Kowa Sales Representatives. Kowa warrants that it has completed a background check of all Kowa Sales Representatives to determine (i) that no Kowa Sales Representative has any felony conviction and (ii) that no Kowa Sales Representative (A) is an excluded person on the OIG’s List of Excluded Individuals/Entities, (B) is on the General Services Administration Excluded Parties List, or (C) is on the FDA Debarment List.

4.3.5 Performance. Kowa agrees with respect to itself and the Kowa Sales Representatives that:

(a) Within five (5) Business Days after the Effective Date, Kowa will provide to Amarin Kowa’s sales force, marketing, Sample and related compliance program standard operating procedures (SOPs) (“**Sales Force SOPs**”), including such procedures as Amarin may specifically identify, to enable Amarin to determine whether such Sales Force SOPs are compliant with Applicable Laws and materially comparable to Amarin’s applicable standard operating procedures. Kowa will instruct the Kowa Sales Representatives to follow and comply with relevant portions of the Sales Force SOPs on or prior to the Effective Date, as such policies may be updated from time to time by Kowa to be compliant with Applicable Laws, and promptly reviewed by Amarin prior to implementation.

(b) Kowa will instruct the Kowa Sales Representatives to use, and will actively monitor and investigate (consistent with an effective comprehensive compliance program required under Applicable Laws) the Kowa Sales Representatives to ensure that such Kowa Sales Representatives use, only Promotional Materials, Samples and literature approved for use by Amarin for the Promotion and Detailing of the Product. Kowa will not, and will ensure that the Kowa Sales Representatives do not, misbrand, change or alter any Promotional Material or Samples (or use, sell or trade any Samples) supplied to it for distribution by Amarin;

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(c) Kowa will instruct the Kowa Sales Representatives to do, and will monitor the Kowa Sales Representatives so that such personnel do, the following: (A) Promote and Detail in full compliance with the Product Labeling and in adherence to all Applicable Laws, Sales Force SOPs, the Codes, and the Promotion Plan, and (B) **not** Promote or Detail the Product using social media, emails, or the internet.

(d) Kowa will comply with all Applicable Laws in the hiring, employment, and discharge of all Kowa Sales Representatives. Kowa represents that it is an Equal Opportunity Employer and does not discriminate against any person because of race, color, creed, age, sex, sexual preference, marital status, or national origin.

(e) Kowa acknowledges and agrees that Amarin does not and will not maintain or procure any worker’s compensation, healthcare, or other insurance for or on behalf of the Kowa Sales Representative, all of which shall be Kowa’s sole responsibility.

(f) Kowa acknowledges and agrees that all Kowa Sales Representatives are employees of Kowa and are not, and are not intended to be or be treated as, employees of Amarin or any of its Affiliates, and that such individuals are not, and are not intended to be, eligible to participate in any benefits programs or in any “employee benefit plans” (as such term is defined in Section 3(3) of ERISA) that are sponsored by Amarin or any of its Affiliates or that are offered from time to time by Amarin or its Affiliates to their own employees (the “**Benefit Plans**”).

(g) Notwithstanding Amarin’s rights to review, monitor or audit Kowa materials or activities, Kowa shall be solely responsible for its acts and omissions and for those acts or omissions of the Kowa Sales Representatives while performing any activities under this Agreement. Kowa shall be solely responsible and liable for all probationary and termination actions taken by it, as well as for the formulation, content and dissemination (including content) of all employment policies and rules (including written probationary and termination policies) applicable to its employees and contractors.

4.3.6 Compensation. Kowa shall be solely responsible for all costs and expenses of recruiting, hiring, maintaining and compensating the Kowa Sales Representatives, including salaries, benefits and incentive compensation; provided, that such incentive compensation shall be subject to Section 4.3.3 and shall not be structured in a manner that would reasonably be expected to inappropriately motivate such individuals to engage in the improper Promotion or Detailing of the Product. Amarin shall not be responsible to Kowa, or to the Kowa Sales Representatives, for any compensation, expense reimbursements or benefits (including vacation and holiday remuneration, healthcare coverage or insurance, life insurance, severance or termination of employment benefits, pension or profit-sharing benefits and disability benefits), payroll-related taxes or withholdings, or any governmental charges or benefits (including unemployment and disability insurance contributions or benefits and workmen’s compensation contributions or benefits) that may be imposed upon or be related to the performance by Kowa and such individuals of this Agreement, all of which shall be the sole responsibility of Kowa, even if it is subsequently determined by any court or governmental agency that any such individual may be an employee or a common law employee of Amarin or any of its Affiliates or is otherwise entitled to such payments and benefits.

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4.3.7 Product Basket Limitations. In connection with the fulfillment of Kowa’s Annual PDE Requirements under this Agreement, a Kowa Sales Representative shall not [***].

4.3.8 Transitioning Kowa Sales Representatives. If a Kowa Sales Representative leaves the employ of Kowa, or otherwise ceases to Detail the Product, Kowa shall, to the extent consistent with, and in a manner similar to, its practices with respect to departures of sales representatives promoting, marketing or detailing other products for Kowa, account for, and shall cause such departing Kowa Sales Representative to return to Kowa and delete from his/her computer files (to the extent such materials or information have been provided in, or converted into, electronic form), all materials relating to the Product that have been provided to such individual, including Samples (if applicable), Promotional Materials and account level information and training program materials, including all copies of the foregoing. Kowa shall reuse such materials for replacement Kowa Sales Representatives, to the extent practicable.

4.3.9 Kowa Sales Representative Audit. Amarin shall be entitled to audit Kowa’s training and compliance programs and the performance of the Kowa Sales Representatives, including compliance with the Sales Force SOPs and including by way of accompanying the Kowa Sales Representatives during their performance of Promotion and Detailing hereunder, in accordance with Section 7.5.5.

4.4 Minimum Sales Support.

4.4.1 By Kowa.

(a) Kowa shall provide the following minimum Details per [***] (“**Annual PDE Requirements**”) using no less than two hundred fifty (250) Kowa Sales Representatives:

[***]	[***]
Primary Details	[***]
Secondary Details	[***]

The [***] reference period for the performance of Kowa’s Annual PDE Requirements (a “**Sales Year**”) shall commence as of the first full calendar month after the date that the first Detail of the Product in the Territory is performed by Kowa (following completion of training obligations described herein with respect to Kowa Sales Representatives performing such Details) and reported in Kowa’s Detail recording system (such first Detail shall commence and constitute the “**Product Launch**”); provided, that Kowa’s Annual PDE Requirements shall be pro-rated for the final Year of the Term on the basis of such Detailing obligations being allocated evenly over an entire Sales Year (e.g., if the final Year of the Term overlaps with only three (3) months of a Sales Year, then Kowa shall only be obligated to perform one-fourth (1/4) of such Details). Kowa shall promptly advise Amarin in writing regarding any vacancies among the Kowa Sales Representatives that cause it to fall beneath the minimum Kowa Sales Representatives described above and shall, in any event, fill any such vacancies with appropriately qualified persons within [***]. “**Sales Quarter**” means the three (3)-month period commencing with the first full calendar month after Product Launch and each consecutive three (3)-month period thereafter. If Kowa fails to satisfy Kowa’s Annual PDE Requirements in a Sales Quarter, then[***].

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(b) In addition to its obligations under Section 4.4.1(a), Kowa shall expend [***] during the [***] in Marketing Expenses (which amount, for clarity, is exclusive of Kowa’s sales force-related costs); provided, that if Net Sales of the Product in the Field in the Territory during [***] exceed [***], then amounts that Kowa spent purchasing Samples during [***] shall reduce Kowa’s “Other Marketing Expenses” obligation under this Section 4.4.1(b) for [***] on a [***] to be pro-rated depending on the first day of Product Launch, assuming an effective Sales Year of [***]. For clarity, [***]. Kowa shall expend the foregoing sums on a [***] as follows:

[***]	[***]	[***]	[***]	[***]	[***]	[***]
Sample Costs	[***]	[***]	[***]	[***]	[***]	[***]
Other Marketing Expenses	[***]	[***]	[***]	[***]	[***]	[***]
Sub-Total	[***]	[***]	[***]	[***]	[***]	[***]

If Kowa fails to expend the amount required with respect to [***], then Kowa shall [***]. In the event that Kowa has not [***] and [***], Kowa shall [***]; provided, that, with respect to [***].

4.4.2 By Amarin.

(a) Amarin shall provide [***]; provided, that such Detailing obligations shall be [***] on the basis of such Detailing obligations being [***]. If Amarin fails to satisfy Amarin’s Annual PDE Requirements in any Sales Quarter then[***].

(b) In addition to its obligations under Section 4.4.2(a), Amarin shall [***] during the Initial Term in Marketing Expenses [***].

[***]	[***]	[***]	[***]	[***]	[***]	[***]
Sample Costs	[***]	[***]	[***]	[***]	[***]	[***]
Other Marketing Expenses	[***]	[***]	[***]	[***]	[***]	[***]
Sub-Total	[***]	[***]	[***]	[***]	[***]	[***]

If Amarin fails to expend the amount required with respect to [***], then Amarin shall [***].

4.5 Records and Reports.

4.5.1 Record Keeping. Commencing the month in which Product Launch occurs, Kowa shall record, [***]: (i) the number of Kowa Sales Representatives assigned to Detail the Product in the Territory, (ii) the territories of their assignments, (iii) the proportion of their time devoted to Promoting the Product, (iv) the number of Product-related Details and PDEs for Product made by Kowa Sales Representatives in the Territory, (v) the position of such Details, (vi) the amount of Marketing Expenses incurred, (vii) the amount of Samples dispensed to each physician Target, (viii) the prescriber identity (including applicable NPI number) of those receiving Samples, (ix) data required for government, state and other regulatory reporting requirements (including, data required under Section 1128G of the United States Social Security Act (i.e., the Physician Payment Sunshine Law) such as food, drops of literature, any gifts, payments or other transfers of value, state law data such as total spends in Minnesota, Massachusetts and California, and total marketing costs expended in Washington and West Virginia), and (x) such other information as the JSC may reasonably require and as may be required by Applicable Laws (collectively, the “**Promotional Activity Data**”).

4.5.2 Reporting by Kowa. In addition to the record keeping requirement set forth in Section 4.5.1, within [***] after the end of each [***] commencing with the [***] in which Product Launch occurs, Kowa shall furnish to Amarin a written report setting forth Kowa’s Promotional Activity Data for such month. In addition, within [***] after the end of each Year commencing with Year 2014, Kowa shall furnish to Amarin a written report setting forth, in the aggregate, the number of Kowa Sales Representatives assigned to the Product in the Territory, the number of PDEs for the Product provided by Kowa in the Territory during such Year, and the total Marketing Expenses incurred. Unless otherwise agreed by the JSC, Kowa’s reporting and record keeping with respect to Promotional Activity Data, including the calculation of Details and PDEs shall be in a format in reasonably acceptable to Amarin.

4.5.3 Reporting by Amarin. Within [***] after the end of each [***] commencing with the [***] in which Product Launch occurs, Amarin shall furnish to Kowa a written report setting forth the number of Product-related Details and the PDEs for Product made by Amarin Sales Representatives in the Territory for such [***].

4.6 Promotional Materials.

4.6.1 Generally. Amarin shall provide Kowa with all Promotional Materials to be used by the Kowa Sales Representatives in performing Promotion and Detailing activities under this Agreement. Kowa covenants that it shall use only Promotional Materials provided by Amarin in the performance of its responsibilities under this Agreement, and such materials shall not be modified, changed, misbranded, or altered by Kowa or any Kowa Sales Representative at any time, and Kowa and its Kowa Sales Representatives shall not use any Product Labeling that was not supplied by Amarin. Amarin shall create and control any digital marketing materials and Kowa shall not Promote or Detail the Product using social media, email or the internet. Kowa shall be timely provided such quantity of Promotional Materials as is set forth in the Promotion Plan or as may be determined by the JSC from time-to-time, which shall be reasonably sufficient to enable Kowa to meet its objectives under this Agreement. The Promotional Materials shall be in compliance in all material respects with the Product Labeling approved by the FDA and all Applicable Laws in the Territory and shall be suitable for use for Promotion of the Product in the Field.

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4.6.2 Costs. Notwithstanding anything to the contrary herein, Kowa shall be responsible for any incremental costs (including Out-of-Pocket Expenses, but excluding personnel costs) that Amarin incurs in providing Kowa with Promotional Materials or any other items or services hereunder. “Incremental costs” under this Section 4.6.2 is understood to be [***]. Amarin shall invoice Kowa for such costs from time-to-time, which invoices Kowa shall pay within thirty (30) days of receipt.

4.7 Performance Standards. Each Party will ensure the overall quality of Product Promotional efforts being provided by its Sales Representatives in the Territory, such quality being based on measures of compliance audit results (including those conducted pursuant to Section 7.5.5), call activity, message delivery and consistency, attendance at training seminars and Product meetings, proficiency with Product (including as set forth in Section 4.3.1), and other measures of performance (collectively, “**Performance Standards**”) established by the JSC and communicated to the Parties, including through the Parties’ representatives on the JSC. The JSC shall review the Performance Standards on an annual basis and update the Performance Standards if and when necessary based on evolving measurement tools, market conditions, commercial strategy and/or other relevant factors.

4.8 Samples.

4.8.1 Samples Generally. Amarin shall supply the quantity of Samples specified in the Promotion Plan to Kowa or Kowa’s designee in accordance with ARTICLE 6. Amarin shall be responsible for the design, production and procurement of all aspects of all Samples.

4.8.2 Sample Accountability Policies and Procedures.

(a) Kowa shall, and shall ensure that Kowa Sales Representatives, store, handle, transport and distribute Samples, and conduct Details, in accordance with the conditions set forth in the Product Labeling, the Sales Force SOPs, Kowa’s other applicable standard operating procedures, and otherwise in accordance with the PDMA and all other Applicable Laws governing the storage and distribution of pharmaceutical samples, and shall employ such measures as are necessary (including compliance with any Product insert) to prevent Sample contamination, deterioration or adulteration.

(b) Kowa will not distribute Samples to any Kowa Sales Representative that has not been trained in accordance with the Sales Force SOPs. From and after receipt by Kowa, Kowa’s distribution facilities and Kowa Sales Representatives shall (A) secure Samples against theft, tampering and diversion during and after storage and transport and (B) store Samples in a proper environment in accordance with the Product Labeling and any instructions received from Amarin with respect thereto.

(c) Amarin may, upon reasonable notice to Kowa, review Kowa’s sample accountability program for the Product. Amarin may choose to utilize the services of an outside vendor to perform this review.

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(d) Kowa will validate, or cause to be validated, the licensing status/sample eligibility of the prescribers selected to receive Samples and will maintain, or cause to be maintained, an up to date status file thereafter. Amarin shall be entitled to periodically conduct, or have conducted, an audit of Kowa’s license/sample eligibility status file for the Product to ensure that Kowa is properly validating such prescribers. Such status file shall be validated not less than (A) once per Year and (B) periodically throughout the Year when new Targets are added to the list of Targets eligible to receive Samples.

(e) Kowa covenants and warrants that it and the Kowa Sales Representatives shall: (A) only use Samples directly in connection, and accordance, with the PDMA and other Applicable Laws, and this Agreement and (B) not resell, repack, trade, use deconstruct, reverse engineer or otherwise use Samples or their packaging in any other non-compliant manner.

4.8.3 Certain Issues Involving Samples. Kowa shall notify Amarin within one (1) Business Day after receipt of information suggesting that (i) any Sample has been lost or stolen, (ii) any person has falsified a Sample request, a Sample receipt or Sample records, (iii) any Person is diverting Samples, (iv) any Samples have otherwise not been handled in accordance with the terms of this Agreement or Applicable Laws, or (v) any Sample is defective. Kowa and Amarin shall cooperate in making such investigations and reports related thereto as may be necessary under Applicable Laws. Kowa shall make drug accountability reports, Sample requests and receipts, and any other records pertaining to Samples or matters subject to PDMA, available to Amarin within twenty-four (24) hours of Amarin’s request. Kowa shall keep full and accurate books and records with respect to all of its obligations under the PDMA and Amarin shall have the right to audit such books and records in accordance with ARTICLE 8.

4.9 No Sales or Distribution; Returns. With respect to the Territory, Amarin shall sell (whether directly or through a designee) all Product to each customer, and shall book each sale. The Parties recognize that Kowa may from time to time receive orders for the Product directly from Third Parties for delivery in the Territory. In such event, Kowa promptly shall advise such Third Party that Kowa is not authorized to accept orders for the Product and shall immediately and accurately forward such order to Amarin, or its designee, which order Amarin may accept or reject in its sole discretion. Amarin (whether directly or through a designee) shall be responsible for handling all returns of the Product with respect to the Territory. If any Product sold in the Territory is returned to Kowa, Kowa shall either instruct the returning Party to, or shall itself if providing such instructions in a timely manner is not feasible (e.g., if Kowa receives a return through the mail), return such Product with appropriate documentation directly to Amarin or its designee, as directed by Amarin, at Amarin’s expense and in accordance with all Applicable Laws, as amended by the Drug Quality and Security Act (DQSA), but shall take no other actions with respect to such return without the prior written consent of Amarin. Amarin shall (whether directly or through a designee) have sole responsibility for shipping, distribution and warehousing, for the invoicing and billing of purchasers of the Product and for the collection of receivables resulting from the sales of the Product in the Territory.

4.10 Managed Care Organizations. Amarin will have sole responsibility for Promoting to, contracting with, and undertaking any and all other interactions regarding the Product with, managed health care organizations, group purchasing organizations, pharmacy benefit managers, large employers, long-term care organizations, insurers, formularies, government agencies and programs (e.g., Medicare and the Veterans Health Administration and other federal, state and local agencies), or similar organizations.

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4.11 Joint Activities. From time to time during the Term, the Parties may agree to permit joint promotional activities including both Kowa Sales Representatives and Amarin Sales Representatives, and the Parties will [***].

4.12 Communication with Sales Representatives. Each Party shall only communicate with designated representatives of the other Party (including, for example, through members of the JSC and designated subcommittees). Notwithstanding the foregoing, nothing herein shall restrict the Kowa Sales Representatives and Amarin Sales Representatives from communicating directly with one another. For clarity, as noted in Section 1.53, Kowa Sales Representatives shall not include MSLs; provided, however, that Amarin may provide information with respect to the Product to MSLs of Kowa for purposes of informing such MSLs about the Product in connection with such MSLs presence at relevant conferences.

4.13 Prohibition on Solicitation. Without the prior written consent of the other Party, neither Party nor its Affiliates shall, during the Term and for the longer of (i) a period of [***] following the expiration or termination of this Agreement or (ii) the duration of any Tail Period, solicit (directly), or attempt to solicit, any employee, director, or consultant who was employed or engaged by the other Party or its Affiliates. This provision shall not restrict either Party or its Affiliates from advertising employment opportunities in any manner that does not directly target employees, directors, or consultants of the other Party or its Affiliates or from employing anyone who responds to such advertisements.

ARTICLE 5

FINANCIAL PROVISIONS

5.1 Consideration Generally. In consideration for the performance of Kowa’s obligations hereunder, including compensation for Kowa’s Detailing efforts hereunder, during the Term Amarin shall pay Kowa a Quarterly percentage of the Gross Margin for the Product in the Territory (the “**Co-Promote Fee**”). In addition, following the expiration or earlier termination of the Term, under certain circumstances, Amarin shall pay to Kowa the Tail Period Payments, all as detailed herein.

5.2 Co-Promote Fee. The percentage used to calculate the Co-Promote Fee shall vary from Year-to-Year in accordance with Schedule 5.2. For clarity, in calculating Net Sales and Gross Sales for purposes of determining Gross Margin and the Co-Promote Fee the following principles shall apply: [***]

5.3 Tail Period Payments.

5.3.1 Upon Expiration. In the event that this Agreement expires in accordance with Section 12.1, and subject to Section 2.2, then Amarin shall pay Kowa the following “**Co-Promote Fee Tail Payment**” in accordance with Section 13.5(a): [***]

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5.3.2 Upon Certain Terminations. In the event that this Agreement is terminated prior to the expiration of the Term under the circumstances described in this Section 5.3.2 then Amarin shall pay Kowa the indicated “**Net Sales Tail Payment**” for the relevant indicated period in accordance with Section 13.5(b):

(a) if such termination occurs pursuant to Section 12.4.1 in connection with a Change of Control of Amarin (regardless whether such termination is initiated by Amarin, Amarin’s successor or Kowa) and on or prior to the second anniversary of the Effective Date, and subject to Section 2.2: [***]

(b) if such termination occurs pursuant to (1) Section 12.4.1 in connection with a Change of Control of Amarin (regardless whether such termination is initiated by Amarin, Amarin’s successor or Kowa) and following the [***] of the Effective Date, or (2) Section 12.4.1 in connection with a Change of Control of Kowa and such termination is initiated by Amarin (regardless whether such termination occurs prior to, on or after the [***] of the Effective Date), or (3) Section 12.3(a) in connection with a material breach by Amarin and is initiated by Kowa (regardless whether such termination occurs prior to, on or after the [***] of the Effective Date), and, in all cases of clauses (1), (2) and (3), subject to Section 2.2: [***]

(c) if such termination occurs pursuant to Section 12.2 in accordance with the Parties’ mutual agreement (which termination, for clarity, may not be effective prior to the [***] of the Effective Date), and subject to Section 2.2:

(i) if such mutual termination occurs in connection with a Major Market Event: [***]

(ii) if such mutual termination occurs between the [***] of the Effective Date (and is not in connection with a Major Market Event):

[***]

(iii) if such mutual termination occurs between the [***] of the Effective Date (and is not in connection with a Major Market Event):

[***]

(iv) if such mutual termination occurs between the [***] of the Effective Date (and is not in connection with a Major Market Event):

[***]

5.3.3 Tail Period Payments Generally. Kowa shall be entitled to receive the Tail Period Payments solely under the circumstances described in Sections 5.3.1 and 5.3.2 and as further described in Section 13.5. For clarity, but without limitation, if this Agreement is terminated prior to expiry of the Term by (i) Amarin due to a material breach by Kowa or in accordance with Sections 4.4.1(a) and/or 12.6, (ii) Kowa, or its successor, in connection with a Change of Control of Kowa in accordance with Section 12.4.1, or in connection with a waiver in accordance with Section 2.2.2(ii), or in accordance with Sections 4.4.2(a) and/or 12.7, or (iii) either Party for any reason other than those expressly described in Section 5.3.1 or Section 5.3.2 then, in each case of the foregoing clauses (i) through (iii), inclusive, Kowa shall not be entitled to receive, and Amarin shall not be obligated to pay Kowa, any Tail Period Payments.

5.4 Reporting and Payment.

5.4.1 Quarterly Reports, Invoicing and Co-Promotion Fee Payments. [***] Amarin shall deliver to Kowa a written report setting forth its calculations of Gross Margins and the Co-Promote Fee due to Kowa in connection with such Gross Margins for the just-ended Quarter.

5.4.2 Payments. All payments under this Agreement shall be in Dollars in immediately available funds. Unless instructed otherwise by the receiving Party, payments shall be made via wire transfer to an account designated in writing from time to time by the receiving Party.

5.5 Taxes. Any withholding or other similar taxes that either Amarin or its Affiliates is required by Applicable Law to withhold or pay on behalf of Kowa, with respect to any payments to it hereunder, shall be deducted from such payments and paid contemporaneously with the remittance to Kowa; provided, however, that Amarin will furnish Kowa with proper evidence of the taxes so paid. Kowa will furnish Amarin with appropriate documents to secure application of the most favorable rate of withholding tax under Applicable Law. All sums due under this Agreement shall be paid without deduction of sales tax that may be imposed, except insofar as Amarin is required to withhold or deduct the same to comply with Applicable Laws. Each Party shall render the other reasonable assistance in respect of its efforts to apply for and receive any refunds of tax to which it may seek.

5.6 Costs Generally. [***]

5.7 Offset Rights. Notwithstanding anything to the contrary in this Agreement, either Party may, in its sole discretion and from time to time, offset against any payments due to the other Party or its Affiliates under this Agreement, any amount that the other Party owes or has failed to pay in accordance with the applicable terms of this Agreement.

ARTICLE 6

SUPPLY OF SAMPLES

6.1 Sample Ordering and Delivery. Amarin will ship Sample supplies in quantities, and on timing, set forth in the Promotion Plan. Amarin will ship (FCA (Incoterms 2010) – Amarin’s or its contract manufacturer’s facility) Samples to Kowa’s warehouse located at 530 Industrial Park Blvd, Montgomery, AL 36117. Kowa shall confirm in writing the receipt of all Samples within one (1) Business Day of any such delivery of Samples and in compliance with Applicable Laws. Kowa may not change the location of the warehouse to where the Samples are shipped without the prior written consent of Amarin. Shipping costs from Kowa’s warehouse to Kowa Sales Representatives or Targets will be at Kowa’s cost and responsibility.

6.2 Receipt and Inspection.

6.2.1 Inspection. Kowa will perform an initial visual inspection (which shall at least be in accordance with PDMA and Kowa’s standard operating procedures) of each shipment of Samples immediately upon receipt of a shipment and communicate shortages, damages or

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other issues to Amarin or its designee via phone call and confirmed in writing. Thereafter, Kowa shall comply with the PDMA and other Applicable Laws. If any Samples are damaged, shorted or misbranded, Kowa will promptly notify Amarin. Kowa will return any non-conforming Samples in accordance with Amarin’s direction at Amarin’s cost. Amarin will replace the non-conforming Samples at Amarin’s expense and shall supply such Samples to Kowa under conditions no less favorable than Amarin’s then-current supply of Samples to Amarin Sales Representatives. Kowa’s sole remedy with respect to any damaged, misbranded or shorted Samples shall be the replacement of such Samples by Amarin.

6.2.2 Records. Amarin will maintain records of all Sample shipments and quantities sent to and received by Kowa or its designee. Kowa will maintain Sample shipment records of each Kowa Sales Representative by employee ID and territory number for the current Year plus the three (3) most recent previous Years. The information maintained must include the following: (i) product code, name and strength, (ii) lot number and quantity shipped, and (iii) shipment date. For clarity, Amarin will not ship Samples directly to Kowa Sales Representatives.

6.2.3 Storage & Reporting. Kowa represents and warrants that it and the Kowa Sales Representatives have a secure and proper environment for storage of Samples in accordance with the Product Labeling. Kowa agrees to provide monthly reporting of Sample stock levels to Amarin in a mutually agreed upon format.

6.3 Sample Cost. Samples supplied to Kowa under this Agreement will be supplied by Amarin [***]. Amarin will provide invoices to Kowa that are consistent with the definition of Sample Cost and the quantities of Samples shipped under such invoice. Sample-related invoices will be paid by Kowa within [***] of receipt thereof.

ARTICLE 7

REGULATORY MATTERS, COMPLIANCE AND PHARMACOVIGILANCE

7.1 Responsibility. Amarin shall generally have responsibility for all regulatory matters associated with the sales of the Product except that Kowa is responsible for (a) obtaining all federal, state or local licenses or credentialing necessary for Kowa Sales Representatives to Detail the Product in the Territory, (b) federal, state and local aggregate spend filings in respect of its activities, except for filings in District of Columbia, West Virginia, and Massachusetts, (c) any issues related to PDMA sample accounting/auditing, thefts or losses with respect to Samples supplied by Amarin to Kowa hereunder, and (d) notwithstanding the foregoing, compliance with Applicable Laws. Kowa will provide a copy of all correspondence and/or PDMA audit results to Amarin within two (2) days of completion thereof. Amarin’s responsibilities shall specifically include all communications with the FDA related to the Product and Amarin shall have sole responsibility to seek and/or obtain any necessary approvals of the Product Labeling used in connection with the Product in the Territory, and for determining whether the same requires approval.

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7.2 Reporting. Amarin shall be responsible for any reporting of matters, or other communications regarding manufacture, medical/scientific, sale, or promotion of the Product, including Adverse Events, to or with the FDA and other relevant regulatory authorities, in accordance with Applicable Laws. Without limiting the foregoing, Kowa shall promptly, but in any event within one (1) Business Day, notify Amarin of any information that it receives regarding an Adverse Event, suspect, counterfeit, misbranded or illegitimate Product, or otherwise obtains that may require a recall, field alert, notice to FDA or other Regulatory Authority, Product withdrawal or field correction arising from any defect in the Product or that may have an impact on Regulatory Approval for the Product or the continued commercialization of the Product or Product sampling.

7.3 Kowa Involvement. Subject to Section 7.1 herein or a specific requirement of Applicable Law, Kowa shall provide a copy of, and obtain Amarin’s written consent prior to communicating or corresponding with the FDA or with any other Governmental Authority, concerning the Product, or otherwise take any action concerning any authorization or permission under which the Product is sold. Kowa shall provide to Amarin, upon receipt, copies of any communication from the FDA or other Governmental Authority related to the Product. If Kowa has a good faith belief that it is legally obligated to communicate with the FDA or other Governmental Authority, then Kowa shall promptly so advise Amarin and Kowa shall, if Applicable Law permits, comply with any and all reasonable direction from Amarin concerning any meeting or communication with the FDA or other Governmental Authority; provided, that, Amarin shall, unless prohibited by Applicable Law, have the right to participate in any meetings or other communications between Kowa and any Governmental Authority with respect to the Product.

7.4 Regulatory Inspection or Audit. The Parties agree that they will conduct all audits required under PDMA and, additionally, if a Regulatory Authority desires to conduct an inspection or audit of either Party’s facility or a facility under contract with either Party with regard to the Product in the Field in the Territory, such Party shall cooperate and cause the contract facility to cooperate with such Regulatory Authority during such inspection or audit. Following receipt of the inspection or audit observations of such Regulatory Authority (a copy of which such Party will promptly provide to the other Party), such Party will prepare the response to any such observations. Such Party agrees to conform its activities under this Agreement to any commitments made in such a response, except to the extent it believes in good faith that such commitments violate Applicable Laws.

7.5 Compliance.

7.5.1 General Compliance Obligations. During the Term, the Parties, through a compliance subcommittee under the JSC, shall consult on all medical and regulatory compliance matters solely as it relates to the Product, including any reports as to their compliance with the Act, the Physicians Payment Sunshine Act, PDMA, HIPAA, the Codes and OIG Guidance. The Parties agree to work jointly in good faith to ensure that their internal policies are consistent with Applicable Law and, to the extent desirable, each other’s policies. In performing its duties hereunder, Amarin and Kowa shall and shall cause its respective Sales Representatives to: (i) Promote the Product in conformity with its FDA approved Product Labeling, and (ii) comply with all Applicable Laws, including all regulations and other guidelines concerning the advertising of prescription drug products, the OIG Guidance, the Codes, the Accreditation Council for Continuing Medical Education standards, and its standard operating procedures, in

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each case, to the extent applicable to the activities to be performed hereunder and as may be amended or supplemented from time to time. Kowa and Amarin shall each use Commercially Reasonable Efforts to ensure that each of its employees, agents and consultants do not make any representation, statement, warranty or guaranty with respect to the Product (1) that is inconsistent with its current FDA approved Product Labeling or with the Promotional Materials, (2) that is deceptive or misleading, (3) that misbrands or adulterates the Products, or (4) that disparages the Product or the good name, goodwill or reputation of Amarin, Kowa or their respective Affiliates. Each Party shall use Commercially Reasonable Efforts to ensure that its activities under this Agreement will be provided in a professional, ethical and competent manner. Unless otherwise required by Applicable Law, Kowa and Amarin shall each maintain sole responsibility for its compliance with Applicable Law regarding Promotion and Detailing of prescription drug products, including the maintenance of an effective comprehensive compliance programs and the reporting of respective sales force activities.

7.5.2 OIG Guidance. Consistent with the ‘Compliance Program Guidance for Pharmaceutical Manufacturers,’ published by the Office of Inspector General, United States Department of Health and Human Services (the “**OIG Guidance**”), each Party agrees to maintain an effective compliance program with respect to its Promotion and Detailing activities pursuant to this Agreement containing all of the elements described in such guidance document.

7.5.3 Compliance Reporting Obligations.

(a) Each Party shall maintain an effective comprehensive corporate compliance program (including an investigation system that is compliant with Applicable Laws) that will include a mechanism for its employees to report, anonymously if they choose, any concerns about potential illegal activity relating to Promotion of Product in the Territory, and that will require a Party to investigate any such report. Kowa shall give written notice to Amarin of the substance of any such report within a reasonable time (but in no event later than five (5) Business Days) after such report is received, and before reporting any such activity to any Regulatory Authority or law enforcement authority. Kowa shall inform Amarin of the result of any investigation of such report (unless the reporting Party concludes in good faith that doing so would violate Applicable Laws) within five (5) Business Days after learning of such result, and cooperate in good faith with Amarin on all reasonably requested corrective actions necessary under Kowa’s standard operating procedures or relevant practices and activities.

(b) If a Party receives any written or oral communication from any Governmental Authority relating to its activities hereunder, then such Party shall as soon as reasonably practicable (but in any event within twenty-four (24) hours) notify the other Party and provide such other Party with a copy of any written communication received by the first Party or, if applicable, complete and accurate minutes of such oral communication. Each Party shall keep the other Party reasonably informed, including by way of promptly providing updates upon such Party’s request, with respect to the status and resolution of any issues raised by any Governmental Authority relating to such Party activities hereunder. To the extent not prohibited by Applicable Law, Kowa shall reasonably consider and implement any guidance provided by Amarin with respect to such issues and interactions with Governmental Authorities.

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(c) Without limiting the foregoing, each Party’s comprehensive corporate compliance program shall also include, and each Party shall carry out, a broad training program in ethics and compliance with Applicable Laws, such Party’s standard operating procedures and the Codes, in addition to the training provided for in this Agreement.

7.5.4 Compliance Safe Harbor. Notwithstanding anything to contrary in this Agreement, neither Party shall be required to undertake any obligation, or incur any cost or reimbursement obligation, in connection with any activity under this Agreement that it believes, in good faith, is not compliant with any Applicable Law.

7.5.5 Compliance Audit. Without limiting the records-specific audit rights described in ARTICLE 8, during the Term and for six (6) years thereafter, each Party shall, for the purpose of auditing and monitoring the performance of its compliance with this Agreement and particularly its compliance obligations hereunder, permit the other Party, its Affiliates, and any auditors of any of them to have, upon reasonable notice, access to any premises of such Party or its Affiliates used in connection with this Agreement (“**Audit**”). To the extent that any Audit by a Party requires access and review of any commercially or strategically sensitive information of the other Party or its Affiliates relating to the business of such Party or Affiliate, such activity shall be carried out by a Third Party professional advisor appointed by the other Party and such professional advisors shall only report back to the other Party such information as is directly relevant to informing the other Party on such Party’s compliance with the particular provisions of the Agreement being Audited (and shall enter into a commercially reasonable confidentiality agreement consistent with the foregoing). The costs and fees of any Audit shall be paid by the auditing Party, except that if an Audit reveals any material breach or violation by the audited Party (including through any Affiliate) of any representation, warranty or undertaking set forth in Sections 4.3.2, 4.3.5, 4.8.2, 7.5, 11.1(e), 11.1(i) and 11.1(j), the costs of such inspection or Audit shall be paid by the Audited Party. The Audited Party shall bear its own costs of rendering reasonable assistance to the Audit.

7.5.6 Compliance Certification. Within thirty (30) days of each anniversary of the Effective Date, Kowa shall submit to Amarin a written certification by an appropriate corporate officer of Kowa, in a form reasonably acceptable to Amarin, regarding Kowa’s (and its Kowa Sales Representatives, as applicable) compliance with the terms of Sections 4.3.2, 4.3.5, 4.8.2, 7.5, 11.1(e), 11.1(i) and 11.1(j) (i.e., certain of those provisions dealing with compliance-related matters).

7.6 Pharmacovigilance.

7.6.1 Generally. Amarin shall be responsible for all pharmacovigilance activities regarding the Product, including product complaints, signal detection, medical surveillance, risk management, global medical literature review and monitoring, Adverse Event reporting and responses to Regulatory Authority requests or enquiries; provided, that, in the event Kowa receives (i) Safety Information regarding the Product, or information regarding any safety-related regulatory request or inquiry, Kowa shall notify Amarin as soon as practicable, but, in any event, not later than one (1) Business Day after it receives such Safety Information, Regulatory Authority request or query, or (ii) reports of any Adverse Events, such Adverse Event reports shall be immediately (but in any event within one (1) Business Day called-in to Amarin at (855) 827-2372 (i.e., 855-VASCEPA).

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7.6.2 Assistance. Each Party shall provide the other Party with such information as the other Party may reasonably request during the Term in order to support the requesting Party’s compliance with Applicable Laws and its Sales Representatives Promotion and Detailing of the Product in the Field in the Territory. Kowa shall report to Amarin, in accordance with commercially reasonable methodologies requested by Amarin, all information necessary to permit Amarin to make timely reports as required by any Regulatory Authority in the Territory regarding the Product, and shall advise Amarin if there is any respect in which it has been unable to do so. To facilitate efficient communication and data sharing between Amarin and Kowa, Amarin shall establish and maintain a secure method of transferring information between the Parties. The Parties shall work together to identify any support hardware, software and services appropriate for the sharing of information with respect to Promotion of the Product. Wherever possible, the Parties agree that all technologies and platforms used for such purposes shall be in accordance with each Party’s technology architecture and security standards. Except as provided in this Agreement, each Party shall be solely responsible for all costs and expenses of acquiring and maintaining its infrastructure and reporting systems to support its Sales Representatives.

7.6.3 Separate Agreement. Contemporaneous with the Effective Date, the Parties shall enter into a separate safety data exchange / pharmacovigilance agreement containing the specific terms, conditions and obligations of the Parties with respect to the collection, reporting and monitoring of adverse drug reactions, Adverse Events, Product complaints, other relevant drug safety matters, and medical inquiries with respect to the Product during the Term.

7.7 Medical Inquiries. Amarin shall respond to all unsolicited requests for medical information. Promptly after the Effective Date, the Parties shall establish procedures in accordance with the applicable portions of Amarin’s processes and procedures, to enable Kowa to send such requests to Amarin or its designee to enable prompt response to any medical inquiries.

7.8 Recalls and Market Withdrawals. Amarin shall have the sole right and responsibility, at its expense (but subject to Section 11.5), to control any product quarantine, recall, field correction, or withdrawal of the Product in the Territory. To the extent practicable, the Parties shall discuss the circumstances of any potential product quarantine, recall, field correction or withdrawal of any Product and possible appropriate courses of action. Each Party shall maintain complete and accurate records of any recall in its territory for such periods as may be required by Applicable Laws, but in no event for less than five (5) years.

7.9 Reporting Responsibilities. Each Party shall be responsible for its federal and state reporting requirements in the Territory arising from conducting Details or related activity(ies) in the Territory or in a given state, as applicable; provided, that, with respect to state level reporting, Kowa shall not be responsible for direct state reporting in those states where relevant reports are required to be submitted by the Regulatory Approval holder for the relevant product, in which states Kowa shall promptly (but no later than five (5) Business Days before any such reporting deadline) provide Amarin any and all assistance and information that Amarin requires or reasonably requests to enable Amarin (or its designee) to submit such reports with respect to the Product and activities hereunder.

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7.10 Rebate Liability. Notwithstanding Kowa’s reporting obligations under Section 7.2, Amarin agrees and acknowledges that it shall be solely responsible for any and all rebate, chargeback or adjustment amounts or liabilities owed by any party in connection with any sale or disposition of the Product in the Territory, under applicable rules and regulations relating to the United States Medicaid Drug Rebate Program (42 U.S.C. § 1396r-8) and any state supplemental rebate program, Medicare average sales price reporting (42 U.S.C. § 1395w-3a), the United States Public Health Service Act (42 U.S.C. § 256b), the United States VA Federal Supply Schedule (38 U.S.C. § 8126) or under any state pharmaceutical assistance program or United States Department of Veterans Affairs agreement, and any successor government programs. Notwithstanding anything to the contrary herein, all amounts associated with any rebate, chargeback or adjustment amounts or liabilities owed by any party in connection with any sale or disposition of the Product in the Territory shall be included in the deductions from Gross Sales in calculating Net Sales.

ARTICLE 8

AUDIT RIGHTS

Without limiting any other express audit rights granted herein, each Party shall have the right, upon reasonable written notice during the Term, and for [***] after expiration or termination of this Agreement, at such Party’s expense, through an independent certified public accountant reasonably acceptable to the other Party and upon execution of a confidentiality agreement, to examine the records (including records relating to the Product, Sales Representatives, Detailing of the Product and other Promotional Activity Data, and sampling and related records) that such other Party is required to keep in accordance with the terms of this Agreement during regular business hours; provided, however, that (i) such examination shall not take place more often than once per Year, (ii) such examination shall not cover records that have previously been audited, and (iii) such accountant shall report to such Party only as to the accuracy of the reports or payments provided or made by the other Party under this Agreement. Any undisputed adjustments required as a result of overpayments or underpayments identified through a Party’s exercise of audit rights shall be made by subtracting or adding, as appropriate, amounts from or to the next payment or, if no further payments are due, by payment to the Party owed such adjustment within [***] days after identification of such adjustment. The Party requesting the audit shall bear the full cost of the audit; provided, however, the audited Party shall reimburse the requesting Party for such fees and expenses in the event the audit reveals an error of overstatement or understatement equal to or exceeding [***] in the numbers reported in any Year.

ARTICLE 9

INTELLECTUAL PROPERTY

9.1 Ownership of Intellectual Property. Each Party shall have and retain sole and exclusive right, title and interest in and to all inventions, discoveries, writings, trade secrets, know-how, methods, practices, procedures, engineering information, designs, devices, improvements, manufacturing information and other technology, whether or not patentable or copyrightable, and any patent applications, patents, or copyrights based thereon (“**Inventions**”) that are made, discovered, conceived, reduced to practice or generated by such Party (or its employees or representatives) related to such Party’s products (including, in the case of Amarin Ireland, the Product) during the Term and as a result of performance of this Agreement. Notwithstanding anything to the contrary herein, Amarin Ireland shall solely own all right, title and interest in and to all Inventions relating to the Product, the active ingredients in the Product, and the uses thereof first made, discovered, conceived, reduced to practice or generated during the Term and as a result of performance of this Agreement by Amarin Pharma (or its employees or representatives) or Kowa (or its employees or representatives) or Amarin Pharma (or its employees or representatives) and Kowa (or its employees or representatives) working together jointly (each, a “**Product Invention**”). Kowa and Amarin Pharma each agrees to assign, and hereby does assign, to Amarin Ireland any and all right, title and interest Kowa or Amarin Pharma, as applicable, may have in or to any Product Invention. Kowa shall not represent to any Third Party that it has any proprietary or property right or interest in the Product, or in any patent relating thereto, or in any trademark (other than Kowa Trademarks) used in connection therewith. For clarity, and notwithstanding anything to the contrary contained herein, any and all Product Inventions and any information contained therein or related thereto shall constitute Confidential Information of Amarin.

9.2 Prosecution, Maintenance, Enforcement and Defense of Amarin Intellectual Property. Amarin shall use Commercially Reasonable Efforts to prosecute and maintain the Amarin Intellectual Property in the Territory, and Amarin shall have the sole right to enforce and defend Amarin Intellectual Property, and to settle or otherwise resolve related litigation, at Amarin’s sole discretion. Without limiting the foregoing, Kowa shall provide assistance reasonably requested by Amarin, at the reasonable and pre-approved cost and expense of Amarin. Kowa shall neither be required to provide assistance for which Amarin has not pre-approved the cost, nor shall Kowa’s reasonable assistance include an obligation on the part of Kowa to be named a party plaintiff in any claim or cause of action. In connection with the enforcement or defense of the Amarin Intellectual Property (e.g., Amarin’s suit against Omthera Pharmaceuticals, Inc., a Delaware corporation, and its parent company, AstraZeneca Pharmaceuticals LP, seeking injunctive relief and monetary damages for infringement of Amarin’s U.S. Patent No. 8,663,662, filed in federal court in Delaware in March 2014), Amarin shall have the right, at Amarin’s sole discretion, to grant Third Parties a license or other rights under the Amarin Intellectual Property to develop and commercialize products other than the Product (and, for clarity, any such products shall not constitute a “Product” for purposes of this Agreement).

9.3 Title to Trademarks. The ownership, and all goodwill from the use, of any Amarin Trademarks shall at all times vest in and inure to the benefit of Amarin. The ownership and all goodwill from the use of any Kowa Trademarks shall at all times vest in and inure to the benefit of Kowa. Except as expressly provided in this Agreement or as mutually agreed by the Parties, neither Party shall use the trademarks of the other Party for any purpose.

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9.4 Protection of Trademarks. The Parties agree to take reasonable actions at the cost and expense of Amarin, as provided in this Section 9.4, in the name of Amarin, to protect the Amarin Trademarks against any Third Party who either infringes the Amarin Trademarks or brings a Claim against either or both of the Parties for infringement of the Third Party’s trademarks in relation to the use of the Amarin Trademarks. Each Party shall give notice to the other of any infringement of, or challenge to, the validity or enforceability of the Amarin Trademarks promptly after learning of such infringement or challenge. If Amarin institutes an action against Third Party infringers or takes action to defend the Amarin Trademarks, Kowa shall cooperate fully with Amarin. Any recovery obtained by Amarin as a result of such proceeding or other actions, whether obtained by settlement or otherwise, shall be retained by Amarin except that Amarin shall pay to Kowa any reasonable Out-of-Pocket Expenses incurred by Kowa relating to such cooperation. Kowa shall not have any right to institute any action to defend or enforce the Amarin Trademarks.

ARTICLE 10

CONFIDENTIALITY

10.1 Disclosure of Know-How. To the extent that one Party has disclosed, or in the future discloses, to the other Party any Know-How or other intellectual property of such Party or its Affiliates, the receiving Party shall not acquire any ownership rights in such Know-How or other intellectual property by virtue of this Agreement.

10.2 Confidential Information. Amarin and Kowa shall neither use nor disclose to Third Parties any confidential information received from the other Party or otherwise developed or obtained (including prior to the Term, during the Term, or during any period in which the Parties have audit rights hereunder) by either Party in the performance of activities in furtherance of this Agreement (“**Confidential Information**”) without first obtaining the written consent of the disclosing Party, except as may be otherwise provided in, or required for a Party to fulfill its obligations or exercise its rights under this Agreement. Any and all information and materials disclosed, whether by one Party to the other Party or otherwise, pursuant to that certain Confidentiality Agreement between Kowa Research Institute, Inc. (an Affiliate of Kowa) and Amarin Corporation plc (an Affiliate of Amarin) dated August 31, 2009 (the “**Confidentiality Agreement**”) shall be deemed Confidential Information disclosed pursuant to this Agreement. The Parties shall take reasonable measures to assure that no unauthorized use or disclosure is made by others to whom access to such Confidential Information is granted. If either Party is required by Applicable Law to disclose any of the Confidential Information of the other Party it shall be permitted to do so; provided, that it shall first notify the disclosing Party in writing and shall permit the disclosing Party to contest the disclosure requirement at its sole expense. The Party required to make the legal disclosure shall fully cooperate with the disclosing Party in order to limit such disclosure to the extent legally permissible. Notwithstanding the foregoing, the confidentiality obligations contained in this Section 10.2 shall not apply to such information that:

(a) is or becomes a matter of public knowledge (other than by breach of this Agreement by the receiving Party), provided, information shall not be deemed to be public knowledge by reason of its having been filed with the FDA or any other regulatory authority except to the extent available for public inspection or subject to disclosure under the Freedom of Information Act or comparable state statutes;

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(b) the receiving Party can establish by competent evidence was already known to it or was in its possession at the time of disclosure;

(c) is disclosed to the receiving Party by a Third Party having the right to do so; or

(d) is independently developed by or on behalf of the receiving Party, without the aid, use or application of the Confidential Information, as evidenced by contemporaneously created written records of such receiving Party.

10.3 Disclosure to Affiliates. Nothing in this Agreement shall be construed as preventing either Party from disclosing any Confidential Information received from the other to an Affiliate of the receiving Party which is necessary for the purposes of enabling the receiving Party to fulfill its obligations under this Agreement; provided, the receiving Party shall be responsible for breaches of the confidentiality obligations contained in this ARTICLE 10 by such Affiliate.

10.4 Press Releases and Disclosure.

10.4.1 Initial Press Release. The Parties shall reasonably agree regarding a public announcement with respect to the execution of this Agreement.

10.4.2 Subsequent Press Releases.

(a) Kowa may not make any subsequent press release or public announcements regarding this Agreement, the Product, Amarin or any matter covered by this Agreement, without the prior written consent of Amarin. In the event that Kowa believes it is required to issue a press release or make any other public announcement to comply with Applicable Law and Amarin does not believe such public announcement is so required, Kowa may only issue such press release if (a) it obtains an opinion of legal counsel, from a reputable law firm approved by Amarin, that it is required to make such disclosure to comply with Applicable Law, and (b) after receiving such opinion, provides the text of such planned disclosure to Amarin no less than [***] prior to disclosure, and has incorporated all reasonable comments of Amarin regarding such disclosure.

(b) Amarin may publicly disclose without violation of this Agreement, such terms of this Agreement as are, on the advice of Amarin’s counsel, required by the rules and regulations of the SEC or The NASDAQ Stock Market, Inc.; provided, that Amarin shall advise Kowa of such intended disclosures and provide Kowa with reasonable opportunity to request that Amarin seek confidential treatment of such disclosures to be filed with the SEC. Subject to the immediately preceding sentence, Amarin shall consult with Kowa, and Kowa shall have the right to review and comment with respect to the redaction of the terms of this Agreement or Kowa’s Confidential Information as part of the confidential treatment request to the SEC. After release of the press release announcing this Agreement and excluding any public disclosures of the terms of this Agreement that are authorized by the preceding sentences, if Amarin desires to make a public announcement concerning the material terms of this Agreement, milestones achieved under this Agreement or Kowa’s Confidential Information, then Amarin shall give reasonable prior advance notice of the proposed text of such announcement to Kowa for its prior review and

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approval (except as otherwise provided herein), such approval not to be unreasonably withheld, conditioned or delayed; provided, that Kowa shall provide its comments, if any, within [***] (or [****] in the event Amarin is required to make such disclosure pursuant to Applicable Laws or stock exchange rules) after receiving the public announcement for review (and failure for Kowa to provide comments within such time period shall be deemed to constitute Kowa’s consent to such public announcement). In relation to Kowa’s review of such an announcement, Kowa may make specific, reasonable comments on such proposed press release or other public disclosure within the prescribed time for commentary. Amarin shall not be required to seek the permission of Kowa to disclose any information already disclosed or otherwise in the public domain, provided such information remains accurate.

ARTICLE 11

REPRESENTATIONS, WARRANTIES, COVENANTS AND INDEMNIFICATION

11.1 Representations and Warranties of both Parties. Each Party represents and warrants as of the Effective Date that:

(a) It has the corporate power and authority to execute and deliver this Agreement and to perform its obligations hereunder, and the execution, delivery and performance of this Agreement has been duly and validly authorized and approved by proper corporate action on the part of such Party. Assuming due authorization, execution and delivery on the part of the other Party, this Agreement constitutes a legal, valid and binding obligation of such Party, enforceable against such Party, in accordance with its terms.

(b) The execution and delivery of this Agreement by it and the performance by it contemplated hereunder will not violate any Applicable Laws.

(c) To its knowledge, it is in compliance in all material respects with all material Applicable Laws applicable to the subject matter of this Agreement.

(d) It is not a party to any agreement or arrangement with any Third Party or under any obligation or restriction (including any outstanding order, judgment or decree of any court or administrative agency) which in any way limits or conflicts with its ability to fulfill any of its obligations under this Agreement.

(e) As of the Effective Date and during the Term, neither it nor its Affiliates nor any of their respective directors, officers, employees, or consultants, and, to its knowledge based upon reasonable inquiry, any Third Party (and its directors, officers, employees and consultants), in each case whose responsibilities involve the Promotion and Detailing of the Product hereunder:

(i) are debarred under Section 306(a) or 306(b) of the Act;

(ii) have been charged with, or convicted of, any felony or misdemeanor under Applicable Laws related to any of the following: (A) the development or approval of any drug product or the regulation of any drug product under the Act; (B) a conspiracy to commit, aid or abet the development or approval of any drug product or regulation

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of any drug product; (C) health care program-related crimes (involving Medicare or any State health care program); (D) patient abuse, controlled substances, bribery, payment of illegal gratuities, fraud, perjury, false statement, racketeering, blackmail, extortion, falsification or destruction of records; (E) interference with, obstruction of an investigation into, or prosecution of, any criminal offense; or (F) a conspiracy to commit, aid or abet any of these listed felonies or misdemeanors; or

(iii) is excluded, suspended or debarred from participation, or otherwise ineligible to participate, in any federal or state health care programs (including convicted of a criminal offense that falls within the scope of 42 U.S.C. §1320a-7 but not yet excluded, debarred, suspended, or otherwise declared ineligible), or excluded, suspended or debarred from participation, or otherwise ineligible to participate, in any Federal procurement or nonprocurement programs.

(f) Each Party will notify the other Party immediately, but in no event later than five (5) days, after knowledge of any exclusion, debarment, suspension or other ineligibility set forth in Section 11.1(e)(iii) occurring during the Term, or if such Party concludes based on its good faith business judgment that a pending action or investigation is likely to lead to the exclusion, debarment, suspension or other ineligibility of such Party.

(g) Each Party at its own expense hereby covenants that it shall, as part of the pre-hiring or pre-contracting process, screen against Exclusion Lists (as defined below) all of its directors, officers, employees, consultants, and any Third Party (and those of such Third Party’s directors, officers, employees and consultants that are known to such Party), in each case that such Party hires or engages whose responsibilities, to such Party’s knowledge based on reasonable inquiry, involve the Promotion or Detailing of the Product as authorized by this Agreement, and will conduct such screens on an annual basis thereafter. Upon request by a Party, the other Party shall certify the results of such screening to the requesting Party. For purposes of this Agreement, “Exclusion Lists” include at a minimum: (i) the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://www.oig.hhs.gov>) or any successor list; and (ii) the General Services Administration’s List of Parties Excluded from Federal Programs (available through the Internet at <http://www.epls.gov>) or any successor list.

(h) It has provided or made available, when requested by the other Party to conduct its due diligence review, any and all documents and communications in its possession from and to the FDA or any other Governmental Authority, or prepared by the FDA or any other Governmental Authority, that may bear on compliance with the requirements of the FDA or any other Governmental Authority, including any notice of inspection, inspection report, warning letter, deficiency letter, or similar communication. In connection with the foregoing, each Party represents and warrants to the other that it is not subject, as of the Effective Date, to any corporate integrity agreement(s) and each Party further covenants that it shall promptly notify the other Party in the event that it becomes subject to a corporate integrity agreement at any time during the Term.

(i) Neither it nor any of its Affiliates has received any oral or written communication (including any warning letter, untitled letter, or similar notices) from the FDA and there is no action pending or, to its knowledge, threatened (including any prosecution, injunction, seizure, civil fine, suspension or recall), in each case alleging that it or any of its Affiliates is not currently materially in compliance with any and all Applicable Laws implemented by the FDA.

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(j) To its knowledge, it nor any of its Affiliates or any of their respective officers, employees or agents has made an untrue statement of a material fact to the FDA or other Governmental Authority or failed to disclose a material fact required to be disclosed to the FDA or other Governmental Authority; and

(k) There is no material matter known to it as of the Effective Date which has not been disclosed by it to the other Party concerning the safety or efficacy of the Product.

11.2 Additional Representations, Warranties and Covenants of Amarin. Amarin additionally represents, warrants and covenants as of the Effective Date that:

(a) Amarin has no knowledge that the Promotion or Detailing of the Product in the Territory under this Agreement will infringe a claim in an issued patent of a Third Party, but nothing in this Agreement shall be construed as a warranty or representation that the Promotion or Detailing of the Product pursuant to this Agreement is or will be free from infringement of any Third Party patent.

(b) The Product was approved for sale by the FDA in the United States as of July 26, 2012 for use as an adjunct treatment to diet to reduce triglyceride (TG) levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia.

(c) Amarin will maintain (or cause to be maintained in the case of manufacturing facilities of Third Parties) continuously in full force and effect during the Term all Regulatory Approvals pertaining to the Product that are necessary for Amarin to meet its obligations hereunder, including the approval referred to in Section 11.2(b) above, and that are necessary for the lawful manufacturing and sale of the Product for human therapeutic use in the Field in the Territory.

(d) Amarin owns the rights it purports to grant to Kowa under this Agreement.

11.3 Additional Representations, Warranties and Covenants of Kowa. Kowa additionally represents, warrants and covenants as of the Effective Date that:

(a) Kowa is not commercializing, marketing, Promoting, selling, offering for sale, importing and/or distributing, and is not undertaking any clinical development of, any Competing Product in the Territory; and

(b) Kowa has conducted such due diligence as it believes is necessary, including having had an opportunity to ask questions of, and receive answers from, representatives of Amarin.

11.4 Indemnification by Amarin. Amarin shall indemnify and defend Kowa and its Affiliates and each of their respective employees, officers, directors and agents (the “**Kowa Indemnitees**”) from and against any and all Losses to the extent arising out of Claims of Third Parties related to: (a) Amarin’s negligence or willful misconduct, (b) Amarin’s performance of its obligations under this Agreement, (c) breach by Amarin of this Agreement or Applicable Laws, (d) infringement or misappropriation of Third Party intellectual property rights directly or indirectly related to the Product, (e) use of the Product, including the toxicity, carcinogenicity, immunogenicity, teratogenicity and other inherent effects of the Product, and (f) Promotional Materials that are in violation of Applicable Laws; provided, however, that Amarin’s obligations pursuant to this Section 11.4 shall not apply (i) to the extent such claims or suits result from the negligence or willful misconduct of any of the Kowa Indemnitees, or (ii) with respect to Losses for which Kowa is obligated to indemnify Amarin pursuant to Section 11.5.

11.5 Indemnification by Kowa. Kowa shall indemnify and defend Amarin and its Affiliates and each of their respective agents, employees, officers and directors (the “**Amarin Indemnitees**”) against any and all Losses to the extent arising out of Claims of Third Parties (except as provided in clauses (d) and (e)) related to: (a) Kowa’s negligence or willful misconduct, (b) Kowa’s performance of its obligations under this Agreement, (c) breach by Kowa of this Agreement or Applicable Laws, (d) Kowa’s use, in violation of Applicable Laws, of Promotional Materials that comply with Applicable Laws, (e) any claims for benefits that any Kowa Sales Representative may make for performance under this Agreement under or with respect to any Benefit Plan, and (f) any payment or obligation to make a payment to any Kowa Sales Representative for performance under this Agreement relating in any way to any compensation or benefits or the payment or withholding of any contributions, payroll taxes, or any other payroll-related item by or on behalf of Kowa or any of the Kowa Sales Representative (even if it is subsequently determined by any court or any governmental agency that any such Kowa Sales Representative may be a common law employee of Amarin or otherwise entitled to such benefits); provided, however, that Kowa’s obligations pursuant to this Section 11.5 shall not apply (i) to the extent that such claims or suits result from the negligence or willful misconduct of any of the Amarin Indemnitees, or (ii) with respect to Losses for which Amarin is obligated to indemnify Kowa pursuant to Section 11.4.

11.6 Indemnification Procedures. The obligations to indemnify and defend set forth in Sections 11.4 and 11.5 shall be contingent upon the Party seeking indemnification (the “**Indemnitee**”): (a) notifying the indemnifying Party of a claim, demand or suit within fifteen (15) Business Days of receipt of same (provided, however, that an Indemnitee’s failure or delay in providing such notice shall not relieve the indemnifying Party of its indemnification obligation except to the extent the indemnifying Party is prejudiced thereby), (b) allowing the indemnifying Party and/or its insurers the right to assume direction and control of the defense of any such Claim, (c) using diligent efforts to cooperate with the indemnifying Party and/or its insurers in the defense of such Claim at the indemnifying Party’s expense, and (d) agreeing not to settle or compromise any Claim without prior written authorization of the indemnifying Party. Indemnitee shall have the right to participate in the defense of any such Claim referred to in this Section 11.6 utilizing attorneys of its choice, at its own expense; provided, however, that the indemnifying Party shall have full authority and control to handle any such Claim. The indemnifying Party shall have the right to settle or compromise any action or otherwise seek to terminate any pending or threatened action for which indemnity may be sought hereunder (whether or not any indemnified Party is a party thereto); provided, that such settlement, compromise or termination includes an unconditional release of and no admission of liability by each indemnified Party from all liability in respect of such Claim.

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11.7 Limitation of Liability. NOTWITHSTANDING ANY OTHER PROVISION CONTAINED HEREIN, UNLESS RESULTING FROM A PARTY’S FRAUDULENT BEHAVIOR, IN NO EVENT SHALL AMARIN OR KOWA BE LIABLE TO THE OTHER OR ANY OF THE OTHER’S AFFILIATES FOR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, SPECIAL, PUNITIVE OR EXEMPLARY DAMAGES (INCLUDING LOST PROFITS, BUSINESS OR GOODWILL) SUFFERED OR INCURRED BY SUCH OTHER PARTY OR ITS AFFILIATES IN CONNECTION WITH A BREACH OR ALLEGED BREACH OF THIS AGREEMENT. THE FOREGOING SENTENCE SHALL NOT LIMIT THE OBLIGATIONS OF EITHER PARTY TO INDEMNIFY THE OTHER PARTY FROM AND AGAINST THIRD PARTY CLAIMS UNDER SECTION 11.4 OR SECTION 11.5.

11.8 Disclaimer of Warranty. EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH IN THIS AGREEMENT, AMARIN AND KOWA MAKE NO REPRESENTATIONS AND GRANT NO WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, AND AMARIN AND KOWA EACH SPECIFICALLY DISCLAIM ANY OTHER REPRESENTATIONS AND WARRANTIES, WHETHER WRITTEN OR ORAL, EXPRESS, STATUTORY OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE OR ANY WARRANTY AS TO THE VALIDITY OF ANY PATENTS OR THE NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES (which disclaimer pertaining to non-infringement shall not mitigate Amarin’s obligations under Section 11.4(d)).

11.9 Insurance. During the Term, each Party shall obtain and maintain, at its sole cost and expense, general liability insurance and product liability insurance (including any self-insured arrangements) in amounts that are reasonable and customary in the United States pharmaceutical and biotechnology industry for companies engaged in comparable activities. It is understood and agreed that this insurance shall not be construed to limit either Party’s liability with respect to its indemnification obligations hereunder. Each Party will, except to the extent self-insured, provide to the other Party upon request a certificate evidencing the insurance such Party is required to obtain and keep in force under this Section 11.9. Without limiting the foregoing, Amarin does not and will not maintain or procure any worker’s compensation, healthcare, or other insurance for or on behalf of any Kowa Sales Representative, all of which shall be Kowa’s sole responsibility. For clarity, the insurance requirements of this Section 11.9 shall not be construed to create a limit of either Party’s liability with respect to its indemnification obligations under this ARTICLE 11.

ARTICLE 12

TERM AND TERMINATION

12.1 Term. The term of this Agreement shall commence on the Effective Date and end on December 31, 2018 (the “**Initial Term**”). After the Initial Term, and subject to Gross Sales during Year 2018 exceeding [***], this Agreement may be extended by mutual agreement of the Parties for an additional two (2) year period (the Initial Term and such renewal term, if any, are collectively referred to as the “**Term**”). For clarity, in the event that the Initial Term is extended in accordance with this Section 12.1, then Amarin shall continue to pay Kowa a Co-Promote Fee at a rate to be agreed as part of the Parties’ mutual decision to extend the Term.

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12.2 Early Termination by Mutual Agreement. The Parties may, at each Party’s sole discretion, mutually agree in writing to terminate this Agreement following the [***] of the Effective Date.

12.3 Reciprocal Early Termination Rights. Each Party shall have the right to terminate this Agreement before the end of the Term as follows:

(a) by either Party upon written notice to the other Party in the event of a material breach of this Agreement by such other Party where such breach is not cured within ninety (90) days following such other Party’s receipt of written notice of such breach;

(b) by either Party on five (5) days written notice to the other Party upon (A) the making or seeking to make or arrange an assignment for the benefit of creditors of such other Party, (B) the appointment of a receiver of such other Party’s property that is not discharged within ninety (90) days, or (C) the stockholders or equity holders of such other Party approve a plan of complete liquidation of such other Party, other than to an Affiliate of such other Party;

(c) by either Party on five (5) days written notice to the other Party due to a Force Majeure event in accordance with Section 15.4 that persists for ninety (90) days or more; or

(d) by either Party on five (5) days written notice to the other Party in the event of (A) the filing of federal or state criminal charges against the such Party or one of such other Party’s directors, officers or senior management employees relating to such person’s activities on behalf of such other Party or (B) the felony conviction of such other Party or one of such other Party’s directors, officers or senior management employees.

12.4 Early Termination Due to Change of Control.

12.4.1 Termination. In the event of a Change of Control of either Party during the Term, the Party experiencing the Change of Control shall deliver a written notice of such Change of Control to the other Party within thirty (30) days of the Change of Control event. At any time within sixty (60) days after receipt of the notice of the Change of Control, including as part of the notice of such Change of Control, either Party (or its successor) may terminate this Agreement by written notice to the other Party (or its successor).

12.4.2 Alternative to Termination. Without limiting the foregoing, in the event that the Party not undergoing the Change of Control does not exercise its right to terminate this Agreement in accordance with Section 12.4.1, then such Party shall have the right to require the Party experiencing the Change of Control (including its Affiliates following such Change of Control) to adopt procedures as reasonably requested by the Party not undergoing the Change of Control to prevent the disclosure of such Party’s Confidential Information beyond personnel having access to and knowledge of such Confidential Information prior to the Change of Control and to control the dissemination of such Party’s Confidential Information disclosed after the Change of Control. The purposes of such procedures shall be to strictly limit such disclosures to only those personnel having a need to know Confidential Information in order for the Party experiencing the Change of Control to perform its obligations under this Agreement and to prohibit the use of Confidential Information for competitive reasons.

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12.5 Early Termination Due to Deficient Sales. Each Party shall have the right to terminate this Agreement, following [***], on [***] advance written notice to the other Party in the event that Gross Sales of the Product in the Field in the Territory for the [***] did not exceed the minimum thresholds set forth below; provided, that such right to terminate must be exercised by a Party within [***] of Amarin providing to Kowa the report required by Section 5.4.1 regarding the fourth Quarter of such previous Year. For clarity, (i) this right to terminate shall be available each Year during the Term to each Party but must be exercised within such [***] period, (ii) the terminating Party shall have performed [***] required to be performed by such Party, and expended [***] required to be spent by such Party, pursuant to Section 4.4 for the previous Year and (iii) the failure to reach the minimum Gross Sales Thresholds set forth below shall not in and of itself be deemed to be a breach of this Agreement.

[***]

12.6 Early Termination by Amarin.

12.6.1 Related Product. Amarin shall have the right to terminate this Agreement upon sixty (60) days’ notice in the event that Kowa is commercializing or otherwise promoting or detailing any product (other than the Product) that, despite its approved label, is being used to reduce triglyceride levels in fifty percent (50%) or more of its prescribed applications according to NDTI data.

12.6.2 Diligence. Amarin shall have the right to terminate this Agreement immediately upon written notice to Kowa in accordance with Section 4.4.1.

12.7 Early Termination by Kowa.

12.7.1 [*].** Kowa shall have the right to terminate this Agreement upon [***] written notice to Amarin in order to make, have made, use, develop, market, promote, co-promote, sell, offer for sale, import, distribute and/or exploit in all regards [***]; provided, that (i) such notice may not be provided prior to [***], and (ii) as a condition precedent to Kowa’s right to terminate pursuant to this Section 12.7.1, Kowa must have provided Amarin with the notice regarding filing for Regulatory Approval for [***] as required by Section 2.2.2.

12.7.2 Diligence. Kowa shall have the right to terminate this Agreement immediately upon written notice to Amarin in accordance with Section 4.4.2.

ARTICLE 13

RIGHTS AND DUTIES UPON EXPIRATION OR TERMINATION

13.1 Effects of Termination. Upon the effective date of expiration or termination of this Agreement, (a) all rights granted to Kowa hereunder shall immediately terminate and Kowa shall immediately cease all Promotion and Detailing activities with respect to the Product, (b)

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Kowa, at Amarin’s direction, shall immediately return to Amarin or destroy all Promotional Materials, reports and other tangible items provided by or on behalf of Amarin to Kowa or otherwise developed or obtained by Kowa (including all data, reports and materials generated by Kowa relating to the Promotion and Detailing of the Product) pursuant to the terms of this Agreement (and at the request of Amarin, Kowa shall certify destruction of such materials if Kowa does not to return such materials to Amarin), (c) Kowa shall return to Amarin (or its designee), or destroy (and subject to Kowa providing Amarin appropriate documentation supporting the destruction of such Samples, and making such documentation available upon Amarin’s reasonable request therefor) any and all Samples in Kowa’s or the Kowa Sales Representatives’ possession, and (d) each Party shall, at the other Party’s direction, either return to the other Party or destroy all Confidential Information of the other Party (provided that such Party may retain one copy of such Confidential Information of the other Party for archival purposes).

13.2 Survival; Continuing Obligations. In addition to any provisions of this Agreement that by their express terms shall survive its expiration or termination, the following provisions shall survive any expiration or termination of this Agreement: Sections 2.2, 2.3, 2.4, 4.3.6, 4.9, 4.13, 5.7, 7.1, 7.2, 7.5.5, 7.8, 9.1, 10.2, 11.7, and 11.8 (provided, that Sections 2.2, 2.3, 2.4, 4.13, 7.5.5 and 7.8 shall only survive for the periods set forth in each such respective provision), and Articles 8, 13 and 14 (provided, that Article 8 shall only survive for the period set forth in such provision), as well as any provisions required to interpret and enforce the Parties’ rights and obligations under this Agreement shall survive this Agreement, but only to the extent required for the full observation and performance of this Agreement.

13.3 Remedies. Termination of this Agreement, in accordance with its provisions, shall not limit the remedies that may be available to either Party in law or equity; provided, that, for clarity, the rightful exercise of a right to terminate under this Agreement shall not be, in and of itself, the basis for a claim by the non-terminating Party.

13.4 Continuing Detailing Obligations. For clarity, Kowa shall continue to perform its Detailing and other obligations until the effective date of termination.

13.5 Tail Period Payments. During the Tail Period, Amarin shall pay Kowa the applicable Tail Period Payments as follows:

- (a) the Co-Promote Fee Tail Payments shall be paid [***] on a [***] during the period indicated in Section 5.3.1; and
- (b) the Net Sales Tail Payment shall be paid [***] in the applicable sub-clause of Section 5.3.2.

For clarity, if this Agreement is terminated for any reason other than those reasons specifically set forth in Section 5.3.1 or Section 5.3.2, then Kowa shall not be entitled to receive any Tail Period Payments.

ARTICLE 14

GOVERNING LAW AND DISPUTE RESOLUTION

14.1 Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the New York, excluding the choice of law rules thereof.

14.2 Dispute Resolution. The Parties recognize that disputes as to certain matters may from time to time arise during the Term which relate to either Party’s rights and/or obligations hereunder. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the Parties agree to follow the procedures set forth in this ARTICLE 14 if and when a dispute arises under this Agreement.

14.2.1 Referred From Committee. Any dispute, controversy or difference arising from the JSC pursuant to ARTICLE 3 shall be resolved in accordance with Section 3.1.4.

14.2.2 Arising Between the Parties. Other than any dispute, controversy or difference which may arise from the JSC as described in Section 14.2.1, any disputes, controversies or differences which may arise between the Parties out of or in relation to or in connection with this Agreement, including any alleged failure to perform, or breach, of this Agreement, or any issue relating to the interpretation or application of this Agreement, then upon the request of either Party, the Parties agree to meet and discuss in good faith a possible resolution thereof, which good faith efforts shall include at least one in-person meeting between the chief executive officers of each Party. If the matter is not resolved within thirty (30) days following the request for discussions, either Party may then invoke the provisions of Section 14.3.

14.3 Arbitration. Any dispute, controversy or claim arising out of or relating to the validity, construction, interpretation, enforceability, breach, performance, application or termination of this Agreement that is not resolved pursuant to Section 14.2.2, shall be settled by binding arbitration administered by JAMS pursuant to its Comprehensive Arbitration Rules and Procedures of JAMS then in effect (the “**JAMS Rules**”), except as otherwise provided herein. The arbitration shall be governed by the United States Federal Arbitration Act, 9 U.S.C. §§ 1-16 (the “**Federal Arbitration Act**”), to the exclusion of any inconsistent state laws. The United States Federal Rules of Civil Procedure shall govern discovery and the rules of evidence for the arbitration. The arbitration will be conducted in New York, New York, and the Parties consent to the personal jurisdiction of the United States federal courts, for any case arising out of or otherwise related to this arbitration, its conduct and its enforcement. Any situation not expressly covered by this Agreement shall be decided in accordance with the JAMS Rules.

14.3.1 Arbitrator. The arbitrator shall be one (1) neutral, independent and impartial arbitrator selected from a pool of retired federal judges or magistrates to be presented to the Parties by JAMS. Failing the agreement of the Parties as to the selection of the arbitrator within thirty (30) days, the arbitrator shall be appointed by JAMS in accordance with the JAMS Rules.

14.3.2 Decision. The power of the arbitrator to fashion procedures and remedies within the scope of this Agreement is recognized by the Parties as essential to the success of the arbitration process. The arbitrator shall not have the authority to fashion remedies which would

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not be available to a federal judge hearing the same dispute. The arbitrator is encouraged to operate on this premise in an effort to reach a fair and just decision. Reasons for the arbitrator’s decisions should be set forth in accordance with the JAMS Rules. Such a written decision shall be rendered by the arbitrator following a full comprehensive hearing, no later than twelve (12) months following the selection of the arbitrator as provided for in Section 14.3.1.

14.3.3 Award. Any award shall be promptly paid in Dollars free of any tax, deduction or offset; and any costs, fees or taxes incident to enforcing the award shall, to the maximum extent permitted by Applicable Law, be charged against the Party resisting enforcement. If as to any issue the arbitrator should determine under the Applicable Law that the position taken by a Party is in violation of the standards of Rule 11(b) of the Federal Rules of Civil Procedure, the arbitrator shall also award an appropriate allocation of the adversary’s reasonable attorney fees, costs and expenses to be paid by the offending Party, the precise sums to be determined after a bill of attorney fees, expenses and costs consistent with such award has been presented following the award on the merits. Each Party agrees to abide by the award rendered in any arbitration conducted pursuant to this ARTICLE 14, and agrees that, subject to the Federal Arbitration Act, judgment may be entered upon the final award in any court of competent jurisdiction and that other courts may award full faith and credit to such judgment in order to enforce such award. The award shall include interest from the date of the award until paid in full, at a rate fixed by the arbitrator and the arbitrator may, in his or her discretion, award pre-judgment interest. With respect to money damages, nothing contained herein shall be construed to permit the arbitrator or any court or any other forum to award punitive or exemplary damages. By entering into this agreement to arbitrate, the Parties expressly waive any claim for punitive or exemplary damages.

14.3.4 Costs. Except as set forth in Section 14.3.3, each Party shall bear its own legal fees. The arbitrator shall assess his or her costs, fees and expenses against the Party losing the arbitration unless he or she believes that neither Party is the clear loser, in which case the arbitrator shall divide his or her fees, costs and expenses according to his or her sole discretion.

14.3.5 Injunctive Relief. Provided a Party has made a sufficient showing under the rules and standards set forth in the Federal Rules of Civil Procedure and applicable case law, the arbitrator shall have the freedom to invoke, and the Parties agree to abide by, injunctive measures after either Party submits in writing for arbitration claims requiring immediate relief. Additionally, nothing in this ARTICLE 14 will preclude either Party from seeking equitable relief or interim or provisional relief from a court of competent jurisdiction, including a temporary restraining order, preliminary injunction or other interim equitable relief, concerning a dispute either prior to or during any arbitration if necessary to protect the interests of such Party or to preserve the status quo pending the arbitration proceeding.

14.3.6 Confidentiality. The arbitration proceeding shall be confidential and the arbitrator shall issue appropriate protective orders to safeguard each Party’s Confidential Information. Except as required to comply with Applicable Laws, including rules and regulations promulgated by the SEC, The NASDAQ Stock Market or any securities exchanges, no Party shall make (or instruct the arbitrator to make) any public announcement with respect to the proceedings or decision of the arbitrator without prior written consent of the other Party. The existence of any dispute submitted to arbitration, and the award, shall be kept in confidence by the Parties and the arbitrator, except as required in connection with the enforcement of such award or as otherwise required by Applicable Law.

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14.3.7 Survivability. Any duty to arbitrate under this Agreement shall remain in effect and be enforceable after termination of this Agreement for any reason.

ARTICLE 15

MISCELLANEOUS

15.1 Engagement of Contract Sales Force or Subcontracting.

15.1.1 Kowa. Kowa shall not engage a contract sales organization to fulfill its obligations under this Agreement nor shall it subcontract any of its obligations under this Agreement, except its audit rights, to a Third Party or to its Affiliates, without the prior written consent of Amarin.

15.1.2 Amarin. Amarin may engage a contract sales organization to perform Promotion and Detailing in the Territory[***].

15.2 Assignment. Neither Party shall assign or transfer its rights or obligations under this Agreement, except to an Affiliate (including entities that become Affiliates following a Change of Control), without the prior written consent of the other Party. In the event of any permitted assignment, the assigning or transferring Party must confirm to the other Party in writing that it will remain fully liable for all obligations under this Agreement as if such assignment or transfer had not occurred. Any attempted assignment or transfer in contravention of this Section 15.2 shall be of no legal effect.

15.3 Notices. Any notice, request, approval or other document required or permitted to be given under this Agreement shall be in writing and shall be deemed to have been given when delivered in person, or sent by overnight courier service, postage prepaid, or sent by certified or registered mail, return receipt requested to the following addresses of the Parties and to the attention of the persons identified below (or to such other address, addresses or persons as may be specified from time to time in a written notice). Any notices given pursuant to this Agreement shall be deemed to have been given and delivered upon the earlier of (a) if sent by overnight courier service, on the date when received at the address set forth below as proven by a written receipt from the delivery service verifying delivery, or (b) if sent by certified or registered mail, three (3) Business Days after mailed by certified or registered mail postage prepaid and properly addressed, with return receipt requested, or (c) if delivered in person, on the date of delivery to the address set forth below as proven by written signature of the recipient.

If to Kowa:

Name: Kowa Pharmaceuticals America, Inc.
Street: 530 Industrial Park Boulevard
City/State: Montgomery, AL 36117
Country: U.S.A
Attn: Chief Executive Officer and Chief Operating Officer, respectively

With a copy to:

Name: Foley & Lardner LLP
Street: 3579 Valley Centre Drive, Suite 300
City/State: San Diego, CA 92138
Country: U.S.A.
Attn: Richard A. Kaufman

If to Amarin Pharma:

Name: Amarin Pharma, Inc.
Street: 1430 Route 206, Suite 101
City/State: Bedminster, NJ 07921
Country: U.S.A.
Attn: Chief Executive Officer

With a copy to:

Name: Amarin Pharma, Inc.
Street: 1430 Route 206, Suite 101
City/State: Bedminster, NJ 07921
Country: U.S.A.
Attn: General Counsel

If to Amarin Ireland:

Name: Amarin Pharmaceuticals Ireland Limited
Street: 88 Harcourt Street, Dublin 2, Co
City/State: Dublin
Country: Ireland
Attn: Chief Executive Officer

With a copy to:

Name: Amarin Pharma, Inc.
Street: 1430 Route 206, Suite 101
City/State: Bedminster, NJ 07921
Country: U.S.A.
Attn: Chief Executive Officer and General Counsel, respectively

Any notice to Amarin Pharma and/or Amarin Ireland shall also include a copy to:

Name: Morgan, Lewis & Bockius, LLP
Street: 502 Carnegie Center
City/State: Princeton, NJ 08540
Country: U.S.A.
Attn: Randall B. Sunberg

Any notice to Amarin Pharma and/or Amarin Ireland shall also include a copy to:

Name: Goodwin Procter LLP
Street: 53 State Street
City/State: Boston, MA 02109
Country: U.S.A.
Attn: Michael Bison

15.4 Force Majeure. If the performance of any part of this Agreement by either Party, or of any obligation under this Agreement, is prevented, restricted, interfered with or delayed by reason of a Force Majeure affecting the Party liable to perform, unless conclusive evidence to the contrary is provided, the Party so affected shall, upon giving written notice to the other Party, be excused from such performance to the extent of such Force Majeure, provided that the affected Party shall use its Commercially Reasonable Efforts to avoid or remove such causes of nonperformance and shall continue performance with the utmost dispatch whenever such Force Majeure ceases. When such circumstances arise, the Parties shall discuss what, if any, modification of the terms of this Agreement may be required in order to arrive at an equitable solution.

15.5 No Partnership or Joint Venture. Amarin and Kowa shall be independent contractors and the relationship between the Parties hereunder shall not constitute a partnership, joint venture or agency. Neither Amarin nor Kowa shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other, without the prior written consent of such other Party to do so.

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH “[***]”. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT UNDER RULE 24b-2 OF THE SECURITIES EXCHANGE ACT OF 1934.

15.6 No Waiver Of Breach. The failure of either Party at any time or times to require performance of any provision hereof shall in no manner affect its rights at a later time to enforce the same. No waiver by either Party of any condition or term in any one or more instances shall be construed as a further or continuing waiver of such condition or term or of another condition or term.

15.7 Severability. In the event that any portion of this Agreement is held illegal, void or ineffective, the remaining portions of this Agreement shall remain in full force and effect. If any of the terms or provisions of this Agreement are in conflict with any Applicable Law, then such terms or provisions shall be deemed to be modified to conform with such Applicable Law to the extent necessary in order that such terms or provisions be valid and enforceable and such amendment shall apply only with respect to the operation of such terms or provisions in the particular jurisdiction in which such declaration is made or, if such modification is not feasible, then such terms and provisions shall be deemed to be inoperative to the extent that such terms or provisions conflict with Applicable Law. In the event that the terms and conditions of this Agreement are materially altered as a result of this Section 15.7, the Parties shall renegotiate the terms and conditions of this Agreement to resolve any inequities and to achieve the original intent of the Parties.

15.8 Entire Agreement. This Agreement and all Schedules attached hereto, and including the safety agreement referred to in Section 7.6.3, shall constitute the entire agreement between the Parties relating to the subject matter hereof and thereof and shall supersede all previous writings and understandings including the Confidential Disclosure Agreement. No terms or provisions of this Agreement shall be varied or modified by any prior or subsequent statement, conduct or act of either of the Parties, except that the Parties may amend this Agreement by written instruments specifically referring to and executed in the same manner as this Agreement.

15.9 Interpretation. The words “include,” “includes” and “including” shall be deemed to be followed by the phrase “without limitation.” All references herein to Articles, Sections, and Schedules shall be deemed references to Articles and Sections of, and Schedules to, this Agreement unless the context shall otherwise require. Except as otherwise expressly provided herein, all terms of an accounting or financial nature shall be construed in accordance with generally accepted accounting principles in the United States, as in effect from time to time.

15.10 Execution In Counterparts. This Agreement may be executed in two (2) counterparts, each of which shall be deemed an original but which together shall constitute one (1) and the same instrument. A facsimile or a portable document format (PDF) copy of this Agreement, including the signature pages, will be deemed an original.

[Signature page follows.]

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IN WITNESS WHEREOF, the Parties, through their authorized representatives, have executed this Co-Promotion Agreement as of the Effective Date.

KOWA PHARMACEUTICALS, AMERICA, INC.

By: /s/ Benjamin Stakely
Name: Benjamin Stakely
Title: President and CEO

AMARIN PHARMA, INC.

By: /s/ John F. Thero
Name: John F. Thero
Title: President and CEO

AMARIN PHARMACEUTICALS IRELAND LIMITED

By: /s/ Patrick O’Sullivan
Name: Patrick O’Sullivan
Title: Director

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Schedule 1.14
Amarin Trademarks*

[***]

Schedule 1.14 - Amarin Trademarks

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Schedule 1.53
Kowa Trademarks

[***]

Schedule 1.53 - Kowa Trademarks

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Schedule 1.86
Example of Sample Costs Calculation*

[***]

Schedule 1.86 - Example of Sample Costs Calculation

Schedule 4.4
PDE Adjustment Calculation Example

Example:

[***]

Schedule 4.4 - PDE Adjustment Calculation Example

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Schedule 5.2
Co-Promote Fee

The percentage of Gross Margin to be used to calculate the Co-Promote Fee may vary [***] depending whether (1) the ANCHOR Data is permitted by the FDA or otherwise under Applicable Law to be used in the Promotion of the Product, or (2) the FDA has approved the ANCHOR Indication, and may also vary depending on the total Gross Sales, in all cases as set forth below.

[***]

Schedule 5.2 - Co-Promote Fee

CERTIFICATION

I, John F. Thero, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Amarin Corporation plc;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal controls over financial reporting, or caused such internal controls over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 9, 2014

/s/ John F. Thero

John F. Thero
President and Chief Executive Officer
(Principal Executive Officer)

CERTIFICATION

I, Michael J. Farrell, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Amarin Corporation plc;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 9, 2014

/s/ Michael J. Farrell

Michael J. Farrell
Controller (Principal Financial Officer)

STATEMENT PURSUANT TO 18 U.S.C. § 1350

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), John F. Thero, President and Chief Executive Officer (Principal Executive Officer) of Amarin Corporation plc (the “Company”) and Michael J. Farrell, Controller (Principal Financial Officer) of the Company, each hereby certifies that, to the best of his knowledge:

- (1) The Company’s Quarterly Report on Form 10-Q for the period ended March 31, 2014, to which this Certification is attached as Exhibit 32.1 (the “Quarterly Report”) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Quarterly Report fairly presents, in all material respects, the financial condition and results of operations of the Company at the end of such year.

Date: May 9, 2014

/s/ John F. Thero

John F. Thero

President and Chief Executive Officer (Principal Executive Officer)

Date: May 9, 2014

/s/ Michael J. Farrell

Michael J. Farrell

Controller (Principal Financial Officer)

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not incorporated by reference into any filing of Amarin Corporation plc under the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.