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

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**FORM 10-Q**

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

For the quarterly period ended March 31, 2015

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File No. 000-21392

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**Amarin Corporation plc**

(Exact Name of Registrant as Specified in its Charter)

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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

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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

176,246,652 shares held as American Depository Shares (ADSs), each representing one Ordinary Share, 50 pence par value per share, and 865,904 ordinary shares, were outstanding as of May 1, 2015.

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## PART I

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

	March 31, 2015	December 31, 2014
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 161,195	\$ 119,539
Restricted cash	600	600
Accounts receivable, net	8,545	7,842
Inventory	16,183	13,733
Deferred tax assets	934	934
Prepaid and other current assets	2,293	2,633
Total current assets	<u>189,750</u>	<u>145,281</u>
Property, plant and equipment, net	339	381
Deferred tax assets	12,651	12,556
Other non-current assets	2,697	2,826
Intangible asset, net	9,902	10,063
<b>TOTAL ASSETS</b>	<u>\$ 215,339</u>	<u>\$ 171,107</u>
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
Current Liabilities:		
Accounts payable	\$ 10,756	\$ 8,525
Current portion of long-term debt	14,102	15,394
Accrued expenses and other current liabilities	17,675	16,387
Total current liabilities	<u>42,533</u>	<u>40,306</u>
Long-Term Liabilities:		
Exchangeable senior notes, net of discount	123,192	121,846
Long-term debt	90,082	89,617
Long-term debt derivative liabilities	6,100	7,400
Deferred revenue	14,625	—
Other long-term liabilities	631	386
Total liabilities	<u>277,163</u>	<u>259,555</u>
Commitments and contingencies (Note 7)		
Stockholders' Deficit:		
Common stock, £0.50 par, unlimited authorized; 177,096,650 issued, 176,962,313 outstanding at March 31, 2015; 174,610,451 issued, 174,590,372 outstanding at December 31, 2014	145,026	143,113
Series A Convertible Preferred Stock, £0.05 par, unlimited authorized; 352,150,790 issued and outstanding at March 31, 2015 (equivalent to 35,215,079 ordinary shares upon future consolidation and redesignation at a 10:1 ratio); zero shares issued and outstanding at December 31, 2014	26,179	—
Additional paid-in capital	769,533	738,890
Treasury stock; 134,337 shares at March 31, 2015; 20,079 shares at December 31, 2014	(334)	(217)
Accumulated deficit	(1,002,228)	(970,234)
Total stockholders' deficit	<u>(61,824)</u>	<u>(88,448)</u>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT</b>	<u>\$ 215,339</u>	<u>\$ 171,107</u>

See notes to condensed consolidated financial statements.

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

	<b>Three months ended March 31,</b>	
	<b>2015</b>	<b>2014</b>
Product revenue, net	\$ 15,558	\$ 10,967
Licensing revenue	375	—
<b>Total revenue, net</b>	<b>15,933</b>	<b>10,967</b>
Less: Cost of goods sold	5,627	4,246
<b>Gross margin</b>	<b>10,306</b>	<b>6,721</b>
Operating expenses:		
Selling, general and administrative	24,741	20,585
Research and development	12,614	11,707
<b>Total operating expenses</b>	<b>37,355</b>	<b>32,292</b>
Operating loss	(27,049)	(25,571)
Gain on change in fair value of derivative liabilities	464	4,393
Interest expense, net	(4,885)	(4,393)
Other (expense) income, net	(128)	16
Loss from operations before taxes	(31,598)	(25,555)
Benefit from (provision for) income taxes	472	(425)
Net loss	\$ (31,126)	\$ (25,980)
Preferred stock purchase option	(868)	—
Net loss applicable to common shareholders	<u>\$ (31,994)</u>	<u>\$ (25,980)</u>
Loss per share:		
Basic	\$ (0.18)	\$ (0.15)
Diluted	\$ (0.18)	\$ (0.15)
Weighted average shares:		
Basic	175,582	172,872
Diluted	175,582	174,431

See notes to condensed consolidated financial statements.

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

	Common Shares	Preferred Shares	Treasury Shares	Common Stock	Preferred Stock	Additional Paid-in Capital	Treasury Shares	Accumulated Deficit	Total
<b>December 31, 2014</b>	<b>174,610,451</b>	<b>—</b>	<b>(20,079)</b>	<b>\$ 143,113</b>	<b>\$ —</b>	<b>\$ 738,890</b>	<b>\$ (217)</b>	<b>\$ (970,234)</b>	<b>\$(88,448)</b>
Issuance of Series A Convertible Preferred Stock, net	—	352,150,790	—	—	26,179	26,074	—	—	52,253
Preferred stock purchase option	—	—	—	—	—	1,814	—	(868)	946
Exercise of stock options	2,114	—	—	1	—	3	—	—	4
Exercise of warrants	1,844,585	—	—	1,429	—	1,284	—	—	2,713
Vesting of restricted stock units	639,500	—	(114,258)	483	—	(483)	(117)	—	(117)
Tax provision on stock-based compensation	—	—	—	—	—	(552)	—	—	(552)
Stock-based compensation	—	—	—	—	—	2,503	—	—	2,503
Loss for the period	—	—	—	—	—	—	—	(31,126)	(31,126)
<b>March 31, 2015</b>	<b>177,096,650</b>	<b>352,150,790</b>	<b>(134,337)</b>	<b>\$ 145,026</b>	<b>\$ 26,179</b>	<b>\$ 769,533</b>	<b>\$ (334)</b>	<b>\$(1,002,228)</b>	<b>\$(61,824)</b>

See notes to condensed consolidated financial statements.

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

	<b>Three Months Ended March 31,</b>	
	<b>2015</b>	<b>2014</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (31,126)	\$ (25,980)
Adjustments to reconcile loss to net cash used in operating activities:		
Depreciation and amortization	42	56
Stock-based compensation	3,042	1,957
Stock-based compensation—warrants	(9)	(72)
Excess tax provision on stock-based awards	552	1
Amortization of debt discount and debt issuance costs	1,811	1,173
Amortization of intangible asset	161	161
Gain on changes in fair value of derivative liabilities	(464)	(4,393)
Deferred income taxes	(95)	(24)
Changes in assets and liabilities:		
Restricted cash	—	400
Accounts receivable	(703)	(380)
Inventories	(2,450)	4,861
Prepaid and other current assets	340	(1,380)
Other non-current assets	129	1,339
Accrued interest payable	(1,292)	(405)
Deferred revenue	14,625	(1,703)
Accounts payable and other current liabilities	2,549	(3,105)
Other non-current liabilities	245	—
Net cash used in operating activities	<u>(12,643)</u>	<u>(27,494)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Net cash used in investing activities	<u>—</u>	<u>—</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from issuance of preferred stock, net of transaction costs	52,253	—
Proceeds from exercise of stock options, net of transaction costs	4	285
Proceeds from exercise of warrants, net of transaction costs	2,713	—
Excess provision on stock-based awards	(552)	(1)
Acquisition of treasury stock	(117)	—
Payments under capital leases	(2)	(26)
Net cash provided by financing activities	<u>54,299</u>	<u>258</u>
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b>41,656</b>	<b>(27,236)</b>
<b>CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD</b>	<b>119,539</b>	<b>191,514</b>
<b>CASH AND CASH EQUIVALENTS, END OF PERIOD</b>	<b><u>\$ 161,195</u></b>	<b><u>\$ 164,278</u></b>
Supplemental disclosure of cash flow information:		
Cash paid during the year for:		
Interest	<u>\$ 4,273</u>	<u>\$ 3,636</u>
Income taxes	<u>\$ 17</u>	<u>\$ 33</u>
Non-cash transactions:		
Transfer of preferred stock purchase option derivative liability to equity	<u>\$ 868</u>	<u>\$ —</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  $\geq$ 500 mg/dL) hypertriglyceridemia. Vascepa is available in the United States by prescription only. The Company began selling and marketing Vascepa in the United States in January 2013. The Company sells Vascepa principally to a limited number of major wholesalers, as well as selected regional wholesalers and specialty pharmacy providers, or collectively, its Distributors, that in turn resell Vascepa to retail pharmacies for subsequent resale to patients and health care providers. The Company markets Vascepa through its sales force of approximately 150 sales professionals, including sales representatives and their managers. In May 2014, Kowa Pharmaceuticals America, Inc. commenced co-promotion of Vascepa in accordance with a co-promotion agreement the Company entered into with Kowa Pharmaceuticals America, Inc. Kowa Pharmaceuticals America, Inc. co-promotes Vascepa through its approximately 250 sales representatives who now devote a substantial portion of their time to promoting Vascepa in conjunction with the promotion of Kowa Pharmaceutical America, Inc.’s primary product, a branded statin for patients with high cholesterol. The Company operates in one business segment.

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

**Basis of Presentation**

The condensed consolidated financial statements included herein have been prepared by the Company, without audit, in accordance with accounting principles generally accepted in the United States of America (the “U.S.” or the “United States”) and pursuant to the rules and regulations of the Securities and Exchange Commission, or the SEC. Certain information in the footnote disclosures of the financial statements has been condensed or omitted where it substantially duplicates information provided in the Company’s latest audited consolidated financial statements, in accordance with the rules and regulations of the SEC. These condensed consolidated financial statements should be read in conjunction with the Company’s audited consolidated financial statements and notes included in its Annual Report on Form 10-K for the fiscal year ended December 31, 2014, or the 2014 Form 10-K, filed with the SEC. The balance sheet amounts at December 31, 2014 in this report were derived from the Company’s audited 2014 consolidated financial statements included in the 2014 Form 10-K.

The condensed consolidated financial statements reflect all adjustments of a normal and recurring nature that, in the opinion of management, are necessary to present fairly the Company’s financial position, results of operations and cash flows for the periods indicated. The preparation of the Company’s condensed consolidated financial statements in conformity with 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. The results of operations for the three months ended March 31, 2015 and March 31, 2014, respectively, are not necessarily indicative of the results for the entire fiscal year or any future period.

The accompanying consolidated financial statements of the Company and subsidiaries have been prepared on a basis which assumes that the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The 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, 2015, the Company had cash and cash equivalents of \$161.2 million. The Company’s consolidated balance sheets also include derivative liabilities as well as long-term debt and exchangeable senior notes. The outstanding January 2012 exchangeable senior notes, or the 2012 Notes, and May 2014 exchangeable senior notes, or the 2014 Notes, may be redeemed on or after January 19, 2017 and January 19, 2019, respectively, at the option of the holders and it is not puttable by the holders prior to these dates except upon the occurrence of certain contingent events. The 2012 Notes are exchangeable under certain circumstances into cash, American

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Depository Shares, or ADSs, or a combination of cash and ADSs, at the Company's election. The 2014 Notes are exchangeable under certain circumstances into ADSs. Accordingly, the long-term debt and exchangeable senior notes do not represent a short term claim on the liquid assets of the Company.

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

### **(2) Significant Accounting Policies**

#### **Principles of Consolidation**

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

#### **Use of Estimates**

Accounting estimates are based on historical experience and other factors that are considered reasonable under the circumstances. Estimates are used in determining such items as provisions for sales returns, rebates and incentives, chargebacks, and other sales allowances, depreciable/amortizable lives, asset impairments, valuation allowance on deferred taxes, amounts recorded for licensing revenue, contingencies and accruals, and valuations of derivative and long-term debt instruments. Because of the uncertainties inherent in such estimates, actual results may differ from these estimates. Management periodically evaluates estimates used in the preparation of the condensed consolidated financial statements for continued reasonableness. The results of operations for the three months ended March 31, 2015 and 2014, respectively, are not necessarily indicative of the results for any future period.

#### **Use of Forecasted Financial Information in Accounting Estimates**

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

#### **Revenue Recognition**

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

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

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

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

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

**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, 2015, the Company had experienced a de minimis quantity of product returns. The Company estimates future product returns on sales of Vascepa based on: (i) data provided to the Company by its Distributors (including weekly reporting of Distributors' sales and inventory held by Distributors that provided the Company with visibility into the distribution channel in order to determine what quantities were sold to retail pharmacies and other providers), (ii) information provided to the Company from retail pharmacies, (iii) data provided to the Company by a third party data provider which collects and publishes prescription data, and other third parties, (iv) historical industry information regarding return rates for similar pharmaceutical products, (v) the estimated remaining shelf life of Vascepa previously shipped and currently being shipped to Distributors and (vi) contractual agreements intended to limit the amount of inventory maintained by the Company's Distributors.

**Other Incentives:** Other incentives that the Company offers to indirect customers include co-pay mitigation rebates provided by the Company to commercially insured patients who have coverage for Vascepa and who reside in states that permit co-pay mitigation programs. The Company's co-pay mitigation program is intended to reduce each participating patient's portion of the financial responsibility for Vascepa's purchase price to a specified dollar amount. Based upon the terms of the program and information regarding programs provided for similar specialty pharmaceutical products, the Company estimates the average co-pay mitigation amounts and the percentage of patients that it expects to participate in the program in order to establish its accruals for co-pay mitigation rebates and deducts these estimated amounts from its gross product revenues at the time the revenues are recognized. The Company adjusts its accruals for co-pay mitigation rebates based on actual redemption activity and estimates regarding the portion of issued co-pay mitigation rebates that it estimates will be redeemed.

The following table summarizes activity in each of the net product revenue allowance and reserve categories described above for the three months ended March 31, 2015 and 2014 (in thousands):

	<u>Trade Allowances</u>	<u>Rebates, Chargebacks and Discounts</u>	<u>Product Returns</u>	<u>Other Incentives</u>	<u>Total</u>
<b>Balance at December 31, 2014</b>	<b>\$ 2,207</b>	<b>\$ 3,610</b>	<b>\$ 481</b>	<b>\$ 792</b>	<b>\$ 7,090</b>
Provision related to current period sales	2,756	5,145	127	1,717	9,745
Provision related to prior period sales	—	74	—	—	74
Credits/payments made for current period sales	(462)	(1,288)	—	(1,085)	(2,835)
Credits/payments made for prior period sales	(1,555)	(3,367)	—	(607)	(5,529)
<b>Balance at March 31, 2015</b>	<b>\$ 2,946</b>	<b>\$ 4,174</b>	<b>\$ 608</b>	<b>\$ 817</b>	<b>\$ 8,545</b>

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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>
<b>Balance at December 31, 2013</b>	<b>\$ 1,071</b>	<b>\$ 1,137</b>	<b>\$ 72</b>	<b>\$ 189</b>	<b>\$ 2,469</b>
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)
<b>Balance at March 31, 2014</b>	<b><u>\$ 1,134</u></b>	<b><u>\$ 1,391</u></b>	<b><u>\$ 152</u></b>	<b><u>\$ 118</u></b>	<b><u>\$ 2,795</u></b>

### *Multiple-Element Arrangements and Licensing Revenue*

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

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

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

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

### *Milestones*

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

### *Distribution Costs*

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

### *Cash and Cash Equivalents*

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

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### ***Accounts Receivable, net***

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

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

	<b>March 31, 2015</b>	<b>December 31, 2014</b>
Gross trade accounts receivable	\$ 11,796	\$ 10,215
Trade allowances	(2,946)	(2,207)
Chargebacks	(305)	(166)
Accounts receivable, net	<u>\$ 8,545</u>	<u>\$ 7,842</u>

### ***Inventory***

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

### ***Property, Plant and Equipment***

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

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

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

### ***Long-Lived Asset Impairment***

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

### ***Intangible Asset, net***

Intangible assets consist of a milestone payment paid to the former shareholders of Laxdale Limited related to the 2004 acquisition of the rights to Vascepa, which is the result of Vascepa receiving marketing approval for the first indication and is amortized over its estimated useful life on a straight-line basis. See Note 7—Commitments and Contingencies for further information regarding other obligations related to the acquisition of Laxdale Limited.

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### **Costs for Patent Litigation and Legal Proceedings**

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

### **Research and Development Costs**

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

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

The Company charges selling, general and administrative costs to operations as incurred. Selling, general and administrative costs include costs of salaries, programs and infrastructure necessary for the general conduct of the Company's business, including those incurred as a result of the commercialization of Vascepa in the United States for the MARINE indication as well as co-promotion fees payable to Kowa Pharmaceuticals America, Inc.

### **Income Taxes**

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

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

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

### **Derivative Instruments**

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

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

### **Loss per Share**

Basic net loss per share is determined by dividing net loss by the weighted average shares of common stock outstanding during the period. Diluted net loss per share is determined by dividing net loss by diluted weighted average shares outstanding. Diluted weighted average shares reflects the dilutive effect, if any, of potentially dilutive common shares, such as common stock options and warrants 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.

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

The calculation of net loss and the number of shares used to compute basic and diluted earnings per share for the three months ended March 31, 2015 and 2014 are as follows:

<b>In thousands</b>	<b>March 31, 2015</b>	<b>March 31, 2014</b>
Net loss	\$ (31,126)	\$ (25,980)
Preferred stock purchase option (see Note 8)	(868)	—
Net loss applicable to common shareholders—basic	(31,994)	(25,980)
Gain on warrant derivative liability	(119)	(965)
Net loss—diluted	(32,113)	(26,945)
Net loss per share—basic	(0.18)	(0.15)
Weighted average shares outstanding—basic	175,582	172,872
Effect of dilutive warrants	—	1,559
Weighted average shares outstanding—diluted	175,582	174,431
Net income loss per share—diluted	\$ (0.18)	\$ (0.15)

For the three months ended March 31, 2015 and 2014, the following potentially dilutive securities were not included in the computation of net loss per share because the effect would be anti-dilutive:

<b>In thousands</b>	<b>March 31, 2015</b>	<b>March 31, 2014</b>
Stock options	12,078	11,577
Restricted stock and restricted stock units	4,071	2,168
Warrants	—	1,685
Exchangeable senior notes (if converted)	49,215	17,021
Preferred stock (if converted)	35,215	—

### **Debt Instruments**

Debt instruments are initially recorded at fair value, with coupon interest and amortization of debt issuance discounts recognized in the statement of operations as interest expense each period in which such instruments are outstanding. If the Company issues shares to discharge the liability, the debt obligation is derecognized and common stock and additional paid-in capital are recognized on the issuance of those shares. The conversion features in both the 2012 Notes and 2014 Notes qualify for the exception from derivative accounting in accordance with ASC 815-40. The 2012 Notes may be settled, at the Company's discretion, in any combination of ADSs or cash upon conversion and have been accounted for in accordance with ASC 470-20. Under ASC 470-20, the fair value of the liability component of the 2012 Notes was determined and deducted from the initial proceeds to determine the proceeds allocated to the conversion option, which has been recorded in equity. The difference between the initial fair value of the liability component and the amount repayable was amortized over the expected term of the instrument. The conversion feature in the 2014 Notes may only be settled in ADSs upon conversion and has been accounted for as part of the debt host.

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

### **Stock-Based Compensation**

Stock-based compensation cost is generally measured at the grant date, based on the fair value of the award, and is recognized as compensation expense over the requisite service period. For awards with performance conditions, if the achievement of the performance conditions is deemed probable, the Company recognizes compensation expense based on the fair value of the award over the estimated service period. The Company reassesses the probability of achievement of the performance conditions for such awards each reporting period.

### **Concentration of Credit Risk**

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

A significant portion of the Company's sales are to wholesalers in the pharmaceutical industry. The Company monitors the creditworthiness of customers to whom it grants credit terms and has not experienced any credit losses. The Company does not require collateral or any other security to support credit sales. The Company's top three customers accounted for 94% and 96% of gross product sales for the three months ending March 31, 2015 and 2014, respectively, and represented 94% and 95% of the gross accounts receivable balance as of March 31, 2015 and 2014, respectively. The Company has not experienced any write-offs of its accounts receivable.

### **Concentration of Suppliers**

The Company entered into Vascepa API supply agreements with Nisshin Pharma, Inc., or Nisshin, in 2010. In 2011, the Company entered into agreements with two additional suppliers, Chemport, Inc., or Chemport, and BASF (formerly Equateq Limited) for the supply of API. In 2012, the Company agreed to terms with a fourth API supplier, a consortium of companies led by Slanmhor Pharmaceutical, Inc. (Slanmhor). The Company terminated its agreement with BASF in February 2014. While the Company has contractual freedom to source the API for Vascepa and has 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 the Company's API for Vascepa. The Company cannot provide assurance that the efforts of its contractual suppliers will continue to be successful, that it will be able to renew such agreements or that it will be able to enter into new agreements in the future. Any alteration to or termination of the Company's current API supply, manufacturing, and distribution agreements, its failure to enter into new and similar agreements, or the interruption of the supply of its products under such agreements, could have a material adverse effect on its business, condition (financial and other), prospects or results of operations. For the three months ended March 31, 2015 and 2014, all of the Company's net product sales were generated from API purchased from Nisshin and Chemport.

The Company currently has agreements with three commercial API encapsulators for the encapsulation of Vascepa: Patheon, Inc. (formerly Banner Pharmacaps), Catalent Pharma Solutions, and Capsugel US, LLC. These companies have qualified their manufacturing processes and are capable of manufacturing Vascepa. There can be no guarantee that other suppliers with which the Company has contracted to encapsulate API will be qualified to manufacture the product to its specifications or that these and any future suppliers will have the manufacturing capacity to meeting anticipated demand for Vascepa.

### **Foreign Currency**

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

### **Debt Issuance Costs**

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

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

The following table presents information about the Company’s assets and liabilities as of March 31, 2015 and December 31, 2014 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 thousands</i>	March 31, 2015			
	Total	Level 1	Level 2	Level 3
<b>Asset:</b>				
Cash equivalents—money markets	\$40,163	\$40,163	\$ —	\$ —
<b>Liabilities:</b>				
Long-term debt derivative liabilities	\$ 6,100	\$ —	\$ —	\$6,100
<i>In thousands</i>	December 31, 2014			
	Total	Level 1	Level 2	Level 3
<b>Asset:</b>				
Cash equivalents—money markets	\$65,156	\$65,156	\$ —	\$ —
<b>Liabilities:</b>				
Warrant derivative liability	\$ 119	\$ —	\$ —	\$ 119
Long-term debt derivative liability	\$ 7,400	\$ —	\$ —	\$7,400

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

<i>In thousands</i>	March 31, 2015		December 31, 2014	
	Carrying Value	Estimated Fair Value	Carrying Value	Estimated Fair Value
Long-term debt—December 2012 financing	\$90,082	\$ 84,900	\$89,617	\$ 81,000
2012 Notes	31,266	26,521	31,266	25,689
2014 Notes	91,926	124,932	90,580	75,533

The estimated fair value of the long-term debt pursuant to the December 2012 financing is calculated utilizing the same Level 3 inputs utilized in valuing the related derivative liability (see Long-Term Debt Derivative Liabilities below). The estimated fair value of the 2012 Notes and 2014 Notes is calculated based on Level 1 quoted bond prices. The carrying value of the 2012 Notes at March 31, 2015 and December 31, 2014 does not include a debt discount, as it had been fully amortized as non-cash interest expense over the expected term of the 2012 Notes. The carrying value of the 2014 Notes at March 31, 2015 and December 31, 2014 includes a debt discount of \$26.8 million and \$28.2 million, respectively, which is being amortized as non-cash interest expense over the expected term of the 2014 Notes. The change in the estimated fair values of these liabilities from December 31, 2014 to March 31, 2015 is largely related to the quoted bond prices.

### **Derivative Liabilities**

#### *Warrant Derivative Liability*

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

As of December 31, 2014, the fair value of the warrant derivative liability was determined to be \$0.1 million using the Black-Scholes option valuation applying the following assumptions: (i) risk-free rate of 0.04%, (ii) remaining term of 0.16 years, (iii) no dividend yield (iv) volatility of 79%, and (v) the stock price on the date of measurement. As there were no warrants outstanding as of March 31, 2015, the warrant derivative liability was extinguished. The \$0.1 million decrease in the fair value of the warrants during the three months ended March 31, 2015 was recognized as a \$0.1 million gain on change in fair value of derivative liability.

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### *Long-Term Debt Redemption Features*

The Company's December 2012 financing agreement with BioPharma Secured Debt Fund II Holdings Cayman LP (discussed in Note 6 below) contains a redemption feature whereby, upon a change of control, the Company would have been required to pay \$140 million, less any previously repaid amount, if the change of control occurred 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 of future revenues and for a potential change in control, and by determining the fair value of the debt with and without the change in control provision included. The difference between the two was determined to be the fair value of the embedded derivative. At March 31, 2015, the fair value of the derivative was determined to be \$4.8 million, and the debt was valued by comparing debt issues of similar companies with (i) remaining terms of between 2.0 and 5.9 years, (ii) coupon rates of between 8.9% and 10.8% and (iii) market yields of between 11.2% and 20.3%. The Company recognized no change in fair value of derivative liability for the three months ended March 31, 2015. At December 31, 2014, the fair value of the derivative was determined to be \$4.8 million, and the debt was valued by comparing debt issues of similar companies with (i) remaining terms of between 2.3 and 3.6 years, (ii) coupon rates of between 9.8% and 10.8% and (iii) market yields of between 10.0% and 16.8%.

The Company's 2014 Notes contain a redemption feature whereby, upon occurrence of a change in control, the Company would be required to repurchase the notes. The Company determined this redemption feature to be an embedded derivative, requiring bifurcation in accordance with ASC 815. The derivative is carried at fair value and is classified as Level 3 in the fair value hierarchy due to the use of significant unobservable inputs. The fair value of the embedded derivative was calculated using a probability-weighted model incorporating management estimates of the probability of a change in control occurring, and by determining the fair value of the debt with and without the change in control provision included. The difference between the two was determined to be the fair value of the embedded derivative. At March 31, 2015, the fair value of the derivative was determined to be \$1.3 million, and the debt was valued by using (i) the estimated remaining term of the notes, (ii) a bond yield of 20.6%, (iii) a risk-free interest rate of 2.5% and (iv) volatility of 82.0%. The Company recognized a \$1.3 million gain on change in fair value of derivative liability for the three months ended March 31, 2015. At December 31, 2014, the fair value of the derivative was determined to be \$2.6 million, and the debt was valued by using (i) the estimated remaining term of the notes, (ii) a bond yield of 24.8%, (iii) a risk-free interest rate of 2.7% and (iv) volatility of 82.0%.

### *Preferred Stock Purchase Option Derivative Liability*

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

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

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

	October 2009 Warrants	Long-Term Debt Derivative Liabilities	Preferred Stock Purchase Option	Totals
<b>Balance at December 31, 2014</b>	<b>\$ 119</b>	<b>\$ 7,400</b>	<b>\$ —</b>	<b>\$ 7,519</b>
Record derivative liability	—	—	868	868
Gain on change in fair value of derivative liabilities	(110)	(1,300)	946	(464)
Compensation income for change in fair value of warrants issued to former employees	(9)	—	—	(9)
Transfer derivative liability to equity	—	—	(1,814)	(1,814)
<b>Balance at March 31, 2015</b>	<b>\$ —</b>	<b>\$ 6,100</b>	<b>\$ —</b>	<b>\$ 6,100</b>

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	<u>October 2009 Warrants</u>	<u>Long-Term Debt Derivative Liability</u>	<u>Totals</u>
<b>Balance at December 31, 2013</b>	<b>\$ 6,894</b>	<b>\$ 11,100</b>	<b>\$17,994</b>
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)
<b>Balance at March 31, 2014</b>	<b><u>\$ 5,929</u></b>	<b><u>\$ 7,600</u></b>	<b><u>\$13,529</u></b>

### **Segment and Geographical Information**

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

### **Recent Accounting Pronouncements**

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board, or FASB, and are adopted by the Company as of the specified effective date. The Company considered the following recent accounting pronouncements which were not yet adopted as of March 31, 2015:

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*. This amendment provides principles for recognizing revenue for the transfer of promised goods or services to customers with the consideration to which the entity expects to be entitled in exchange for those goods or services, and is effective for annual periods beginning after December 15, 2016 (the original effective date). In April 2015, the FASB issued a proposal to defer the original effective date of this standard by one year, such that the amendment will be effective for the Company's fiscal year beginning January 1, 2018 if the proposal is adopted. Early adoption is permitted, but not before the original effective date. The Company is currently evaluating the accounting, transition and disclosure requirements of the standard and cannot currently estimate the financial statement impact of adoption.

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

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

In April 2015, the FASB issued ASU No. 2015-03, *Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs*. The amendments in this ASU require that debt issuance costs related to a recognized debt liability be presented

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in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The Company is required to adopt this standard in the first quarter of fiscal 2016 on a retrospective basis. The implementation of this standard will result in the reclass of certain debt issuance costs from other assets to a reduction in the carrying amount of the related debt liability within the consolidated balance sheets.

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

### (3) Intangible Assets

Intangible assets consist of the historical acquisition cost of certain technology rights for Vascepa and have an estimated remaining useful life of 15.3 years. The carrying value as of March 31, 2015 and December 31, 2014 is as follows (in thousands):

	<u>March 31, 2015</u>	<u>December 31, 2014</u>
Technology rights	\$ 11,624	\$ 11,624
Accumulated amortization	(1,722)	(1,561)
	<u>\$ 9,902</u>	<u>\$ 10,063</u>

### (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, 2015</u>	<u>December 31, 2014</u>
Raw materials	\$ 8,600	\$ 5,225
Work in process	4,934	4,757
Finished goods	2,649	3,751
Total inventory	<u>\$ 16,183</u>	<u>\$ 13,733</u>

### (5) Warrants and Warrant Derivative Liability

#### *October 2009 Warrants Derivative Liability*

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

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

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

In October 2014, the Company and the holders of the remaining October 2009 warrants mutually agreed to extend the expiration date of such warrants from October 16, 2014 to February 27, 2015. Of the 8,087,388 warrants outstanding as of December 31, 2014, 1,844,585 warrants were exercised, resulting in net proceeds to the Company of \$2.7 million, and the remaining 6,242,803 warrants expired on February 27, 2015. As such, no warrants were outstanding as of March 31, 2015.

July 2009 Warrants

The Company issued several warrants in July 2009. As of March 31, 2015 and December 31, 2014, there were no July 2009 warrants outstanding. During the year ended December 31, 2014, 1,684,888 of the July 2009 warrants were exercised, resulting in proceeds to the Company of \$1.7 million.

**(6) Debt**

Long-Term Debt—December 2012 Financing

On December 6, 2012, the Company entered into an agreement with BioPharma Secured Debt Fund II Holdings Cayman LP, or BioPharma. Under this agreement, the Company granted to BioPharma a security interest in future receivables associated with the Vascepa patent rights, in exchange for \$100 million received at the closing of the agreement which occurred in December 2012. The Company has agreed to repay BioPharma up to \$150 million of future revenue and receivables. As of March 31, 2015, the remaining amount to be repaid to BioPharma is \$142.7 million. During the three months ended March 31, 2015, the Company made repayments under the agreement of \$1.6 million to BioPharma and an additional \$1.6 million is scheduled to be paid in May 2015. These payments were calculated based on the threshold limitation, as described below, as opposed to the scheduled quarterly repayments. Additional quarterly repayments, subject to the threshold limitation, are scheduled to be paid thereafter in accordance with the following schedule: \$10.0 million in the third quarter of 2015 and in each of the next two quarters, \$15.0 million per quarter in each of the next four quarters, and a final payment of \$13.0 million scheduled for payment in May 2017. All such payments reduce the remainder of the \$150 million in aggregate payments to BioPharma. These quarterly payments are subject to a quarterly threshold amount whereby, if a calculated threshold, based on quarterly Vascepa revenues, is not achieved, the quarterly payment payable in that quarter can at the Company's election be reduced and with the reduction carried forward without interest for payment in a future period. The payment of any carried forward amount is subject to similarly calculated threshold repayment amounts based on Vascepa revenue levels. Except upon a change of control in Amarin, the agreement does not expire until \$150 million in aggregate has been repaid. The Company can prepay an amount equal to \$150 million less any previously repaid amount.

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

The Company determined the redemption feature upon a change of control to be an embedded derivative requiring bifurcation. The fair value of the embedded derivative was calculated by determining the fair value of the debt with the change in control provision included and also without the change in control provision. The difference between the two fair values of the debt was determined to be the fair value of the embedded derivative, and upon closing the Company recorded a derivative liability of \$14.6 million as a reduction to the note payable. The fair value of this derivative liability is remeasured at each reporting period, with changes in fair value recognized in the statement of operations and any changes in the assumptions used in measuring the fair value of the derivative liability could result in a material increase or decrease in its carrying value. The Company recognized a gain on change in fair value of derivative liability of zero and \$3.5 million during the three months ended March 31, 2015 and 2014, respectively.

During the three months ended March 31, 2015, the Company recorded \$1.7 million and \$0.5 million of cash and non-cash interest expense, respectively, in connection with the BioPharma debt. 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. The Company will periodically evaluate the remaining term of the agreement and the effective interest will be recalculated each period based on the Company's most current estimate of repayment.

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

*January 2012 Exchangeable Senior Notes*

In January 2012, the Company issued \$150.0 million in principal amount of 3.5% exchangeable senior notes due 2032, a portion of which were subsequently exchanged (see discussion of May 2014 Exchangeable Senior Notes below). The 2012 Notes were issued by Corsicanto Limited, an Irish limited company acquired by Amarin in January 2012. Corsicanto Limited is a wholly-owned subsidiary of Amarin. The general, unsecured, senior obligations are fully and unconditionally guaranteed by Amarin but not by any of the Company's other subsidiaries. Corsicanto Limited has no assets, operations, revenues or cash flows other than those related to the issuance, administration and repayment of the 2012 Notes and 2014 Notes. There are no significant restrictions on the ability of Amarin to obtain funds from Corsicanto Limited in the form of cash dividends, loans, or advances. Net proceeds to the Company, after payment of underwriting fees and expenses, were approximately \$144.3 million.

The 2012 Notes have a stated interest rate of 3.5% per year, payable semiannually in arrears on January 15 and July 15 of each year beginning on July 15, 2012, and ending upon the 2012 Notes' maturity on January 15, 2032. The 2012 Notes are subject to repurchase by the Company at the option of the holders on each of January 19, 2017, January 19, 2022, and January 19, 2027, at a price equal to 100% of the principal amount of the 2012 Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the repurchase date. The 2012 Notes are exchangeable under certain circumstances into cash, ADSs, or a combination of cash and ADSs, at the Company's election, with an initial exchange rate of 113.4752 ADSs per \$1,000 principal amount of 2012 Notes. If the Company elected physical settlement, the net remaining outstanding portion of the 2012 Notes would be exchangeable into 3,547,916 ADSs after the May 2014 exchange of a portion of the 2012 Notes (see below for further discussion of the May 2014 exchange). Based on the closing price of the Company's stock at March 31, 2015, the principal amount of the 2012 Notes would exceed the value of the shares if converted on that date by \$23.0 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 Securities Exchange Act of 1934 with both the SEC and the Trustee and (iii) maintaining the tradability of the 2012 Notes. The Company is required to use commercially reasonable efforts to procure and maintain the listing of the 2012 Notes on the Global Exchange Market operated under the supervision of the Irish Stock Exchange (or other recognized stock exchange as defined in the Note Indenture) prior to July 15, 2012. If the 2012 Notes are not freely tradable, as a result of restrictions pursuant to U.S. securities law or the terms of the Indenture or the 2012 Notes, the Company shall pay additional interest on the 2012 Notes at the rate of 0.50% per annum of the principal amount of 2012 Notes outstanding for each day during such period for which the Company's failure to file has occurred and is continuing or for which the 2012 Notes are not freely tradable.

The Company may not redeem the 2012 Notes prior to January 19, 2017, other than in connection with certain changes in the tax law of a relevant taxing jurisdiction that results in additional amounts becoming due with respect to payments and/or deliveries on the 2012 Notes. On or after January 19, 2017 and prior to the maturity date, the Company may redeem for cash all or part of the 2012 Notes at a redemption price equal to 100% of the principal amount of the 2012 Notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date. There is no prepayment penalty or sinking fund provided for the 2012 Notes. If the Company undergoes a change in control, holders may require the Company to repurchase for cash all or part of their 2012 Notes at a repurchase price equal to 100% of the principal amount of the 2012 Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the change in control repurchase date. The 2012 Notes are the Company's senior unsecured obligations and rank senior in right of payment to the Company's future indebtedness that is expressly subordinated in right of payment to the 2012 Notes and equal in right of payment to the Company's future unsecured indebtedness that is not so subordinated. The 2012 Notes are effectively junior in right of payment to future secured indebtedness to the extent of the value of the assets securing such indebtedness.

The 2012 Notes are exchangeable under certain circumstances. At the time of issuance, the Company calculated the fair value of the liability component of the outstanding 2012 Notes to be \$126.2 million, and the excess of the principal amount of the debt over the liability component of \$23.8 million was allocated to the conversion option resulting in a discount on the debt and corresponding increase in equity as a result of the cash settlement feature. The discount created from allocating proceeds to the conversion option was amortized to interest expense using the effective interest method over the 2012 Notes' estimated remaining life, which was calculated to be a period of twenty-four months. As of March 31, 2015 and December 31, 2014, the discount created from the allocation of the proceeds to the conversion option was fully amortized. The conversion option will not be subsequently remeasured as long as it continues to meet the criteria for equity classification.

The Company also recorded a debt discount to reflect the value of the underwriter's discounts and offering costs. A portion of the debt discount from underwriter's discounts and offering costs was allocated to the equity and liability components of the 2012 Notes in proportion to the proceeds allocated to each component. The portion of the debt discount from underwriter's discounts and offering costs allocated to the liability component was amortized as interest expense over the estimated life of the 2012 Notes of twenty-four months. As of March 31, 2015 and December 31, 2014, the debt discount was fully amortized and the carrying value of the 2012 Notes was \$31.3 million after an exchange of a portion of the 2012 Notes (see below for further discussion of the May 2014 exchange).

*May 2014 Exchangeable Senior Notes*

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

The 2014 Notes have a stated interest rate of 3.5% per year, payable semiannually in arrears on January 15 and July 15 of each year beginning on July 15, 2014, and ending upon the 2014 Notes’ maturity on January 15, 2032, unless earlier repurchased or redeemed by Corsicanto or exchanged by the holders. At any time after the issuance of the 2014 Notes and prior to the close of business on the second business day immediately preceding January 15, 2032, holders may exchange the 2014 Notes at their option. If prior to January 15, 2018, a make-whole fundamental change (as defined in the Indenture) occurs or the Company elects to redeem the 2014 Notes in connection with certain changes in tax law, in each case as described in the Indenture, and a holder elects to exchange its 2014 Notes in connection with such make-whole fundamental change or election, as the case may be, such holder may be entitled to an increase in the exchange rate as described in the Indenture. In the event of physical settlement, the 2014 Notes would be exchangeable into 45,666,925 ADSs. The initial exchange rate is 384.6154 ADSs per \$1,000 principal amount of the 2014 Notes (equivalent to an initial exchange price of approximately \$2.60 per ADS, or the Exchange Price), subject to adjustment in certain circumstances. The exchange rate is subject to adjustment from time to time upon the occurrence of certain events, including, but not limited to, the payment of cash dividends. Based on the closing price of the Company’s stock at March 31, 2015, the principal amount of the 2014 Notes would exceed the value of the shares if converted on that date by \$11.9 million.

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

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

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

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allocated \$3.5 million of the \$90.8 million fair value of the 2014 Notes to the derivative liability related to the fundamental change redemption feature (as described above), which will be measured at fair value on an ongoing basis. During the three months ended March 31, 2015, the Company recognized a \$1.3 million gain on the change in fair value of the redemption feature. The fair value of this derivative liability is remeasured at each reporting period, with changes in fair value recognized in the statement of operations and any changes in the assumptions used in measuring the fair value of the derivative liability could result in a material increase or decrease in its carrying value.

Because the conversion option in the 2014 Notes receives an exception from derivative accounting and only requires gross physical settlement in shares, the embedded option does not require separate accounting and is therefore accounted for as part of the debt host at amortized cost. The debt discount is being amortized as interest expense over the estimated life of the 2014 Notes and recognized in the statement of operations as interest expense. As of March 31, 2015 and December 31, 2014, the carrying value of the 2014 Notes, net of the unamortized debt discount, was \$91.9 million and \$90.6 million, respectively. During the three months ended March 31, 2015, the Company recognized aggregate interest expense of \$2.8 million related to the Notes, of which \$1.5 million represents amortization of the debt discount and \$1.3 million represents contractual coupon interest. During the three months ended March 31, 2014, the Company recognized aggregate interest expense of \$2.0 million related to the Notes, of which \$0.7 million represents non-cash interest and \$1.3 million represents contractual coupon interest.

At March 31, 2015 and December 31, 2014, the Company had accrued interest on the Notes of \$1.1 million and \$2.4 million, respectively, which is included in other current liabilities. The Company made the contractual interest payments due on the Notes during the three months ended March 31, 2015 and 2014 of \$2.6 million.

### **(7) Commitments and Contingencies**

#### Litigation

In the ordinary course of business, the Company is from time to time involved in lawsuits, claims, investigations, proceedings, and threats of litigation relating to its business. “Item 3. Legal Proceedings” of the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2014 includes a discussion of the Company’s current legal proceedings. There have been no material changes to those disclosures as of the date of this filing other than as disclosed in Note 11—Subsequent Events.

#### Milestone and Supply Purchase Obligations

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

The Company has Vascepa API supply agreements with two independent companies for the purchase of qualified API supply: Nisshin Pharma, Inc., or Nisshin, and Chemport, Inc., or Chemport. The Company’s agreement with Chemport contains minimum purchase obligations and a provision requiring the Company to pay Chemport in cash for any shortfall in the minimum purchase obligations. To date, the Company has met or exceeded its minimum purchase obligations with Chemport. The Company has no royalty, milestone or minimum purchase commitments with Nisshin.

Pursuant to the agreements with the Company’s API suppliers, there is a total of \$54.3 million that is potentially payable over the term of such agreements based on minimum purchase obligations.

Under the 2004 share repurchase agreement with Laxdale Limited, or Laxdale, upon receipt of marketing approval in Europe for the first indication for Vascepa (or first indication of any product containing Amarin Neuroscience intellectual property acquired from Laxdale in 2004), the Company must make an aggregate stock or cash payment to the former shareholders of Laxdale (at the sole option of each of the sellers) of £7.5 million (approximately \$11.1 million at March 31, 2015). Also under the Laxdale agreement, upon receipt of a marketing approval in the United States or Europe for a further indication of Vascepa (or further indication of any other product using Amarin Neuroscience intellectual property), the Company must make an aggregate stock or cash payment (at the sole option of each of the sellers) of £5 million (approximately \$7.4 million at March 31, 2015) for each of the two potential market approvals (i.e. £10 million maximum, or approximately \$14.8 million at March 31, 2015).

The Company has no provision for any of the obligations above since the amounts are either not probable or able to be estimated at March 31, 2015.

**(8) Equity**

Warrants

During the three months ended March 31, 2015, the Company issued 1,844,585 shares upon the exercise of warrants, resulting in gross and net proceeds of \$2.8 million and \$2.7 million, respectively.

Incentive Equity Awards

During the three months ended March 31, 2015 and 2014, the Company issued 2,114 and 215,000 shares, respectively, as a result of the exercise of stock options, resulting in gross and net proceeds of \$4 thousand and \$0.3 million, respectively, for each period.

On January 29, 2015, the Company granted a total of 2,564,251 restricted stock units (RSUs) and 1,622,500 stock options to employees under the Amarin Corporation plc 2011 Stock Incentive Plan (the "2011 Plan"). The RSUs vest annually over a three year period and the stock options vest monthly over a four year period. Also on January 29, 2015, the Company granted 5,455,500 RSUs to employees under the 2011 Plan that vest upon the achievement of certain performance conditions.

On March 11, 2014, the Company granted a total of 173,348 restricted stock units, or RSUs, and 205,890 stock options to members of the Company's Board of Directors under the 2011 Plan. The RSUs vest in equal installments over a three year period commencing with each installment vesting each year upon the earlier of the anniversary of the grant date or the Company's annual general meeting of shareholders in such anniversary year. Upon termination of service to the Company, each Director shall be entitled to a payment equal to the fair market value of one share of Amarin common stock, which is required to be made in shares. The stock options vest in full upon the earlier of the anniversary of the grant date or the Company's annual general meeting of shareholders in such anniversary year. The stock options will become fully vested upon a change of control of the Company.

On January 8, 2014, the Company granted a total of 2,082,000 RSUs and 2,605,500 stock options to employees under the 2011 Plan. The RSUs vest annually over a three year period and the stock options vest monthly over a four year period. During the three months ended March 31, 2015, the Company issued 639,500 common shares related to the vesting of these RSUs, of which 114,258 shares were retained as treasury shares as settlement of employee tax obligations.

RSUs will become fully vested upon a change of control of the Company.

Preferred Stock

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

For each restricted American Depositary Share, the Purchasers paid a negotiated price of \$0.15 (equating to \$1.50 on an as-converted to ordinary share basis), resulting in \$52.8 million in aggregate gross proceeds to the Company, before deducting estimated offering expenses of approximately \$0.6 million. The net proceeds are reflected as preferred stock in the accompanying consolidated balance sheets.

Each ten (10) Series A Preference Shares may be consolidated and redesignated as one (1) ordinary share, par value £0.50 per share, in the capital of the Company, each ordinary share to be represented by American Depositary Shares ("ADSs"), provided that consolidation will be prohibited if, as a result, the holder of such Series A Preference Shares and its affiliates would beneficially own more than 4.99% of the total number of Amarin ordinary shares or ADSs outstanding following such redesignation (the "Beneficial Ownership Limitation"). By written notice to the Company, a holder may from time to time increase or decrease the Beneficial Ownership Limitation to any other percentage not in excess of 19.9% specified in such notice; provided that any such increase will not be effective until the sixty-first (61st) day after such notice is delivered to the Company. Subject to certain adjustments for dilutive events, a maximum of 35,215,079 ordinary shares, each represented by one ADS, are issuable upon the consolidation and redesignation of the Series A Preference Shares currently outstanding. This consolidation and redesignation may be effected by a holder of Series A Preference Shares following the first to occur of the resale of the ADSs representing the ordinary shares being registered for resale under the Securities Act pursuant to an effective registration statement, following any sale of the ADSs representing the ordinary shares pursuant to Rule 144 under the Securities Act, or if such ADSs representing the ordinary shares are eligible for sale under Rule 144, following the expiration of the one-year holding requirement under Rule 144.

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

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

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

The Series A Preference Shares contain a contingent beneficial conversion feature (“BCF”) because they contain a conversion feature at a fixed rate that was in-the-money when issued. The BCF will be recorded in the second quarter of 2015 as a result of the related Form S-3 Registration Statement being declared effective, which represents the resolution of the contingency to convert the Series A Preference Shares. The BCF will be recognized in stockholders’ deficit and was measured by allocating a portion of the proceeds equal to the intrinsic value of that feature to additional paid-in capital. The effective purchase price of the ordinary shares into which the preferred shares are convertible was \$1.50, which was used to compute the intrinsic value. The intrinsic value was calculated as the difference between the effective purchase price of the ordinary shares and the market value (\$2.39 per share) on the date the preferred shares were issued, multiplied by the number of shares into which the preferred shares are convertible. The BCF resulting from the issuance of the Series A Preference Shares was determined to be \$31.3 million. The BCF will be recorded as a non-cash dividend to preferred shareholders through retained earnings. Therefore, net loss applicable to common shareholders will be reduced by the value of the BCF for earnings per common share purposes in accordance with GAAP.

On March 30, 2015, in connection with the closing of the private placement, and pursuant to a pre-existing contractual right to participate in certain private placement transactions effected by the Company, the Company entered into a separate subscription agreement with an existing investor, Sofinnova Venture Partners VII L.P. (Sofinnova), for the purchase of an additional \$5.8 million of restricted American Depositary Shares, each representing one (1) share of the Company’s Series A Preference Shares, at the same price per share and otherwise on substantially the same terms as the initial private placement. In accordance with applicable marketplace rules of the NASDAQ Stock Market, the consummation of the second private placement is conditioned upon approval by the Company’s shareholders at a future meeting of the Company’s shareholders. Dr. James Healy, a member of the Company’s Board, is a managing member of Sofinnova Management VII, L.L.C., the general partner of Sofinnova.

The existence of this preferred stock purchase option was determined to be a derivative liability effective March 5, 2015, the date in which the private placement was initially subscribed. The fair value of this liability was calculated using a Black-Scholes model and was determined to be \$0.9 million at inception and was charged to retained earnings as a deemed non-cash dividend to Sofinnova. The liability was then marked to fair value as of March 30, 2015, the date on which the Company executed a subscription agreement with Sofinnova, resulting in a charge of \$0.9 million through gain (loss) on change in fair value of derivatives. The liability of \$1.8 million was reclassified to permanent equity (additional paid-in capital) on such date.

### **(9) Co-Promotion Agreement**

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

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

In exchange for Kowa Pharmaceuticals America, Inc.’s co-promotional services, Kowa Pharmaceuticals America, Inc. is entitled to a quarterly co-promotion fee based on a percentage of Vascepa gross 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

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FDA has approved an ANCHOR indication labeling expansion for Vascepa or has permitted the use of data generated to support obtaining FDA approval of the ANCHOR indication in the promotion of Vascepa, in which case the co-promotion fee would be decreased if specified requirements are met. In certain circumstances, upon the earlier of the expiration or termination of the Agreement in accordance with its terms, Kowa Pharmaceuticals America, Inc. may be eligible for a co-promotion tail fee equal to declining fractions of the co-promote fee in effect prior to such expiration or termination for periods ranging from one to three years following such expiration or termination.

As of March 31, 2015 and December 31, 2014, the Company had a net payable of \$0.7 million and a net receivable of \$0.6 million, respectively, from Kowa Pharmaceuticals America, Inc. representing reimbursable amounts incurred for samples and other marketing expenses less the co-promotion fees payable to Kowa Pharmaceuticals America, Inc.

### **(10) Development, Commercialization and Supply Agreement**

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

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

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

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

Upon closing of the DCS Agreement, the Company received a non-refundable \$15.0 million up-front payment, which it will recognize as revenue over the estimated period in which the Company is required to provide initial and on-going regulatory and development support and clinical supply for obtaining regulatory approvals in the China Territory and through the estimated period in which the Company is required to provide commercial supply. Consequently, the Company recognized \$0.4 million of the up-front payment as licensing revenue during the three months ended March 31, 2015 and recorded \$14.6 million as deferred revenue as of March 31, 2015. In addition to the non-refundable, up-front payment, the Company is entitled to receive development, regulatory and sales-based milestone payments of up to an additional \$154.0 million as well as tiered double-digit percentage royalties on net sales of Vascepa in the China Territory escalating to the high teens. Revenues relating to these milestone payments and royalties will be recognized upon satisfaction of the applicable performance obligations or over the period in which such performance obligations are completed, as applicable.

### **(11) Subsequent Events**

The Company has evaluated subsequent events from March 31, 2015 through the date of the issuance of these condensed consolidated financial statements.

On April 27, 2015, the Company received a Complete Response Letter (“CRL”) from the FDA regarding its ANCHOR trial supplemental New Drug Application (the “ANCHOR sNDA”). The ANCHOR sNDA sought to expand approved Vascepa labeling to

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include use as an adjunct to diet to reduce triglyceride levels in adult patients on statin therapy with mixed dyslipidemia (one or more lipid disorder) and triglyceride levels from 200 to 499 mg/dL. Vascepa remains FDA approved for use as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia, and current Vascepa labeling remains unchanged.

On May 7, 2015, Amarin Pharma, Inc., a wholly-owned subsidiary of the Company, and a group of independent physicians filed a federal lawsuit to permit the Company to share truthful and non-misleading information, including the ANCHOR trial clinical data, with healthcare professionals in the United States about uses of Vascepa that are consistent with multiple national and international treatment guidelines and relevant to patients in the United States at risk of cardiovascular disease. The lawsuit, captioned, Amarin Pharma, Inc. et al. v. Food & Drug Administration, et al., was filed in the United States District Court for the Southern District of New York and seeks a judicial declaration based on several legal theories.

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

*This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. These forward-looking statements reflect our plans, estimates and beliefs. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terms such as “anticipates,” “believes,” “could,” “estimates,” “expects,” “intends,” “may,” “plans,” “potential,” “predicts,” “projects,” “should,” “would” and similar expressions intended to identify forward-looking statements. Forward-looking statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Because of these risks and uncertainties, the forward-looking events and circumstances discussed in this report may not transpire. We discuss many of these risks in Part I, Item 1A under the heading “Risk Factors” of our Annual Report on Form 10-K for the fiscal year ended December 31, 2014 and below under Part II, Item IA, “Risk Factors”.*

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

**Overview**

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

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

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

Triglycerides are fats in the blood. Hypertriglyceridemia refers to a condition in which patients have high levels of triglycerides in the bloodstream. It is estimated that over 70 million adults in the United States have elevated triglyceride levels (TG  $\geq$ 150 mg/dL), approximately 40 million adults in the United States have high triglyceride levels (TG  $\geq$ 200 mg/dL), and approximately 4.0 million people in the United States have severely high triglyceride levels (TG  $\geq$ 500 mg/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.

We are currently focused on completing the ongoing REDUCE-IT (Reduction of Cardiovascular Events with EPA—Intervention Trial) cardiovascular outcomes study of Vascepa, which we started in December 2011. REDUCE-IT, a multinational, prospective, randomized, double-blind, placebo-controlled study, is the first prospective cardiovascular outcomes study of any drug in a population of patients who, despite stable statin therapy, have elevated triglyceride levels. Based on the results of REDUCE-IT, we plan to seek additional indicated uses for Vascepa. In REDUCE-IT, cardiovascular event rates for patients on stable statin therapy plus four grams per day of Vascepa will be compared to cardiovascular event rates for patients on stable statin therapy plus placebo. The REDUCE-IT study is designed to be completed after reaching an aggregate number of cardiovascular events. Based on projected event rates, we estimate the REDUCE-IT study can be completed in or about 2017 with results then expected to be available and published in 2018. An interim review of the efficacy and safety results of the trial is scheduled to occur upon reaching 60% of the target aggregate number of cardiovascular events. We currently expect this interim review by the independent data monitoring committee (DMC) to occur during 2016. The DMC has been more frequently examining interim reviews of the safety data from the

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study. Following each of these reviews, the DMC has communicated to us that we should continue the study as planned. We remain blinded to all data from the study. Approximately 93% of the 8,000 patients targeted for enrollment in the REDUCE-IT study have been enrolled.

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

We also developed Vascepa for 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 views the ANCHOR indication as ostensibly and impliedly an indication to reduce cardiovascular risk.

On October 16, 2013, the FDA convened an advisory committee to review our supplemental new drug application, or sNDA, seeking marketing approval of Vascepa for use in the ANCHOR indication. This advisory committee was not asked by the FDA to evaluate whether Vascepa is effective in lowering triglycerides in the studied population, the ANCHOR indication as specified in the sNDA. Rather, the advisory panel was asked whether Vascepa would improve cardiovascular outcomes or whether approval of the ANCHOR indication should wait for successful completion of the REDUCE-IT study. The advisory committee voted 9 to 2 against recommending approval of the ANCHOR indication based on information presented at the meeting.

The ANCHOR clinical study was conducted under a special protocol assessment, or SPA, agreement with the FDA. On October 29, 2013, the FDA rescinded the ANCHOR study SPA agreement because the FDA determined that a substantial scientific issue essential to determining the effectiveness of Vascepa in the studied population was identified after testing began. On April 27, 2015, following three attempts by us to appeal the SPA agreement rescission decision by the FDA, we received a Complete Response Letter, or CRL, from the FDA regarding our ANCHOR sNDA. In the CRL, the FDA acknowledged that Vascepa yielded a treatment difference showing reduced triglyceride levels compared to placebo in patients treated in the ANCHOR study. The FDA concluded that, for regulatory approval purposes, there are insufficient data at this time to support a drug-induced change in serum triglycerides as a surrogate for reducing cardiovascular risk in the ANCHOR population. The FDA did not determine that the drug-induced effects of Vascepa, which go beyond triglyceride-lowering, would not actually reduce cardiovascular risk in this population. We had proposed to the FDA multiple alternative indications, data presentations, disclaimers and other regulatory pathways to approval under the ANCHOR sNDA, but the FDA determined not to approve label expansion reflecting the ANCHOR clinical trial efficacy data at this time. Safety data from the ANCHOR study remains in the currently approved label for Vascepa. Vascepa remains FDA approved for use as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia, and current Vascepa labeling remains unchanged. The CRL has no effect on the SPA agreement for the REDUCE-IT study or the anticipated timing for results from the REDUCE-IT study.

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

### *Commercialization – United States*

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. We commenced the commercial launch of Vascepa in the United States in January 2013 with approximately 275 sales representatives. Vascepa has not yet been approved or commercially launched outside of

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the United States. 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, Inc. sales representatives began promoting Vascepa. We also employ various marketing personnel to support our commercialization of Vascepa.

Under the co-promotion agreement with Kowa Pharmaceuticals America, Inc., under which promotion commenced in May 2014, both parties have agreed to use commercially reasonable efforts to promote, detail and optimize sales of Vascepa in the United States and have agreed to specific performance requirements detailed in the related agreement. The performance requirements include a negotiated minimum number of sales details to be delivered by each party in the first and second position, the use of a negotiated number of minimum sales representatives from each party, including no less than 250 Kowa Pharmaceuticals America, Inc. sales representatives and the achievement of minimal levels of Vascepa revenue in 2015 and beyond. Kowa Pharmaceuticals America, Inc. has also agreed to continue to bear the costs incurred for its sales force associated with the commercialization of Vascepa and to pay for certain incremental costs associated with the use of its sales force, such as sample costs and costs for promotional and marketing materials. We will continue to recognize all revenue from sales of Vascepa. In exchange for Kowa Pharmaceuticals America, Inc.'s co-promotional services, Kowa Pharmaceuticals America, Inc. is entitled to a quarterly co-promotion fee based on a percentage of aggregate Vascepa gross margins that increases during the term. The percentage of aggregate Vascepa gross margins earned by Kowa Pharmaceuticals America, Inc. is scheduled to increase from the high single digits in 2014, to fifteen percent (15%) in 2015, and to the low twenty percent levels in 2018, subject to certain adjustments. The term of this co-promotion agreement expires on December 31, 2018.

Based on monthly compilations of data provided by a third party, Symphony Health Solutions, the estimated number of normalized total Vascepa prescriptions for the three months ended March 31, 2015 and 2014 was approximately 154,000 and 93,000, respectively. According to data from another third party, IMS Health, the estimated number of normalized total Vascepa prescriptions for the three months ended March 31, 2015 and 2014 was approximately 137,000 and 78,000, respectively. Normalized total prescriptions represent the estimated total number of Vascepa prescriptions shipped to patients, calculated on a normalized basis (i.e., total capsules shipped divided by 120 capsules, or one month's supply). Prescriptions in the three months ended March 31, 2015 were negatively impacted by severe winter storms that occurred primarily during the months of January and February in many regions of the United States. The data reported above is based on information made available to us from third party resources and may be subject to adjustment and may overstate or understate actual prescriptions. Timing of shipments to wholesalers, as used for revenue recognition purposes, and timing of prescriptions as estimated by these third parties may differ from period to period. Although we believe these data are prepared on a period-to-period basis in a manner that is generally consistent and that such results are generally indicative of current prescription trends, these data are based on estimates and should not be relied upon as definitive. Prior to commencing our U.S. commercial launch of Vascepa in January 2013, we had no revenue from Vascepa. Because of our limited selling history, changes in the size of our sales force, our co-promotion agreement, and uncertainty regarding resolution of the ANCHOR sNDA with the FDA, we do not currently provide quantified revenue guidance. 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.

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

### *Commercialization – Outside the United States*

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

Under the agreement, Eddingpharm will be responsible for development and commercialization activities in the China Territory and associated expenses. We will provide development assistance and be responsible for supplying the product. Terms of the

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

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

### *Research and Development*

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

REDUCE-IT is designed to enroll 8,000 patients, of which over 7,400 patients have been enrolled. We currently estimate that we will complete patient enrollment in this study within 2015.

Completion of the REDUCE-IT study is designed to occur after reaching an aggregate number of cardiovascular events. Based on projected event rates, we estimate the REDUCE-IT study can be completed in or about 2017 with results then expected to be available in 2018. An interim review of the efficacy and safety results of the trial is scheduled to occur upon reaching 60% of the target aggregate number of cardiovascular events. We currently expect this interim review by the independent data monitoring committee, or DMC, to occur during 2016. As is typical, the statistical threshold for defining overwhelming efficacy on the primary endpoint at the interim analysis is considerably higher than the threshold for defining statistical significance at the end of the study. Amarin remains blinded to all data from the study.

Our scientific rationale for the REDUCE-IT study is supported by (i) epidemiological data that suggests elevated triglyceride levels correlate with increased cardiovascular disease risk, (ii) genetic data that suggests triglyceride and/or triglyceride-rich lipoproteins (as well as low-density lipoprotein cholesterol (LDL cholesterol), known as bad cholesterol) are independently in the causal pathway for cardiovascular disease and (iii) clinical data that suggest substantial triglyceride reduction in patients with elevated baseline triglyceride levels correlates with reduced cardiovascular risk. Our scientific rationale for the REDUCE-IT study is also supported by research on the differentiated effects of the active ingredient in Vascepa, including the antioxidant properties and effects on inflammation markers associated with atherosclerosis.

### *Commercial Supply*

To date, all of our active pharmaceutical ingredient, or API, has been acquired through two suppliers: Nisshin Pharma, Inc., or Nisshin, and Chemport, Inc., or Chemport. A significant portion of such API was purchased from Nisshin at a price that is higher than expected future average API costs. The amount of supply we seek to purchase in 2015 and beyond will depend on the level of growth of Vascepa revenues.

### *Financial Position*

We believe that our cash and cash equivalents balance of \$161.2 million at March 31, 2015 is sufficient to fund our projected operations for at least the next twelve months. Included in our cash balance at March 31, 2015 was a \$15.0 million non-refundable, up-front payment we received upon the execution of our first ex-U.S. licensing agreement in China and surrounding territories and net proceeds of \$52.2 million we received from the issuance and sale of our Series A Preference Shares to four institutional investors.

## **Financial Operations Overview**

*Product Revenue, net.* All of our product revenue is derived from product sales of Vascepa, net of allowances, discounts, incentives, rebates, chargebacks and returns. We sell product to a limited number of major wholesalers, as well as selected regional wholesalers and specialty pharmacy providers, or collectively, our Distributors, who resell the product to retail pharmacies for purposes of their reselling the product to fill patient prescriptions. We commenced our commercial launch in the United States in January 2013. In accordance with GAAP, until we had the ability to reliably estimate returns of Vascepa from our Distributors, revenue was recognized based on the resale of Vascepa for the purposes of filling patient prescriptions, and not based on our sales to such Distributors. Beginning in January 2014, we concluded that we had developed sufficient history such that we can reliably estimate returns and as a result, began to recognize revenue based on sales to our Distributors. Through March 31, 2015, product returns were de minimis.

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

*Cost of Goods Sold.* Cost of goods sold includes the cost of API for Vascepa on which revenue was recognized during the period, as well as the associated costs for encapsulation, packaging, shipment, supply management, insurance and quality assurance. The cost of the API included in cost of goods sold reflects the average cost method of inventory valuation and relief. This average cost reflects the actual purchase price of Vascepa API, which through March 31, 2015 was sourced from Nissin and Chemport.

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

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

*Gain (Loss) on Change in Fair Value of Derivative Liabilities.* Gain (loss) on change in fair value of derivative liabilities is comprised of: (i) the change in fair value of the warrant derivative liability, (ii) the change in fair value of the derivative liability related to the change in control provision associated with the December 2012 financing with BioPharma Secured Debt Fund II Holdings Cayman LP, or BioPharma, (iii) the change in fair value of the derivative liability related to the change in control provision associated with the May 2014 exchangeable senior notes; and (iv) the change in fair value of the derivative liability related to the preferred stock purchase option.

*Interest and Other (Expense) Income, Net.* Interest expense consists of interest incurred under lease obligations, interest incurred under our 3.5% exchangeable notes and interest incurred under our December 2012 financing arrangement with BioPharma. Interest expense under our exchangeable notes includes the amortization of the conversion option related to our exchangeable debt, the amortization of the related debt discounts and debt obligation coupon interest. Interest expense under our BioPharma financing arrangement is calculated based on an estimated repayment schedule. Interest income consists of interest earned on our cash and cash equivalents. Other (expense) income, net, consists primarily of foreign exchange losses and gains.

### **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 condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our consolidated financial statements.

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

We began recognizing revenue from the sale of Vascepa following our commercial launch in the United States in January 2013. Prior to 2013, we recognized no revenue from Vascepa sales. We sell Vascepa to Distributors. In accordance with GAAP, until we had the ability to reliably estimate returns of Vascepa from our Distributors, revenue was recognized based on the resale of Vascepa for the purposes of filling patient prescriptions, and not based on our sales to such Distributors. Beginning in January 2014, we concluded that we had developed sufficient history such that we can reliably estimate returns and as a result, began to recognize revenue based on sales to our Distributors. Consequently, we recognized revenues of \$15.6 million and \$11.0 million based on sales to Distributors during the three months ended March 31, 2015 and 2014, respectively. Through March 31, 2015, product returns were de minimis.

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

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

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

*Derivative Financial Liabilities*—Derivative financial liabilities are initially recorded at fair value. They are subsequently held at fair value, with gains and losses arising for changes in fair value recognized in the statement of operations. The fair value of derivative financial liabilities is determined using various valuation techniques. We use our judgment to select a variety of methods and make assumptions that are mainly based on market conditions existing at each balance sheet date. Fluctuations in the assumptions used in the valuation model would result in adjustments to the fair value of the derivative liabilities reflected on our balance sheet and, therefore, our statement of operations. If we issue shares to discharge the liability, the derivative financial liability is derecognized and common stock and additional paid-in capital are recognized on the issuance of those shares. For options and warrants treated as derivative financial liabilities, at settlement date the carrying value of the options and warrants are transferred to equity. The cash proceeds received from shareholders for additional shares are recorded in common stock and additional paid-in capital. We have recorded financial derivatives related to certain outstanding warrants (extinguished as of March 31, 2015), the change in control provision associated with our December 2012 debt financing and the change in control provision associated with our May 2014 exchangeable senior notes.

*Inventory*—Prior to July 26, 2012, when we received approval from the FDA to market and sell Vascepa in the United States for the MARINE indication, Vascepa was considered a product candidate under development. All supply of Vascepa purchased prior to July 26, 2012 was not capitalized and instead charged as a component of research and development expense in the period received. After Vascepa was approved, we began to capitalize inventory purchased from Nisshin, the API supplier approved in the NDA. Prior to April 2013, Nisshin was the only FDA-approved supplier of API for Vascepa. In April 2013, the FDA approved our sNDAs covering Chemport and BASF and in July 2014 the FDA approved our sNDA covering Slanmhor such that there are now four suppliers FDA-qualified to produce Vascepa API. All supply from Chemport and BASF prior to FDA approval of these API suppliers was not capitalized and instead charged as a component of research and development expense in the period received. Subsequent to the approval of these suppliers, we capitalize API purchases from them. Until an API supplier is approved, all Vascepa API purchased from such supplier is included as a component of research and development expense. Upon sNDA approval of each additional supplier, we capitalize subsequent Vascepa API purchases from such supplier as inventory. We state inventories at the lower of cost or market value. Cost is determined based on actual cost using the average cost method. An allowance is established when management determines that certain inventories may not be saleable. If inventory cost exceeds expected market value due to obsolescence, damage or quantities in excess of expected demand, we will reduce the carrying value of such inventory to market value. We expense inventory identified for use as marketing samples when they are packaged. The average cost reflects the actual purchase price of Vascepa API, as well as a portion of API carried at zero cost for material which was purchased prior to FDA approval of Vascepa or was purchased prior to the sNDA approval of our suppliers. Additionally, the determination of the classification of our inventory requires the use of estimates in order to determine the portion of inventories anticipated to be utilized within twelve months of the balance sheet date.

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

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

We assess our ability to realize deferred tax assets at each reporting period. The realization of deferred tax assets depends on generating future taxable income during the periods in which the tax benefits are deductible or creditable. We have been historically profitable in the United States. When making our assessment about the realization of its U.S. deferred tax assets at March 31, 2015, we considered all available evidence, placing particular weight on evidence that could be objectively verified. The evidence considered included the (i) historical profitability of our U.S. operations, (ii) sources of future taxable income, giving weight to sources according to the extent to which they can be objectively verified and (iii) the risks to our business related to the commercialization and development of Vascepa. Based on our assessment, we concluded that the U.S. deferred tax assets are more likely than not to be realizable as of March 31, 2015. The majority of our deferred tax assets are held outside of the United States., for which we have established a full valuation allowance. Changes in historical earnings performance and future earnings projections, among other factors, may cause us to adjust our valuation allowance on deferred tax assets, which would impact our income tax expense in the period in which we determine that these factors have changed. In the event sufficient taxable income is not generated in future periods, additional valuation allowances could be required relating to these U.S. deferred tax assets.

### **Recent Accounting Pronouncements**

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board, or FASB, and are adopted by us as of the specified effective date. We considered the following recent accounting pronouncements which were not yet adopted as of March 31, 2015:

In May 2014, the FASB issued ASU No. 2014-09, “Revenue from Contracts with Customers (Topic 606).” This amendment provides principles for recognizing revenue for the transfer of promised goods or services to customers with the consideration to which the entity expects to be entitled in exchange for those goods or services, and is effective for annual periods beginning after December 15, 2016 (the original effective date). In April 2015, the FASB issued a proposal to defer the original effective date of this standard by one year, such that the amendment will be effective for our fiscal year beginning January 1, 2018 if the proposal is adopted. Early adoption is permitted, but not before the original effective date. We are currently evaluating the accounting, transition and disclosure requirements of the standard and cannot currently estimate the financial statement impact of adoption.

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

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

In April 2015, the FASB issued ASU No. 2015-03, *Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs*. The amendments in this ASU require that debt issuance costs related to a recognized debt

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liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. We are required to adopt this standard in the first quarter of fiscal 2016 on a retrospective basis. The implementation of this standard will result in the reclass of certain debt issuance costs from other assets to a reduction in the carrying amount of the related debt liability within the consolidated balance sheets.

We believe 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 our operations.

## **Results of Operations**

### ***Comparison of Three Months Ended March 31, 2015 and March 31, 2014***

*Product Revenue, net.* We recorded product revenue of \$15.6 million and \$11.0 million during the three months ended March 31, 2015 and 2014, respectively, an increase of \$4.6 million, or 42%. All of our product revenue in the three months ended March 31, 2015 and 2014 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, prior to 2014, product 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 product revenue based on sales to our Distributors. Consequently, during the three months ended March 31, 2014, we recognized product revenue of \$11.0 million based on sales to Distributors, compared to product revenue of \$10.0 million that we would have recognized based on the resale of Vascepa for the purposes of filling patient prescriptions. No corresponding effect was realized during the three months ended March 31, 2015. Through March 31, 2015, product returns of Vascepa were de minimis. Timing of shipments to wholesalers, as used for revenue recognition, and timing of prescriptions as estimated by third party sources such as Symphony Health Solutions and IMS Health may differ from period to period.

During the quarters ended March 31, 2015 and 2014, our net product revenue included an adjustment for co-pay mitigation rebates provided by us to commercially insured patients. Such rebates are intended to offset the differential for patients of Vascepa not covered by commercial insurers at the time of launch on Tier 2 for formulary purposes, resulting in higher co-pay amounts for such patients. Our cost for these co-payment mitigation rebates was up to \$75 per prescription filled prior to February 20, 2014 and up to \$70 per prescription filled after February 20, 2014. Since launch, certain third-party payors have added Vascepa to their Tier 2 coverage, which results in lower co-payments for patients covered by these third-party payors. In connection with such Tier 2 coverage, we have agreed to pay customary rebates to these third-party payors on the resale of Vascepa to patients covered by these third-party payors. As a result of expanded commercial coverage and improved formulary positioning, rebates provided for in 2015 will be higher than in prior periods resulting in a slight decrease in the net selling price of Vascepa.

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

*Licensing Revenue.* Licensing revenue during the three months ended March 31, 2015 was \$0.4 million. We did not record licensing revenue prior to 2015. The licensing revenue relates to the amortization of a \$15.0 million up-front payment received in February 2015 associated with a Vascepa licensing agreement for China and surrounding territories. The up-front payment is being recognized over the estimated period in which we are required to provide regulatory and development support and clinical and commercial supply.

*Cost of Goods Sold.* Cost of goods sold during the three months ended March 31, 2015 and 2014 was \$5.6 million and \$4.2 million, respectively, an increase of \$1.4 million, or 33%. Cost of goods sold includes the cost of API for Vascepa on which revenue was recognized during the period, as well as the associated costs for encapsulation, packaging, shipment, supply management, insurance and quality assurance. The cost of the API included in cost of goods sold reflects the average cost of API included in inventory. This average cost reflects the actual purchase price of Vascepa API.

The API included in the calculation of the average cost of goods sold during the year ended December 31, 2014 was sourced from two API suppliers. The contracted cost of supply from our initial API supplier was higher than the contracted cost from our other API suppliers. In the future, we anticipate making continued purchases from this initial supplier and to make additional lower unit cost purchases of Vascepa API from other API suppliers. During the quarters ended March 31, 2015 and 2014, the cost basis of product sold that had a carrying value of zero was zero in both periods. As of March 31, 2015, we maintained no inventory with a carrying value of zero and we classified all of our inventory as current. As a result of lower inventory balances on hand at the end of 2014 compared to the end of 2013 as well as anticipated increases in revenue during 2015 compared to 2014, we anticipate purchasing more API during 2015 than in 2014 with the amount of such purchases dependent on the rate of our revenue growth.

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Our gross margin on product sales for the three months ended March 31, 2015 and 2014 was 64% and 61%, respectively. This improvement was primarily driven by lower unit cost API purchases. In addition, over time we expect continued lower average unit cost purchases of API. We also expect that API costs will be lower in the future due to advantages derived from the mix of our suppliers. The average cost may be variable from period to period depending upon the timing and quantity of API purchased from each supplier.

*Selling, General and Administrative Expense.* Selling, general and administrative expense for the three months ended March 31, 2015 and 2014 was \$24.7 million and \$20.6 million, respectively, an increase of \$4.1 million, or 20%. Selling, general and administrative expenses for the three months ended March 31, 2015 and 2014 are summarized in the table below (in thousands):

	Three Months Ended March 31,	
	2015	2014
Selling, general and administrative expense (1)	\$22,519	\$19,338
Non-cash stock based compensation expense (2)	2,231	1,319
Non-cash warrant related compensation income	(9)	(72)
Total selling, general and administrative expense	<u>\$24,741</u>	<u>\$20,585</u>

- (1) Selling, general and administrative expense, excluding non-cash compensation charges for stock compensation and warrants, for the three months ended March 31, 2015 and 2014 was \$22.5 million and \$19.3 million, respectively, an increase of \$3.2 million, or 17%. The increase is due primarily to higher legal costs associated with various on-going legal matters, which costs vary from period to period, and to co-promotion fees payable to Kowa Pharmaceuticals America, Inc. The co-promotion fees were not applicable in the three months ended March 31, 2014.
- (2) Stock-based compensation expense for the three months ended March 31, 2015 and 2014 was \$2.2 million and \$1.3 million, respectively, an increase of \$0.9 million, or 69%, primarily due to an increase in new stock option and restricted stock awards granted to attract and retain qualified employees.

We currently anticipate that with our existing indication for Vascepa, our selling, general and administrative costs will be largely flat during 2015 as compared to 2014 with the exception of quarterly variability in the timing of legal costs and anticipated increases in the co-promotion fees earned by Kowa Pharmaceuticals America, Inc. based on anticipated increases in net product revenues and the terms of our co-promotion agreement with Kowa Pharmaceuticals America, Inc.

*Research and Development Expense.* Research and development expense for the three months ended March 31, 2015 and 2014 was \$12.6 million and \$11.7 million, respectively, an increase of \$0.9 million, or 8%. Research and development expenses for the three months ended March 31, 2015 and 2014 are summarized in the table below (in thousands):

	Three Months Ended March 31,	
	2015	2014
REDUCE-IT study (1)	\$ 8,420	\$ 7,504
Pre-approval commercial supply (2)	—	308
Regulatory filing fees and expenses (3)	415	643
Internal staffing, overhead and other (4)	2,968	2,614
Research and development expense, excluding non-cash expense	11,803	11,069
Non-cash stock-based compensation (5)	811	638
Total research and development expense	<u>\$12,614</u>	<u>\$11,707</u>

The increase in research and development expenses for the quarter ended March 31, 2015, as compared to the prior year period, is primarily due to an increase in costs associated with the REDUCE-IT study as a result of quarterly variability in such expenses.

- (1) In December 2011, we announced commencement of patient dosing in our cardiovascular outcomes study of Vascepa, titled REDUCE-IT, which is designed to evaluate the efficacy of Vascepa in reducing major cardiovascular events in a high risk patient population on statin therapy. The study duration is dependent on the rate of clinical events in the study, which rate may be affected by the number of patients enrolled in the study, the epidemiology of the patients enrolled in the study, and the length of time that the enrolled patients are followed. We manage the study through a contract research organization (CRO) through which all costs for this outcomes study are incurred with the exception of costs for clinical trial material (CTM) and costs for internal management. Our internal personnel are responsible for managing multiple projects and their costs are not specifically

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allocated to REDUCE-IT or any other individual project. We currently have over 7,400 patients enrolled in REDUCE-IT. We estimate that we will complete patient enrollment in this study within 2015. For the three months ended March 31, 2015 and 2014, we incurred expenses through our CRO in connection with this trial of approximately \$6.6 million and \$5.1 million, respectively. Inclusive of CTM costs, the combined CRO and CTM costs during the three months ended March 31, 2015 and 2014 for REDUCE-IT were approximately \$8.4 million and \$7.5 million, respectively. The increase in expenses in 2015 as compared to 2014 is primarily the result of timing variability for REDUCE-IT costs. We expense costs for CTM upon receipt. The aggregate cost of this outcomes study will depend on the rate of clinical events in the study. We currently estimate that costs incurred for this study in 2015 will be slightly higher than levels we incurred in 2014 and 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 through study completion in 2017 and publication of results in 2018. Our aggregate remaining costs to complete the REDUCE-IT are estimated to be lower than \$100 million if the independent DMC recommends that REDUCE-IT be completed early based on its scheduled interim review of the efficacy and safety results of the study which review we estimate will occur in 2016 upon reaching 60% of the target aggregate number of cardiovascular events for the study. Amarin remains blinded to all data from the study and currently expects the study to be completed in 2017. We anticipate that our costs for this outcomes study will continue to represent the most significant component of our research and development expenditures.

- (2) Until an API supplier is approved by the FDA to manufacture commercial supply of Vascepa, all Vascepa purchased from such supplier is included as a component of research and development expense. Upon approval of the supplier, we capitalize subsequent Vascepa API purchases from such supplier as inventory. Purchases of Vascepa API received and expensed before such regulatory approvals are not subsequently capitalized, and all such purchases are quarantined and not used for commercial supply until such time as the supplier that produced the API is approved. The commercial supply expense for the periods shown above represents inventory received from Nisshin prior to NDA approval of Vascepa on July 26, 2012 or received from our other suppliers prior to their sNDA approvals. The amount of commercial supply that we receive from potential additional API suppliers prior to sNDA approval depends upon production schedules at such suppliers and the timing of regulatory approval, and we are unable to estimate these amounts at this time. We will continue to expense inventory received from the unapproved supplier until such time as FDA approval is obtained.
- (3) The regulatory filing fees in each of the quarters ended March 31, 2015 and 2014 included annual FDA fees for maintaining manufacturing sites.
- (4) Internal staffing, overhead and other research and development expenses primarily relate to the costs of our personnel employed to manage research, development and regulatory affairs activities and related overhead costs including consulting and other professional fees that are not allocated to specific projects. Also included are costs related to qualifying suppliers and legal costs.
- (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.

We anticipate that our research and development costs will be slightly higher during 2015 as compared to 2014 as a result of the timing of REDUCE-IT costs, and that such costs will decline modestly thereafter upon completion of enrollment for REDUCE-IT.

*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, 2015 was \$0.5 million versus \$4.4 million in the prior year period. Gain (loss) on change in fair value of derivative liabilities is comprised of (i) the change in fair value of the warrant derivative liability, (ii) the change in fair value of the derivative liability related to the change in control provision associated with the December 2012 BioPharma financing, (iii) the change in fair value of the derivative liability related to the change in control provision associated with the May 2014 exchangeable senior notes; and (iv) the change in fair value of the derivative liability related to the preferred stock purchase option.

The warrant derivative liability is related to the change in fair value of warrants issued in conjunction with the October 2009 private placement. In October 2009 we issued 36.1 million warrants at an exercise price of \$1.50 and recorded a \$48.3 million warrant derivative liability, representing the fair value of the warrants issued. As these warrants have been classified as a derivative liability, they are revalued at each reporting period, with changes in fair value recognized in the statement of operations. The fair value of the warrant derivative liability at December 31, 2014 was \$0.1 million and we recognized a \$0.1 million gain on change in fair value of derivative liability for the three months ended March 31, 2015 for these warrants. 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 three months ended March 31, 2014. The change in fair value of the warrant derivative liability for the quarter ended March 31, 2015 is due to the expiration of the warrants and the resulting extinguishment of the liability, while the change in fair value for the quarter ended March 31, 2014 is due primarily to the change in the price of our common stock on the date of valuation. In October 2014, we and the holders of the remaining October 2009 warrants mutually agreed to extend the expiration date of such warrants from October 16, 2014 to February 27, 2015. Of the 8,087,388 warrants outstanding as of December 31, 2014, 1,844,585 warrants were exercised and the remaining 6,242,803 warrants expired on February 27, 2015. As such, no warrants were outstanding as of March 31, 2015.

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Our December 2012 financing agreement with BioPharma contains a redemption feature whereby, upon a change of control, we would be required to pay \$140 million, less any previously repaid amount, if the change of control occurs on or before December 31, 2013, or required to repay \$150 million, less any previously repaid amount, if the change of control event occurs after December 31, 2013. The fair value of the derivative liability is recalculated at each reporting period using a probability-weighted model incorporating management estimates for potential change in control, and by determining the fair value of the debt with and without the change in control provision included. The difference between the two fair values of the debt was determined to be the fair value of the embedded derivative. At December 31, 2014, the fair value of the derivative was determined to be \$4.8 million, and at March 31, 2015, the fair value of the derivative was determined to be \$4.8 million. As such, we recognized no change in fair value of derivative liability for the three months ended March 31, 2015. 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. As such, we recognized a \$3.5 million gain on change in fair value of derivative liability for the three months ended March 31, 2014.

Our 2014 Notes, issued in May 2014, contain a redemption feature whereby, upon occurrence of a change in control, we would be required to repurchase the notes. The fair value of the embedded derivative was calculated using a probability-weighted model incorporating management estimates of the probability of a change in control occurring, and by determining the fair value of the debt with and without the change in control provision included. The difference between the two was determined to be the fair value of the embedded derivative. At December 31, 2014, the fair value of the derivative was determined to be \$2.6 million, and at March 31, 2015, the fair value of the derivative was determined to be \$1.3 million. As such, we recognized a \$1.3 million gain on change in fair value of derivative liability for the three months ended March 31, 2015.

In connection with the closing of a private placement transaction in March 2015, we recorded a derivative liability pursuant to a pre-existing contractual right. This preferred stock purchase option was determined to be a derivative liability effective March 5, 2015, the date in which the private placement was initially subscribed. The fair value of this liability was calculated using a Black-Scholes model and was determined to be \$0.9 million at inception and was charged to retained earnings as a deemed non-cash dividend. The liability was then marked to fair value through March 30, 2015, the date on which we executed a subscription agreement with the investor, resulting in a charge of \$0.9 million through gain (loss) on change in fair value of derivatives. The liability was reclassified to permanent equity on such date.

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

*Interest Expense, net.* Net interest expense for the three months ended March 31, 2015 and 2014 was \$4.9 million and \$4.4 million, respectively, an increase of \$0.5 million, or 11%. Net interest expense for the three months ended March 31, 2015 and 2014 is summarized in the table below (in thousands):

	Three Months Ended	
	March 31,	
	2015	2014
Exchangeable senior notes (1):		
Amortization of debt discounts	\$ 1,452	\$ 683
Contractual coupon interest	1,312	1,312
Total exchangeable senior notes interest expense	2,764	1,995
Long-term debt—BioPharma financing (2):		
Cash interest—current	1,556	1,097
Cash interest—deferred	112	821
Non-cash interest	465	489
Total long-term debt interest expense	2,133	2,407
Other interest expense	—	1
Total interest expense	4,897	4,403
Interest income (3)	(12)	(10)
Total interest expense, net	\$ 4,885	\$ 4,393

(1) Cash and non-cash interest expense related to the exchangeable senior notes for the three months ended March 31, 2015 and 2014 was \$2.8 million and \$2.0 million, respectively.

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- (2) Cash and non-cash interest expenses related to the BioPharma financing for the three months ended March 31, 2015 and 2014 were \$2.1 million and \$2.4 million, respectively. These amounts reflect the assumption that our Vascepa revenue levels will not be high enough to support repayment to BioPharma in accordance with the repayment schedule without the optional reduction which is allowed to be elected by us if the threshold revenue levels are not achieved. To date, our revenues have been below the contractual threshold amount each quarter such that each payment reflects the calculated optional reduction amount as opposed to the contractual threshold payments for each quarterly period.
- (3) Interest income for the three months ended March 31, 2015 and 2014 was \$0.01 million in each period. Interest income represents income earned on cash balances.

*Other (Expense) Income, net.* Other (expense) income, net, for the three months ended March 31, 2015 was expense of \$0.1 million versus income of \$0.02 million in the prior year period. Other (expense) income, net, primarily consists of losses and gains on foreign exchange transactions.

*Benefit from (Provision for) Income Taxes.* Benefit from (provision for) income taxes for the three months ended March 31, 2015 was a \$0.5 million benefit versus a \$0.4 million provision in the prior year period. The current provision relates entirely to the U.S. subsidiary operations. We are profitable in the United States as a result of intercompany transactions between our U.S. subsidiary and our other companies.

## Liquidity and Capital Resources

Our sources of liquidity as of March 31, 2015 include cash and cash equivalents of \$161.2 million. In February 2015, we received a \$15.0 million non-refundable, up-front payment upon the execution of our first ex-U.S. licensing agreement which agreement covers China and surrounding territories. In March 2015, we entered into a subscription agreement with four institutional investors for the issuance and sale of our Series A Preference Shares resulting in net proceeds to us of \$52.2 million. Both the \$15.0 million up-front payment from the ex-U.S. licensing agreement and the \$52.2 million in net proceeds from the issuance and sale of Series A Preference Shares are included in our March 31, 2015 cash balance. Our projected uses of cash include commercialization of Vascepa for the MARINE indication, the continued funding of the REDUCE-IT cardiovascular outcomes study, working capital and other general corporate activities. Our cash flows from operating, investing and financing activities, as reflected in the consolidated statements of cash flows, are summarized in the following table (in millions):

	<b>Three Months Ended March 31,</b>	
	<b>2015</b>	<b>2014</b>
<b>Cash (used in) provided by continuing operations:</b>		
Operating activities	\$ (12.6)	\$ (27.5)
Investing activities	—	—
Financing activities	54.3	0.3
<b>Decrease in cash and cash equivalents</b>	<b>\$ 41.7</b>	<b>\$ (27.2)</b>

On December 6, 2012 we entered into a financing agreement with BioPharma. Under this agreement, we granted to BioPharma a security interest in future receivables and all related rights to Vascepa, in exchange for \$100 million received at the closing of the agreement which closing occurred in December 2012. We have agreed to repay BioPharma up to \$150 million of future revenue and receivables. As of March 31, 2015, the net remaining amount to be repaid to BioPharma is \$142.7 million. To date, our revenues have been below the contractual threshold amount such that each payment made has reflected the calculated optional reduction amount as opposed to the contractual threshold payments for each quarterly period. The maximum amount payable under the contractual threshold for 2015 is \$31.6 million. The quarterly repayments through March 31, 2015 represented interest only. In accordance with the agreement with BioPharma, quarterly differences between the calculated optional reduction amounts and the repayment schedule amounts are rescheduled for payment beginning in the second quarter of 2017. Any such deferred payments will remain subject to continued application of the quarterly ceiling in amounts due established by the calculated threshold based on quarterly Vascepa revenues. No additional interest expense or liability is incurred as a result of such deferred repayments. The agreement does not expire until \$150 million in aggregate has been repaid. We can prepay an amount equal to \$150 million less any previously repaid amount. We currently estimate that Vascepa revenue levels will not be high enough in each quarter to support repayment to BioPharma in accordance with threshold amounts in the repayment schedule.

On January 9, 2012, Amarin, through our wholly-owned subsidiary Corsicanto Limited, or Corsicanto, a private limited company incorporated under the laws of Ireland, completed a private placement of \$150.0 million in aggregate principal amount of its 3.5% exchangeable senior notes due 2032, or the 2012 Notes. The proceeds we received from the January 2012 debt offering were approximately \$144.3 million, net of fees and transaction costs. On May 20, 2014, we entered into separate, privately negotiated exchange agreements with certain holders of the 2012 Notes pursuant to which Corsicanto exchanged \$118.7 million in aggregate

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principal amount of the 2012 Notes for \$118.7 million in aggregate principal amount of new 3.50% May 2014 Exchangeable Senior Notes due 2032, or the 2014 Notes, following which \$31.3 million in aggregate principal amount of the 2012 Notes remain outstanding with terms unchanged.

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

The 2014 Notes were issued pursuant to an indenture dated May 20, 2014 by and among Corsicanto, us as grantor, and Wells Fargo Bank, National Association, as trustee. The notes are senior unsecured obligations of Corsicanto and are guaranteed by us. The 2014 Notes have a stated interest rate of 3.5% per year, payable semiannually in arrears on January 15 and July 15 of each year beginning on July 15, 2014, and ending upon the Notes' maturity on January 15, 2032, unless earlier repurchased or redeemed by Corsicanto or exchanged by the holders. At any time after the issuance of the 2014 Notes and prior to the close of business on the second business day immediately preceding January 15, 2032, holders may exchange their 2014 Notes at their option. If prior to January 15, 2018, a make-whole fundamental change (as defined in the Indenture) occurs or we elect to redeem the 2014 Notes in connection with certain changes in tax law, in each case as described in the Indenture, and a holder elects to exchange its 2014 Notes in connection with such make-whole fundamental change or election, as the case may be, such holder may be entitled to an increase in the exchange rate as described in the Indenture. The initial exchange rate is 384.6154 ADSs per \$1,000 principal amount of the 2014 Notes (equivalent to an initial exchange price of approximately \$2.60 per ADS, or the Exchange Price), subject to adjustment in certain circumstances. The exchange rate is subject to adjustment from time to time upon the occurrence of certain events, including, but not limited to, the payment of cash dividends.

On March 30, 2015, in connection with the closing of the initial private placement, and pursuant to a pre-existing contractual preemptive right to participate in certain private placement transactions effected by us, we entered into a separate subscription agreement with an existing investor, Sofinnova Venture Partners VII L.P (Sofinnova), for the purchase of an additional 38,867,180 restricted ADSs, each representing one (1) share of our Series A Preference Shares, at the same price per share and otherwise on substantially the same terms as the initial private placement, for potential proceeds of \$5.8 million. In accordance with applicable marketplace rules of the NASDAQ Stock Market, the consummation of the second private placement is conditioned upon approval by our shareholders at a future meeting of our shareholders. Dr. James Healy, a member of our Board, is a managing member of Sofinnova Management VII, L.L.C., the general partner of Sofinnova.

As of March 31, 2015, we had cash and cash equivalents of \$161.2 million, an increase of \$41.7 million from December 31, 2014. The increase is primarily due to the net proceeds from an equity financing of \$52.2 million and a \$15.0 million up-front payment received from an ex-U.S. licensing agreement offset by net cash used in operating activities in support of the continued commercialization of Vascepa and the continued funding of REDUCE-IT, less accounts receivable collections. We have incurred annual operating losses since our inception and, as a result, we had an accumulated deficit of \$1.0 billion as of March 31, 2015. We believe that our cash and cash equivalents balance of \$161.2 million at March 31, 2015 will be sufficient to fund our projected operations for at least the next twelve months. We anticipate that quarterly net cash outflows in future periods will be variable.

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### Contractual Obligations

The following table summarizes our contractual obligations at March 31, 2015 and the effects such obligations are expected to have on our liquidity and cash flows in future periods (in millions):

#### Payments Due by Period

	<u>Total</u>	<u>2015</u>	<u>2016 to 2017</u>	<u>2018 to 2019</u>	<u>After 2019</u>
Contractual Obligations:					
Purchase obligations (1)	\$54.3	\$ 11.7	\$ 27.3	\$ 15.3	\$ —
Operating lease obligations (2)	1.9	0.5	1.2	0.2	—
Interest payment obligations—exchangeable debt (3)	18.8	2.6	10.0	6.2	—
Total contractual cash obligations	<u>\$75.0</u>	<u>\$14.8</u>	<u>\$ 38.5</u>	<u>\$ 21.7</u>	<u>\$ —</u>

- (1) We have agreements with API suppliers which include minimum purchase levels to enable us to maintain certain exclusivity with each respective supplier and certain agreements require any shortfall in such purchase levels to be paid in cash. The amounts in the table above reflect amounts potentially payable to our suppliers based on our minimum purchase obligations assuming such suppliers are qualified. Each supplier is required to meet certain performance obligations and the agreements may be terminated by us in the event of non-performance.
- (2) Represents operating lease costs, primarily consisting of leases for facilities in Dublin, Ireland and Bedminster, NJ.
- (3) Represents scheduled interest payments due under the terms of the 2012 Notes and 2014 Notes, assuming that the 2012 Notes remain outstanding through January 19, 2017 and that the 2014 Notes remain outstanding through January 19, 2019 and they have not been exchanged for ADSs. The above table does not reflect the repayment of the \$150.0 million notes as they may be exchanged for ADSs.

We do not enter into financial instruments for trading or speculative purposes. At March 31, 2015, we had no outstanding forward exchange contracts.

We have Vascepa API supply agreements with two independent companies from which we purchase qualified API supply: Nisshin, and Chemport. Our agreement with Chemport contains minimum annual purchase levels enabling us to maintain certain supply exclusivity and a provision that any shortfall in the minimum purchase commitments is payable in cash. The maximum amounts payable pursuant to this provision are reflected in the table above.

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 in each of the three months ended March 31, 2015 and 2014. Also under the Laxdale agreement, upon receipt of marketing approval in Europe for the first indication for Vascepa (or first indication of any product containing Amarin Neuroscience intellectual property acquired from Laxdale in 2004), we must make an aggregate stock or cash payment to the former shareholders of Laxdale (at the sole option of each of the sellers) of £7.5 million (approximately \$11.1 million at March 31, 2015). Additionally, upon receipt of a marketing approval in the United States or Europe for a further indication of Vascepa (or further indication of any other product using Amarin Neuroscience intellectual property), we must make an aggregate stock or cash payment (at the sole option of each of the sellers) of £5 million (approximately \$7.4 million at March 31, 2015) for each of the two potential market approvals (i.e. £10 million maximum, or approximately \$14.8 million at March 31, 2015).

In January 2015, we granted a total of 5,455,500 performance-based RSUs (“PSUs”) to employees for the right to receive payment in the form of ordinary shares, or any combination of cash and shares. Payment in the form of ordinary shares is subject to shareholder approval of a sufficient increase in the number of shares reserved for issuance under the Amarin Corporation plc 2011 Stock Incentive Plan at our Annual General Meeting in July 2015. If shareholder approval does not occur prior to a related vesting event or change of control transaction, we are obligated to settle the PSUs based on fair value in cash.

In addition to the obligations in the table above, we have recorded a liability of \$0.4 million for uncertain tax positions that have been recorded in long-term liabilities at March 31, 2015. 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 March 3, 2015.

**Item 4. Controls and Procedures**

**Evaluation of Disclosure Controls and Procedures**

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

As of March 31, 2015, our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer have concluded, based upon the evaluation described above that, as of March 31, 2015, 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, 2015, there have been no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15(d)-15(f) promulgated under the Securities Exchange Act of 1934, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II

### Item 1. *Legal Proceedings*

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

On May 7, 2015, Amarin and a group of independent physicians filed a federal lawsuit to permit Amarin to share truthful and non-misleading information, including the ANCHOR trial clinical data, with healthcare professionals in the United States about uses of Vascepa that are consistent with multiple national and international treatment guidelines and relevant to patients in the United States at risk of cardiovascular disease. The lawsuit, captioned, Amarin Pharma, Inc. et al. v. Food & Drug Administration, et al., was filed in the United States District Court for the Southern District of New York and seeks a judicial declaration based on several legal theories.

### Item 1A. *Risk Factors*

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

*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 March 3, 2015.*

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

***\* FDA recently issued a Complete Response Letter to us regarding our ANCHOR study 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 label expansion for Vascepa.***

Since January 2013 we have marketed Vascepa for use in the MARINE indication in the United States. Our ability to fully commercialize Vascepa beyond the MARINE indication in the United States is dependent upon receiving additional regulatory approvals. In April 2015, we received a Complete Response Letter, or CRL, from the FDA on our Supplemental New Drug Application, or sNDA, that sought approval for the use of Vascepa in patients with high triglyceride levels (TG  $\geq$ 200 mg/dL and  $<$ 500 mg/dL) who are also on statin therapy, which we refer to as the ANCHOR indication.

In the CRL, the FDA acknowledged that Vascepa yielded a treatment difference showing reduced triglyceride levels compared to placebo in patients treated in the ANCHOR study. The clinical rationale for reducing serum triglycerides with Vascepa and modifying other lipid/lipoprotein parameters shown in ANCHOR among statin-treated patients with triglycerides 200-499 mg/dL is to reduce cardiovascular risk. The FDA concluded that, for regulatory approval purposes, there are insufficient data at this time to support a drug-induced change in serum triglycerides as a surrogate for reducing cardiovascular risk in the ANCHOR population. The FDA did not determine that the drug-induced effects of Vascepa, which go beyond triglyceride-lowering, would not actually reduce cardiovascular risk in this population.

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

During the advisory committee meeting held by FDA as part of its review of our sNDA, 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

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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 and that FDA approved labeling reflects safety (but not efficacy) data from the ANCHOR trial. 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 the FDA at the meeting, Vascepa appeared to be safe and effective for the reduction of TGs in patients with mixed dyslipidemia on statin therapy. Amarin, after discussion and agreement with FDA, directed the independent data monitoring committee (DMC) for REDUCE-IT to periodically review unblinded lipid data to monitor for signals that the placebo might not be inert. After each quarterly DMC meeting to date, the DMC has recommended to continue the REDUCE-IT study as planned, and each of these DMC recommendations has been shared with FDA. Amarin and FDA remain blinded. At the advisory committee meeting and in subsequent regulatory dialogue, including in the CRL, FDA acknowledged that in the ANCHOR study Vascepa demonstrated a statistically significant reduction in triglyceride blood levels compared to placebo, the study's primary endpoint. No further mention was made by the FDA in the CRL of any concern regarding the placebo in any of our clinical trials.

Even if we obtain additional regulatory approvals for Vascepa, the timing or scope of any approvals may prohibit or reduce our ability to commercialize the product successfully. For example, if the approval process for any expanded indication takes too long, we may miss market opportunities and give other companies the ability to develop competing products or establish market dominance. If the FDA does not approve any expanded indication at all, it could have a material impact on our future results of operations and financial condition. Additionally, the terms of any approvals, including the approval received from the FDA in July 2012 for the MARINE indication, may prove to not have the scope or breadth needed for us to successfully commercialize Vascepa or become profitable.

***\*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.

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

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

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

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

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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;
- an inability by us or our partners to obtain regulatory and marketing approval or establish marketing channels in foreign jurisdictions; and
- unforeseen costs and expenses associated with operating a new independent sales and marketing organization.

In addition, we believe that investors should view with caution both the results for the twelve months ended December 31, 2014 and the results for quarterly periods for the foreseeable future, as data for this limited period may not be representative of a trend consistent with the results presented or otherwise predictive of future results, especially in light of competitive developments in the market in which we operate, our interactions with FDA on potential label expansions with Vascepa (including the April 2015 CRL), the October 2013 approximately 50% reduction in our sales force, the March 2014 co-promotion Agreement with Kowa Pharmaceuticals America, Inc., and the February 2015 DCS Agreement with Eddingpharm. We commenced our commercial launch of Vascepa in January 2013. Accordingly, there is a very limited amount of information available at this time to determine the actual number of total prescriptions for Vascepa. We believe investors should consider our results to date together with results over several future quarters, or longer, before making an assessment about potential future performance.

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

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

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

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

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

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

On October 29, 2013, the FDA notified us that it rescinded the ANCHOR study SPA agreement because the FDA determined that a substantial scientific issue essential to determining the effectiveness of Vascepa in the studied population was identified after testing began. In April 2015, we received a CRL from the FDA stating that the FDA determined not to approve label expansion reflecting the ANCHOR clinical trial efficacy data at this time.

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

***\*Our suit against FDA to allow for the sharing of truthful and non-misleading information with healthcare professionals in the United States about uses of Vascepa may not achieve its intended goal to allow for the sharing of such information or otherwise benefit us.***

On May 7, 2015, we and a group of independent physicians commenced a lawsuit against the FDA to permit us to share truthful and non-misleading information, including the ANCHOR study results, with healthcare professionals in the United States about uses of Vascepa that are consistent with multiple national and international treatment guidelines and relevant to patients in the United States at risk of cardiovascular disease. Because the efficacy results from the ANCHOR trial have not been approved by the FDA for inclusion in FDA labeling of Vascepa, truthful and non-misleading promotion of such information is considered off-label and thus illegal under FDA's regulatory structure. The lawsuit, captioned, *Amarin Pharma, Inc. et al. v. Food & Drug Administration, et al.*, was filed in the United States District Court for the Southern District of New York and seeks a judicial declaration based on applicable precedent, First Amendment freedom of speech principles and Fifth Amendment restrictions against overly vague laws. The physicians in the suit regularly treat patients at risk of cardiovascular disease and, as the complaint contends, have First Amendment rights to receive accurate information. The goal of the lawsuit is to supply accurate information to physicians about Vascepa so they can make informed decisions on how to treat patients based on current, scientific data and consistent with numerous national and international cardiovascular treatment guidelines and position statements.

We may not be successful in this lawsuit against the FDA. Even if we are successful at the federal district court level, the FDA may appeal. The legal process can be unpredictable, costly and time-consuming and even if we are successful the remedies available to us may be less beneficial to us or the medical community in general than we currently believe.

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

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

Our competitors both in the United States and Europe include large, well-established pharmaceutical companies, specialty pharmaceutical sales and marketing companies, and specialized cardiovascular treatment companies. GlaxoSmithKline plc, which currently markets Lovaza<sup>®</sup>, a prescription-only omega-3 fatty acid indicated for patients with severe hypertriglyceridemia was approved by FDA in 2004 and has been on the market in the United States since 2005. As described below, multiple generic versions of Lovaza are now available in the United States. Other large companies with competitive products include AbbVie, Inc., which currently markets Tricor<sup>®</sup> and Trilipix<sup>®</sup> for the treatment of severe hypertriglyceridemia and mixed dyslipidemia and Niaspan<sup>®</sup>, which

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is primarily used to raise HDL-C, but is also used to lower triglycerides. Generic versions of Tricor, Trilipix, and Niaspan are also now available in the United States. In addition, in May 2014, Epanova® (omega-3-carboxylic acids) capsules, a free fatty acid form of omega-3 (comprised of 55% EPA and 20% DHA), was approved by the FDA for patients with severe hypertriglyceridemia. Epanova was developed by Omthera Pharmaceuticals, Inc., and is now owned by AstraZeneca Pharmaceuticals LP (AstraZeneca). We expect AstraZeneca will utilize its substantial commercial resources to market its product imminently. Also, in April 2014, Omtryg, another omega-3-acid fatty acid composition developed by Trygg Pharma AS, received FDA approval for severe hypertriglyceridemia. We are not aware of the commercialization plan for Omtryg. Each of these competitors, other than Trygg, has greater resources than we do, including financial, product development, marketing, personnel and other resources.

In April 2014, Teva Pharmaceuticals USA Inc., or Teva, launched a generic version of Lovaza after winning its patent litigation against Pronova BioPharma Norge AS, now owned by BASF, which owns such patents rights. In June 2014 and September 2014, Par Pharmaceutical Inc., or Par, and Apotex Inc., or Apotex, received FDA approval of their respective versions of generic Lovaza. In March 2011, Pronova/BASF entered into an agreement with Apotex to settle its patent litigation in the United States related to Lovaza. Pursuant to the terms of the settlement agreement, we believe Pronova/BASF granted Apotex a license to enter the U.S. market with a generic version of Lovaza in the first quarter of 2015, the details of which are not known to us. In the first quarter of 2015, Prasco Labs announced it also has a generic version of Lovaza.

In addition, we are aware of other pharmaceutical companies that are developing products that, if approved and marketed, would compete with Vascepa. We understand that Acasti Pharma, a subsidiary of Neptune Technologies & Bioresources Inc., announced in late 2012 that it intends to conduct a Phase 3 clinical program to assess the safety and efficacy of its omega-3 prescription drug candidate derived from krill oil for the treatment of hypertriglyceridemia. We believe Catabasis Pharmaceuticals, or Catabasis, Resolvix Pharmaceuticals, or Resolvix, and Sancilio & Company are also developing potential treatments for hypertriglyceridemia based on omega-3 fatty acids. To our knowledge, Catabasis initiated a Phase 2 clinical trial of its product in December 2013; Resolvix's compound remains in Phase 1 clinical testing; and Sancilio is preparing to commence Phase 3 clinical testing. In addition, we are aware that Matinas BioPharma, Inc. is developing an omega-3-based therapeutic for the treatment of severe hypertriglyceridemia and mixed dyslipidemia. Matinas BioPharma, Inc. has filed an Investigational New Drug Application with the FDA to conduct a human study in the treatment of severe hypertriglyceridemia. Isis Pharmaceuticals announced favorable Phase 2 results of ISIS-APOCIII<sub>Rx</sub> a drug candidate administered through weekly subcutaneous injections, in patients with high triglycerides and type 2 diabetes and in patients with moderate to severe high triglycerides. Finally, Madrigal Pharmaceuticals has completed Phase 1 clinical testing of MGL-3196 for the treatment of high triglycerides and various lipid parameters in patients.

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

The Food Drug and Cosmetic Act, or FDCA, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, as amended, or the Hatch-Waxman Amendments, permit the FDA to approve abbreviated new drug applications, or ANDAs, for generic versions of brand name drugs like Vascepa. We refer to the process of generic drug applications as the "ANDA process." The ANDA process permits competitor companies to obtain marketing approval for a drug product with the same active ingredient, dosage form, strength, route of administration, and labeling as the approved brand name drug, but without having to conduct and submit clinical studies to establish the safety and efficacy of the proposed generic product. In place of such clinical studies, an ANDA applicant needs to submit data demonstrating that its product is bioequivalent to the brand name product, usually based on pharmacokinetic studies.

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

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

We have received six paragraph IV notices notifying us of submitted ANDAs to Vascepa under the Hatch-Waxman Amendments. We are now engaged in costly litigation with the ANDA applicants to protect our patent rights. If an ANDA filer is

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

In addition to the six paragraph 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, and has been, afforded the benefit of a 30-month stay against the launch of such a competitive product that extends from the period that Amarin receives notice of the patent challenge (the paragraph IV notice), assuming Amarin responds to the patent challenge with 45 days, and Amarin may also be afforded a judicial extension if applicable requirements are met. Currently, Amarin believes its 30-month stay extends until September 2016. This three-year form of exclusivity may also not prevent the FDA from approving an NDA that relies only on its own data to support the change or innovation.

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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 dismiss the currently pending ANDA-related patent litigation if we do win our NCE suit. The legal process can be unpredictable, costly and time-consuming and even if we are successful the remedies available to us diminish in value over time as we approach the natural expiration of the benefits associated with five-year exclusivity.

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

Our only current product, Vascepa, is a prescription-only omega-3 fatty acid. Mixtures of omega-3 fatty acids are naturally occurring substances contained in various foods, including fatty fish. Omega-3 fatty acids are also marketed by others as non-prescription dietary supplements. We cannot be sure physicians will view the pharmaceutical grade purity and tested safety of Vascepa as having a superior therapeutic profile to naturally occurring omega-3 fatty acids and dietary supplements. In addition, the FDA has not enforced what we view as illegal drug claims made by certain supplement manufacturers to the extent we believe appropriate under applicable law and regulations, for example, claims that such supplements reduce triglyceride levels. Also, for more than a decade now, the FDA has expressly permitted dietary supplement manufacturers that sell supplements containing the omega-3 fatty acids EPA and/or DHA to make the following qualified health claim directly to consumers: Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease. Under FDA's regulatory regime, we cannot make this claim. These factors enable dietary supplements to effectively compete with Vascepa. In addition, to the extent the net price of Vascepa after insurance and offered discounts is significantly higher than the prices of commercially available omega-3 fatty acids marketed by other companies as dietary supplements (through that lack of coverage by insurers or otherwise), physicians may recommend these commercial alternatives instead of writing prescriptions for Vascepa or patients may elect on their own to take commercially available omega-3 fatty acids. Either of these outcomes may adversely impact our results of operations by limiting how we price our product and limiting the revenue we receive from the sale of Vascepa due to reduced market acceptance.

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

In March 2014, we entered into a co-promotion agreement with Kowa Pharmaceuticals America, Inc. to co-promote Vascepa in the United States under which approximately 250 Kowa Pharmaceuticals America, Inc. sales representatives devote a substantial portion of their time to promoting Vascepa with Amarin's approximately 130 sales representatives. Co-promotion under the agreement commenced in May 2014 based on a plan designed to substantially increase both the number of sales targets reached and the frequency of sales calls on existing sales targets. While our agreement provides for minimum performance criteria, we have little control over Kowa Pharmaceuticals America, Inc., and it may fail to devote the necessary resources and attention to promote Vascepa effectively. If that were to occur, depending on Vascepa revenues, we may have to curtail the continued development of Vascepa for approval for additional indications or increase our planned expenditures and undertake additional development or commercialization activities at our own expense. Or, we may seek to terminate the agreement and search for another commercialization partner. If we elect to increase our expenditures to fund development or commercialization activities on our own, depending on Vascepa's revenues, we may need to obtain additional capital, which may not be available to us on acceptable terms, or at all, or which may not be possible due to our other financing arrangements. If we do not generate sufficient funds from the sale of Vascepa or, to the extent needed to supplement funds generated from product revenue, cannot raise sufficient funds, we may not be able to devote resources sufficient to market and sell Vascepa on our own in a manner required to realize the full market potential of Vascepa.

***The commercial value to us of the indications we seek 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, an indication based on a successful outcome of the REDUCE-IT study. Even if we obtain marketing approval for additional indications, the FDA may impose restrictions on the product's conditions for use, distribution or marketing and in some cases may impose ongoing requirements for post-market surveillance, post-approval studies or clinical trials. Also, 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.

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

There can be no assurance as to the adequacy for commercial success under the DCS Agreement with Eddingpharm. Even if we and Eddingpharm obtain marketing approval in countries within the China Territory, applicable regulatory agencies may impose restrictions on the product's conditions for use, distribution or marketing and in some cases may impose ongoing requirements for post-market surveillance, post-approval studies or clinical trials. Also, with regard to any indications for which we may gain approval in these countries, the number of actual patients with the condition included in such approved indication may be smaller than we anticipate. If any such approved indication is narrower than we anticipate, the market potential in these countries for our product would suffer.

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

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

With respect to sales and marketing activities including direct-to-consumer advertising and promotional activities involving the internet, advertising and promotional materials must comply with FDA rules in addition to other applicable federal and local laws in the United States and in other countries. Industry-sponsored scientific and educational activities also must comply with FDA and other requirements. In the United States, the distribution of product samples to physicians must comply with the requirements of the U.S. Prescription Drug Marketing Act. Manufacturing facilities remain subject to FDA inspection and must continue to adhere to the FDA's current good manufacturing practice requirements, or cGMPs. Application holders must obtain FDA approval for product and manufacturing changes, depending on the nature of the change. We also are subject to the new federal transparency requirements under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, which require manufacturers of certain drugs, devices, biologics, and medical supplies to report to the Centers for Medicare & Medicaid Services, or CMS, information related to payments and other transfers of value to physicians and teaching hospitals and physician ownership and investment interests. We may also be subject, directly or indirectly through our customers and partners, to various fraud and abuse laws, including, without limitation, the U.S. Anti-Kickback Statute, U.S. False Claims Act, and similar state laws, which impact, among other things, our proposed sales, marketing, and scientific/educational grant programs. If we participate in the U.S. Medicaid Drug Rebate Program, the Federal Supply Schedule of the U.S. Department of Veterans Affairs, or other government drug programs, we will be subject to complex laws and regulations regarding reporting and payment obligations. We must also comply with requirements to collect and report adverse events and product complaints associated with our products. For example, in September 2014, we participated in a routine inspection from the FDA in which the FDA made observations on perceived deficiencies related to our processes for collection and processing of adverse events. We have responded to FDA with respect to these observations and continue to work with FDA to show that we have improved related systems and we believe that we have demonstrated to FDA that we have adequately responded to these observations. Our activities are also potentially subject to U.S. federal and state consumer protection and unfair competition laws. Similar requirements exist in many of these areas in other countries.

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

***\*The commercial value of Vascepa may be negatively affected by the recent rejection of the application with the FDA for the use of Vascepa in the ANCHOR indication.***

Though we are restricted from promoting Vascepa under applicable regulations for any indication other than the FDA-approved MARINE indication, healthcare professionals are not restricted from prescribing Vascepa for such so-called off-labeled uses. A significant amount of the sales of Vascepa are, in fact, attributable to so-called off-labeled uses of the drug. We expect that among the off-labeled uses of Vascepa are uses that would fall into, or be closely related to, the proposed ANCHOR indication. The October 2013 negative recommendation of the advisory committee meeting against approval of Vascepa in the ANCHOR indication, the October 2013 rescission by the FDA of the ANCHOR SPA, and the April 2015 CRL regarding the FDA's determination not to

approve label expansion reflecting the ANCHOR clinical trial efficacy data at this time 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, Inc. 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, Inc., or our ex-U.S. commercialization partner, Eddingpharm. For example, the Federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

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

***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 adult patients with severe hypertriglyceridemia at a dose of 4 grams per day and is being studied in REDUCE-IT at 4 grams per day.

The only other outcomes study involving the use of a highly-pure formulation of ethyl-EPA, called the Japan EPA Lipid Intervention Study (JELIS), suggested that use of a highly-pure formulation of ethyl-EPA in Japan, when used in conjunction with statins, reduced cardiovascular events by 19% compared to the use of statins alone. However, there are several limitations to the JELIS study. First, the patient population was exclusively Japanese, the majority of the participants were women, and at baseline

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patients had a much higher LDL, limiting its generalizability to the intended target population. Also, a low dose of statins was used. It is unknown whether the positive treatment effects would have persisted if these patients had been optimally treated with statins using contemporary LDL targets in the United States. In addition, JELIS was an open-label trial, which could influence patient and physician behavior and reporting of symptoms, decisions regarding hospitalization, and referral of events for adjudication. This may be particularly relevant since hospitalizations for unstable angina was a primary contributor of the overall positive result, and is considered a softer endpoint than fatal cardiovascular events.

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

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

In accordance with the SPA agreement for our REDUCE-IT cardiovascular outcomes trial, an interim review of the efficacy and safety results of the trial is scheduled to occur upon reaching 60% of the target aggregate number of cardiovascular events. We currently expect this interim review by the study's independent data monitoring committee (DMC) to occur during 2016 based on our understanding of the current event rates in the study and expected future event rates. It may actually take longer to reach the targeted number of events, which would delay the DMC assessment of data for the interim analysis.

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

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

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

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

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

- the lack of efficacy during clinical trials;

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- 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

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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**

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

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

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

We initially purchased all of our supply of the bulk compound (ethyl-EPA), which constitutes the only active pharmaceutical ingredient, or API, of Vascepa, from a single supplier, Nisshin Pharma, Inc., or Nisshin, located in Japan. Nisshin was approved by the FDA as a Vascepa API supplier as part of our FDA marketing approval for the MARINE indication in July 2012. In April 2013, we announced the approval by the FDA of Chemport, Inc. and BASF (formerly Equateq Limited) as additional Vascepa API suppliers. We purchase and use commercial supply from Chemport in addition to Nisshin. We terminated our agreement with BASF due to its inability to meet the agreement requirements, may enter into a new development and supply agreement with BASF, and may purchase API from BASF. In 2014, we obtained sNDA approval for Slanmhor, resulting in a total of four FDA-approved suppliers of API. 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.

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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.

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

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

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

***We have limited experience with the commercial sale of Vascepa, and such inexperience may cause us to purchase too much or not enough supply to satisfy actual demand, which could have a material adverse effect on our financial results and financial condition.***

Certain of our agreements with our suppliers include minimum purchase obligations and limited exclusivity provisions. These purchases are generally made on the basis of rolling twelve-month forecasts which in part are binding on us and the balance of which are subject to adjustment by us subject to certain limitations. Certain of our agreements also include contractual minimum purchase commitments regardless of the rolling twelve-month forecasts. We have limited experience with the commercial sale of Vascepa, and as such expectations regarding expected demand may be wrong. We may not purchase sufficient quantities of Vascepa to meet actual demand or our purchase of supply may exceed actual demand. In either case, such event could have a material adverse effect on our financial results and financial condition.

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

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

Changes in the manufacturing process or procedure, including a change in the location where the product is manufactured or a change of a third party manufacturer, may require prior FDA review and approval of the manufacturing process and procedures in

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accordance with the FDA's cGMPs. Any new facility may be subject to a pre-approval inspection by the FDA and would again require us to demonstrate product comparability to the FDA. There are comparable foreign requirements. This review may be costly and time consuming and could delay or prevent the launch of a product.

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

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

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

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

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

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

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

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

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

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

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

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Amarin has prosecuted, and is currently prosecuting, multiple patent applications to protect the intellectual property developed during the Vascepa cardiovascular program. As of the date of this report, we had 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 sought injunctive relief and monetary damages for infringement of Amarin's U.S. Patent No. 8,663,662. The complaint alleged infringement of the patent arising from the expected launch of Epanova, a product that is expected to compete with Vascepa in the United States. The patent covers methods of lowering triglycerides by administering a pharmaceutical composition that includes amounts of EPA as free acid, and no more than about 30% DHA. In November 2014, based on a representation from AstraZeneca Pharmaceuticals LP that the commercial launch of Epanova was not imminent, the court dismissed our complaint, without prejudice (i.e., preserving our ability to later re-file the suit). The court required the defendant to notify us before any product launch. We intend to pursue this litigation vigorously and aggressively protect its intellectual property rights. However, patent litigation is a time-consuming and costly process. There can be no assurance that we will be successful in enforcing this patent or that it will not be successfully challenged and invalidated. Even if we are successful in enforcing this patent, the process could take years to reach conclusion.

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

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

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

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

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

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

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

### **Risks Related to our Business**

***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 have engaged in a vigorous defense of the consolidated lawsuit, we believe that the plaintiffs have failed to state a claim, and we have moved to dismiss the lawsuit. However, we are unable to predict the outcome of this matter at this time. Moreover, while we expect insurance to cover any financial exposure from this litigation, the conclusion of this matter in a manner adverse to us could have a material adverse effect on our financial condition and business. For example, we could incur substantial costs not covered by our directors' and officers' liability insurance, suffer a significant adverse impact on our reputation and divert management's attention and resources from other priorities, including the execution of business plans and strategies that are important to our ability to grow our business, any of which could have a material adverse effect on our business. In addition, any of these matters could require payments that are not covered by, or exceed the limits of, our available directors' and officers' liability insurance, which could have a material adverse effect on our operating results or financial condition.

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

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

***We are subject to potential product liability.***

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

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

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

In 2007, we purchased Ester Neurosciences Limited, an Israeli pharmaceutical company, and its lead product candidate, EN101, an AChE-R mRNA inhibitor for the treatment of myasthenia gravis, or MG, a debilitating neuromuscular disease. In connection with the acquisition, we assumed a license to certain intellectual property assets related to EN101 from the Yisum Research Development Company of The Hebrew University of Jerusalem. In keeping with our 2009 decision to re-focus our efforts on developing improved treatments for cardiovascular disease and cease development of all product candidates outside of our cardiovascular disease focus, we amended the terms of our acquisition agreement with the original shareholders of Ester.

Following our decision to cease development of EN101, 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.

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

***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 94% and 96% of gross product sales for the three months ended March 31, 2015 and 2014, respectively, and represented 94% and 95% of the gross accounts receivable balance as of March 31, 2015 and 2014, respectively. There can be no guarantee that we will be able to sustain our accounts receivable or gross sales levels from our key customers. If, for any reason, we were to lose, or experience a decrease in the amount of business with our largest customers, whether directly or through our distributor relationships, our financial condition and results of operations could be negatively affected.

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

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

We have not been profitable in any of the last five fiscal years. For the fiscal years ended December 31, 2014, 2013, and 2012, we reported losses of approximately \$56.4 million, \$166.2 million, and \$179.2 million, respectively, and we had an accumulated deficit at December 31, 2014 of \$970.2 million. For the three months ended March 31, 2015 and 2014, we reported losses of approximately \$32.0 million and \$26.0 million, respectively and we had an accumulated deficit as of March 31, 2015 of \$1.0 billion. Substantially all of our operating losses resulted from costs incurred in connection with our research and development programs, from general and administrative costs associated with our operations, costs related to the commercialization of Vascepa, 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

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commercialize Vascepa in the MARINE indication and seek to obtain additional regulatory approval of Vascepa from continuation of the REDUCE-IT cardiovascular outcomes study. Accordingly, our historical financial results reflect a substantially different business from that currently being conducted and from that expected in the future. In addition, we have a limited history of obtaining regulatory approval for, and no demonstrated ability to successfully commercialize, a product candidate. Consequently, any predictions about our future performance may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.

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

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

- the level of demand for Vascepa;
- the extent to which coverage and reimbursement for Vascepa is available from government and health administration authorities, private health insurers, managed care programs and other third-party payers;
- the timing, cost and level of investment in our sales and marketing efforts to support Vascepa sales and the resulting effectiveness of those efforts with our new co-promotion partner, Kowa Pharmaceuticals America, Inc.;
- the timing and ability of Eddingpharm to development and commercialize Vascepa in the China Territory, including obtaining necessary regulatory approvals and establishing marketing channels;
- additional developments regarding our intellectual property portfolio and regulatory exclusivity protections, if any;
- the results of the REDUCE-IT study or post-approval studies for Vascepa;
- outcomes of litigation and other legal proceedings, including the recently initiated lawsuit against the FDA to expand marketing claims for Vascepa, our NCE litigation against the FDA, shareholder litigation, regulatory matters and tax matters; and
- our regulatory dialogue on the REDUCE-IT study.

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

We currently operate with limited resources. We believe that our cash and cash equivalents balance of \$161.2 million at March 31, 2015 will be sufficient to fund our projected operations for at least the next twelve months.

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

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

- revenue generated from the commercial sale of Vascepa in the MARINE 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, Inc., and the cost and timing of securing commercial supply of Vascepa and the timing of entering into any new strategic collaboration with others relating to the commercialization of Vascepa, if at all, and the terms of any such collaboration;
- the continued cost associated with our REDUCE-IT cardiovascular outcomes study;
- continued cost associated with litigation and other legal proceedings, including the recently initiated lawsuit against the FDA to expand marketing claims for Vascepa, our NCE litigation against the FDA, shareholder litigation and patent litigation;
- the time and costs involved in obtaining additional regulatory approvals for Vascepa;
- the extent to which we continue to develop internally, acquire or in-license new products, technologies or businesses; and
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

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

On January 9, 2012, we issued \$150 million in aggregate principal amount of 3.50% exchangeable senior notes due 2032, or the notes. In the event of physical settlement, the notes would initially be exchangeable into a total of 49,214,841 ADS.

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

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

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

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

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

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

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

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

As of May 1, 2015 we had 177,112,556 common shares outstanding including 176,246,652 shares held as ADSs and 865,904 held as common shares (which are not held in the form of ADSs). There is a risk that there may not be sufficient liquidity in the market to accommodate significant increases in selling activity or the sale of a large block of our securities. Our ADSs have historically had limited trading volume, which may also result in volatility. If any of our large investors, such as the participants in our March 2015 private placement, seek to sell substantial amounts of our ADSs, particularly if these sales are in a rapid or disorderly manner, or other investors perceive that these sales could occur, the market price of our ADSs could decrease significantly.

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

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

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

In March 2015, we completed the private placement of American Depositary Shares representing 352,150,790 Series A Preference Shares, each ten (10) of which may be consolidated and redesignated into one (1) ordinary share in the capital of the Company. The consolidation and redesignation of the Series A Preference Shares would result in an additional 35,215,079 ordinary shares outstanding, resulting in substantial dilution to shareholders who held our ordinary shares or ADSs representing such ordinary shares prior to the private placement. Although the Series A Preference Shares do not have voting rights, in general, upon consolidation and redesignation into ordinary shares some of the investors in the private placement could then have significant influence over the outcome of any shareholder vote, including the election of directors and the approval of mergers or other business combination transactions.

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

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***\*If we do not obtain and maintain effectiveness of the registration statement, we will be required to pay certain liquidated damages, which could be material in amount.***

Pursuant to the terms of the March 2015 securities subscription agreement, we have agreed to pay liquidated damages to the investors in the private placement if (a) the resale registration statement we are required to file if (a) the registration statement is not declared effective within 120 days after the closing of the private placement, or (b) after effectiveness and subject to certain specified exceptions, we suspend the use of the registration statement or the registration statement ceases to remain continuously effective as to all the securities for which it is required to be effective. We refer to each of these events as a registration default. Subject to the specified exceptions, for each 30-day period or portion thereof during which a registration default remains uncured, we are obligated to pay liquidated damages to each investor in cash in an amount equal to 1% of the aggregate subscription price paid by each such investor in the private placement, up to a maximum of 8% of such aggregate subscription price. These amounts could be material, and any liquidated damages we are required to pay could have a material adverse effect on our financial condition.

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

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

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

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

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

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

We believe it prudent to assume that we were classified as a PFIC in 2012. We do not believe that we were classified as a PFIC in 2013 or 2014. Our status as a PFIC is subject to change in 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

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excess of a specified amount after such payment; (iii) amend or restate our memorandum and articles of association unless such amendments or restatements do not affect BioPharma's interests under the transaction; (iv) encumber any of the collateral securing our performance under the agreement; and (v) abandon certain patent rights, in each case without the consent of BioPharma.

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

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

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

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

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

Our indebtedness and the related annual debt service requirements may adversely impact our business, operations and financial condition in the future. For example, they could:

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

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

Under the FASB Accounting Standards Codification, or ASC, we are required to separately account for the liability and equity components of the convertible debt instruments (such as the notes) that may be settled entirely or partially in cash upon conversion in a manner that reflects the issuer's economic interest cost. The effect of ASC on the accounting for our outstanding convertible notes may be that the equity component is required to be included in the additional paid-in capital section of stockholders' equity on our 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.

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

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

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

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

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

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

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

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

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

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

- Under English law and our Articles of Association, each shareholder present at a meeting has only one vote unless demand is made for a vote on a poll, in which case each holder gets one vote per share owned. Under U.S. law, each shareholder typically is entitled to one vote per share at all meetings.  
Under English law, it is only on a poll that the number of shares determines the number of votes a holder may cast. You should be aware, however, that the voting rights of ADSs are also governed by the provisions of a deposit agreement with our depository bank.
- Under English law, subject to certain exceptions and disapplications, each shareholder generally has preemptive rights to subscribe on a proportionate basis to any issuance of ordinary shares or rights to subscribe for, or to convert securities into, ordinary shares for cash. Under U.S. law, shareholders generally do not have preemptive rights unless specifically granted in the certificate of incorporation or otherwise.
- Under English law and our Articles of Association, certain matters require the approval of 75% of the shareholders who vote (in person or by proxy) on the relevant resolution (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.

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- 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>
4.1	Form of Series A Preference Share Terms (incorporated herein by reference to Exhibit 4.1 to the Company’s Current Report on Form 8-K filed March 5, 2015, File No. 000-21392)
4.2	Preferred Share Deposit Agreement by and among the Company, Citibank, N.A., as depositary and all holders and beneficial owners of restricted American Depositary Shares issued thereunder (incorporated herein by reference to Exhibit 4.1 to the Company’s Current Report on Form 8-K filed March 30, 2015, File No. 000-21392)
4.3	Form of American Depositary Receipt evidencing restricted American Depositary Shares representing deposited Series A Preference Shares (incorporated herein by reference to Exhibit 4.2 to the Company’s Current Report on Form 8-K filed March 30, 2015, File No. 000-21392)
10.1	Development, Commercialization and Supply Agreement by and between Amarin Pharmaceuticals Ireland Limited, Amarin Pharma, Inc. and Eddingpharm (Asia) Macao Commercial Offshore Limited, dated as of February 26, 2015†

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<u>Exhibit Number</u>	<u>Description</u>
10.2	Securities Subscription Agreement dated March 5, 2015 (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed March 5, 2015, File No. 000-21392)
10.3	Securities Subscription Agreement dated March 30, 2015 (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed March 30, 2015, File No. 000-21392)
31.1	Certification of Chief Executive Officer (Principal Executive Officer) pursuant to Section 302 of Sarbanes-Oxley Act of 2002
31.2	Certification of 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 8, 2015

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.

**DEVELOPMENT, COMMERCIALIZATION AND SUPPLY AGREEMENT**

**DATED AS OF FEBRUARY 26, 2015**

**BY AND AMONG**

**AMARIN PHARMACEUTICALS IRELAND LIMITED AND**

**AMARIN PHARMA, INC.**

**AND**

**EDDINGPHARM (ASIA) MACAO COMMERCIAL OFFSHORE LIMITED**

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.

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## DEVELOPMENT, COMMERCIALIZATION AND SUPPLY AGREEMENT

This Development, Commercialization and Supply Agreement (this “**Agreement**”) is entered into as of the 26th day of February, 2015 (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 200, Bedminster, NJ 07921 (“**Amarin Pharma**”, and collectively with Amarin Ireland, “**Amarin**”), on the one hand, and Eddingpharm (Asia) Macao Commercial Offshore Limited, located at Unit 1505, 15th Floor, AIA Tower, Nos 251A-301, Avenida Comercial De Macau (“**Licensee**”), on the other hand. Amarin and Licensee are sometimes referred to herein individually as a “**Party**” and collectively as the “**Parties**.”

### RECITALS

**WHEREAS**, Amarin Ireland owns certain intellectual property and regulatory rights relating to a drug known as Vascepa® (icosapent ethyl) capsules (the “**Product**” as defined in more detail below);

**WHEREAS**, Amarin Ireland has granted to Amarin Pharma certain rights related the Product;

**WHEREAS**, Licensee has significant experience in the development and commercialization of pharmaceutical products in the Territory; and

**WHEREAS**, Licensee and Amarin desire to establish a collaboration for the further development and commercialization of the Product in the Field in the Territory.

**NOW THEREFORE**, in consideration of the foregoing premises and the mutual promises, covenants and conditions contained in this Agreement, the Parties agree as follows:

### ARTICLE 1 DEFINITIONS

As used in this Agreement, the following initially capitalized terms shall have the meanings set forth in this ARTICLE 1 or as otherwise defined elsewhere in this Agreement:

**1.1 “Accounting Standards”** means generally accepted accounting principles in the United States (GAAP) or the International Financial Reporting Standards (IFRS), as applicable, in each case as consistently applied.

**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 non-covalent 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 “Affiliate”** means, as of the Effective Date or during the Term, as applicable, in relation to a Party, any person, corporation, firm or partnership or other entity, whether *de jure* or *de facto*, that 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 the entity. For the avoidance of doubt, neither of the Parties, or any of their respective Affiliates, shall be deemed to be an “Affiliate” of such other entity.

**1.4 “Amarin Invention”** means an Invention that is Invented solely or jointly with a Third Party, by an employee of Amarin or its Affiliates or a Person under an obligation of assignment to Amarin or its Affiliates. For clarity, “Amarin Invention” shall not include (a) the Amarin Patents or (b) the (i) Amarin Manufacturing Patents or (ii) Amarin Manufacturing Know-How.

**1.5 “Amarin Know-How”** means all Know-How that is (i) Controlled by Amarin (or its Affiliates) as of the Effective Date or at any time during the Term or (ii) an Amarin Invention or Joint Invention, in each case of (i) or (ii) which is necessary for the Development or Commercialization of the Product in the Field in the Territory; provided, however that “Amarin Know-How” shall not include any Amarin Manufacturing Know-How. For clarity, “Amarin Know-How” shall not include (a) the Amarin Patents or (b) the (i) Amarin Manufacturing Patents or (ii) Amarin Manufacturing Know-How.

**1.6 “Amarin Manufacturing Know-How”** means all Know-How that is (i) Controlled by Amarin (or its Affiliates) as of the Effective Date or at any time during the Term or (ii) an Amarin Invention or a Joint Invention, in each case of (i) or (ii) which is necessary for Manufacture of the Product for Commercialization in the Field in the Territory, including any CMC information.

**1.7 “Amarin Manufacturing Patent”** means any Patent that is (i) Controlled by Amarin (or its Affiliates) as of the Effective Date or at any time during the Term or (ii) an Amarin Patent, in each case of (i) or (ii), which is necessary or reasonably useful for the Manufacture of the Product for Commercialization in the Field in the Territory; provided, however, that an “Amarin Manufacturing Patent” shall not include any Amarin Patent.

**1.8 “Amarin Patent”** means any Patent in the Territory that is (i) Controlled by Amarin (or its Affiliates) as of the Effective Date, including the Patents listed in Schedule 1.8, or (ii) that comes under the Control of Amarin during the Term (including a Joint Patent), in each case of (i) or (ii) which is necessary for the Development or Commercialization of the Product in the Field in the Territory; provided, however that “Amarin Patent” shall not include any Amarin Manufacturing Patent.

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**1.9 “Amarin Technology”** means the Amarin Patents and Amarin Know-How.

**1.10 “Anti-Corruption Laws”** means the U.S. Foreign Corrupt Practices Act, as amended, the UK Bribery Act 2010, as amended, anti-corruption legislation of the PRC, including the PRC Anti-Unfair Competition Law, the Interim Provisions on Prohibition of Commercial Bribery adopted by the State Administration of Industry and Commerce, and Articles 164, 389, 391, 392 and 393 of the PRC Criminal Law and their respective People’s Procuratorate, other provincial, municipal or local anti-corruption legislation or regulations of the PRC, and any similar anti-corruption-related Applicable Laws adopted in Hong Kong, Macau or Taiwan, as well as Applicable Laws related to the prevention of fraud, racketeering, money laundering or terrorism.

**1.11 “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.

**1.12 “Bulk Product”** means the finished form of the Product, encapsulated and packaged in labeled bulk cartons ready for Packaging and Labeling.

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

**1.14 “Calendar Quarter”** means each successive period of three (3) calendar months commencing on January 1, April 1, July 1 and October 1; provided, that (a) the first Calendar Quarter hereunder shall be deemed to commence upon the Effective Date and (b) the final Calendar Quarter hereunder shall be deemed to expire upon the effective date of expiration or termination of this Agreement.

**1.15 “Calendar Year”** means (a) for the first calendar year, the period commencing on the Effective Date and ending on December 31, 2015, (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.

**1.16 “Cardiovascular Risk Reduction”** means [\*\*\*]

**1.17 “CFDA”** means the China Food and Drug Administration or its predecessor or successor.

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**1.18 “Change of Control”** means (a) a transaction or series of related transactions that results in the sale or other disposition of all or substantially all of Amarin’s assets; or (b) a merger or consolidation in which Amarin is not the surviving corporation or in which, if Amarin is the surviving corporation, the shareholders of Amarin immediately prior to the consummation of such merger or consolidation do not, immediately after consummation of such merger or consolidation, possess a majority of the voting power of all of Amarin’s outstanding stock and other securities and the power to elect a majority of the members of Amarin’s board of directors; or (c) a transaction or series of related transactions (which may include without limitation a tender offer for Amarin’s stock or the issuance, sale or exchange of Amarin’s stock) if the shareholders of Amarin immediately prior to the initialization of such transaction do not, immediately after consummation of such transaction or any of such related transactions, own stock or other securities of the entity that possess a majority of the voting power of Amarin’s outstanding stock and other securities and the power to elect a majority of the members of Amarin’s board of directors.

**1.19 “Commercialize”, “Commercializing” or “Commercialization”** means all activities directed to the marketing, promotion, selling or offering for sale of a Product for an indication, including planning, market research, Pre-Marketing, advertising, educating, marketing, promoting, importing, exporting, distributing and post-marketing safety surveillance and reporting. For clarity, “Commercialization” shall not include any activities related to clinical research, Manufacturing or Development of the Product.

**1.20 “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, [\*\*\*].

**1.21 “Competing Product”** means (other than the Product) any pharmaceutical product, dietary supplement, health food or medical food with (i) 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, in each case, whether or not targeted or used off-label to treat adult patients with moderately high, high or very high triglyceride levels, (ii) targeted to treat adult patients with moderately high, high or very high triglyceride levels, or (iii) that are recognized by key opinion leaders in the industry mutually selected by the Parties or in accepted medical guidelines as being an alternate treatment to the Product. [\*\*\*]

**1.22 “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.

**1.23 “Cost of Goods”** means, for Finished Product, Bulk Product or placebo, as applicable, manufactured by Amarin or a Third Party, [\*\*\*]

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**1.24 “Cover(ed)”** means, with respect to any Patent and the subject matter at issue, that, but for a license granted under a Valid Claim of such Patent, the manufacture, development, use, sale, offer for sale or importation of the subject matter at issue would infringe such Valid Claim, or in the case of a Patent that is a patent application, would infringe a Valid Claim in such patent application if it were to issue as a patent.

**1.25 “CTA”** means an application to the applicable Regulatory Authority, such as a clinical trial application or a clinical trial exemption, the filing of which is necessary to commence or conduct clinical testing of a pharmaceutical product in humans in such jurisdiction.

**1.26 “Develop”, “Developing” or “Development”** means all activities relating to research, non-clinical, preclinical and clinical trials, toxicology testing, statistical analysis and reporting, necessary or reasonably useful or otherwise requested or required by a Regulatory Authority as a condition or in support of obtaining or maintaining all Regulatory Approvals, including Phase IV Clinical Trials and other post-Regulatory Approval studies that are required to obtain or maintain Regulatory Approval. For clarity, “Development” shall exclude any activities related to Commercialization or Manufacture.

**1.27 “Development Activities”** means those Development activities undertaken by or on behalf of a Party or its Affiliates with respect to the Product in the Field.

**1.28 “Development Costs”** means the costs and expenses incurred by a Party or its Affiliates attributable to, or reasonably allocable to, the Development of the Product in the Field, including costs of conducting clinical trials and Phase IV Clinical Trials (as well as other post-Regulatory Approval studies (including physician-initiated studies)). “Development Costs” shall include (i) Out-of-Pocket Costs and (ii) internal costs (*e.g.*, staff or administrative) that are attributable to, or reasonably allocable to, the Development of the Product in the Field. For clarity, Development Costs shall exclude Regulatory Costs.

**1.29 “Dollar”** means a U.S. dollar, and “\$” shall be interpreted accordingly.

**1.30 “Drug Administration Law”** means the laws, rules and regulation applicable to drug administration in the Territory, as amended from time to time.

**1.31 “Drug Substance”** means icosapent ethyl.

**1.32 “Drug Substance Specifications”** means those Manufacturing, performance and quality-control specifications for the Drug Substance in the Territory, which are initially as set shall be set forth in a schedule to the Quality Agreement, as such specifications may be amended from time to time pursuant to the terms of this Agreement and the Quality Agreement.

**1.33 “Facility”** means, as applicable, a Party’s Manufacturing facility and such other facilities used by such Party (or those of its Affiliates or Third Party contractors) in the manufacture, packaging, labeling or storage of (i) Finished Product, (ii) Bulk Product, (iii) Drug Substance or (iv) materials utilized in the Manufacture or Packaging and Labeling of Product,

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Bulk Product or Drug Substance, including raw materials, auxiliary materials, intermediates, containers and packing materials, in each case with respect to the Product for Development or Commercialization in the Field in the Territory hereunder.

**1.34 “FDA”** means the U.S. Food and Drug Administration or its successor.

**1.35 “FD&C 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.

**1.36 “Field”** means (a) all human therapeutic applications, and (b) to the extent approved by the applicable Regulatory Authority in the U.S. for sale by Amarin and sold by Amarin or on behalf of Amarin by its Affiliates, licensees or subcontractors in the U.S., [\*\*\*]

**1.37 “Finished Product”** means the Bulk Product in full Packaging and Labeling and final presentation form ready for release to end-users.

**1.38 “First Commercial Sale”** means, with respect to a Product, the first sale of such Product in the Territory by or on behalf of Licensee or its Affiliates to a Third Party (including wholesalers or distributors), after receipt of Regulatory Approval for such Product in the Territory.

**1.39 “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, cyber attacks, accidents, strikes or other labor disputes, unforeseen material shortages or supplier failures, compliance with any government action 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.

**1.40 “General Development Activities”** means all Development Activities other than Territory Development Activities.

**1.41 “Good Clinical Practices”** or **“GCP”** means all applicable Good Clinical Practice standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials, including, as applicable, (i) those standards required by the CFDA, (ii) as set forth in the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (“**ICH**”) Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) and any other guidelines for good clinical practice for trials on medicinal products in the Territory, (iii) the Declaration of Helsinki (2004) as last amended at the 52nd World Medical Association in October 2000 and any further amendments or clarifications thereto, (iv) U.S. Code of Federal Regulations Title 21, Parts 50 (Protection of Human Subjects), 56 (Institutional Review Boards) and 312 (Investigational New Drug Application), as may be amended from time to time, and (v) the equivalent Applicable Laws in any relevant country, each as may be amended and applicable from time to time and in each case, that provide for, among other things, assurance that the clinical data and reported results are credible and accurate and protect the rights, integrity, and confidentiality of trial subjects.

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**1.42 “Good Laboratory Practices” or “GLP”** means all applicable Good Laboratory Practice standards, including, as applicable, (i) those standards required by the CFDA, (ii) as set forth in the then-current good laboratory practice standards promulgated or endorsed by the FDA as defined in 21 C.F.R. Part 58, and (iii) the equivalent Applicable Laws in any relevant country, each as may be amended and applicable from time to time.

**1.43 “Good Manufacturing Practices” or “GMP”** means all applicable Good Manufacturing Practices including, as applicable, (i) those standards required by the CFDA, (ii) the principles detailed in the U.S. Current Good Manufacturing Practices, 21 C.F.R. Sections 210, 211, 601 and 610, (iii) the principles detailed in the ICH Q7 guidelines, and (iv) the equivalent Applicable Laws in any relevant country, each as may be amended and applicable from time to time.

**1.44 “Government Official”** means (a) any elected or appointed government official (e.g., a member of a ministry of health), (b) any employee or person acting for or on behalf of a government official, agency, or enterprise performing a governmental function, (c) any political party, candidate for public office, officer, employee, or person acting for or on behalf of a political party or candidate for public office, and (d) any employee or person acting for or on behalf of a public international organization (e.g., the United Nations). For clarity, healthcare providers employed by government-owned hospitals shall be considered Government Officials.

**1.45 “Governmental Authority”** means any multinational, federal, state, local, municipal or other governmental authority of any nature (including any governmental division, prefecture, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal), in each case, having jurisdiction over the applicable subject matter.

**1.46 “High Triglyceride” or “HTG”** means the treatment of adult patients with high triglycerides (TG >200 but <500 mg/dL) [\*\*\*].

**1.47 “Imported Drug License” or “IDL”** means a drug marketing permit issued by CFDA to designate the approval to market imported drug product in China.

**1.48 “Indirect Taxes”** means VAT, sales taxes, consumption taxes and other similar taxes required by law to be disclosed on the invoice.

**1.49 “Invented”** means the acts of (an) inventor(s), as determined in accordance with Applicable Laws relating to inventorship set forth in the patent Applicable Laws of the United States (Title 35, United States Code), in discovering, conceiving and completing an Invention.

**1.50 “Invention”** means any writing, invention, discovery, improvement, technology or other Know-How (in each case, whether patented or not) that is not existing as of the Effective Date and is Invented in the performance of this Agreement during the Term and necessary for the Development and Commercialization of the Product in the Field in the Territory.

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**1.51 “Joint Development Committee” or “JDC”** means the joint steering committee formed by the Parties as described in Section 3.1.

**1.52 “Joint Invention”** means an Invention that is Invented jointly by an employee of, or Person under an obligation of assignment to, each of Amarin and Licensee or their respective Affiliates.

**1.53 “Know-How”** 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, strategies, plans, programs and data.

**1.54 “Licensee Invention”** means an Invention that is Invented, solely or jointly with a Third Party, by an employee of Licensee or its Affiliates or a Person under an obligation of assignment to Licensee or its Affiliates.

**1.55 “Licensee Know-How”** means all Know-How that is (i) (a) Controlled by Licensee (or its Affiliates) as of the Effective Date or comes under the Control of Licensee (or its Affiliates) during the Term (other than as a result of the licenses granted by Amarin to Licensee under this Agreement) and (b) incorporated by Licensee in any Product prior to any termination or expiration of this Agreement (provided, however, that such Know-How is necessary or reasonably useful for the Development, Manufacture or Commercialization of any Product) or (ii) a Licensee Invention.

**1.56 “Licensee Patent”** means any Patent that (a) is Controlled by Licensee (or its Affiliates) as of the Effective Date or comes under the Control of Licensee (or its Affiliates) during the Term (other than as a result of the licenses granted by Amarin to Licensee under this Agreement) and (b) that claims any Licensee Know-How.

**1.57 “Licensee Technology”** means the Licensee Know-How and the Licensee Patents.

**1.58 “Manufacture” or “Manufacturing”** means all activities related to the manufacturing of the Bulk Product, the Finished Product, Drug Substance, or any ingredient thereof, including manufacturing for clinical use or commercial sale, in-process and Bulk Product, Finished Product or Drug Substance testing, quality assurance and quality control required for release of the Bulk Product and the Finished Product in the Field in the U.S., handling and storage of Bulk Product, Finished Product or Drug Substance and ongoing stability tests and regulatory activities related to any of the foregoing; provided, however, that for purposes of clarity “Manufacture” shall exclude (i) Packaging and Labeling (whether in commercial or clinical packaging presentation), and (ii) Territory-Specific Analytical Release Testing.

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**1.59 “Medical Science Liaison”** means an individual who is employed by or on behalf of Licensee or its Affiliates and who provides educational services and other educational efforts directed towards the medical and/or scientific community.

**1.60 “Net Sales”** means [\*\*\*]

- (a) [\*\*\*]
- (b) [\*\*\*]
- (c) [\*\*\*]
- (d) [\*\*\*]
- (e) [\*\*\*]
- (f) [\*\*\*]
- (g) [\*\*\*]

[\*\*\*]

[\*\*\*]

**1.61 “Out-of-Pocket Costs”** means costs and expenses paid to Third Parties (or payable to Third Parties and accrued in accordance with the Accounting Standards), other than Affiliates or employees, by either Party.

**1.62 “Patents”** means patents and patent applications and all substitutions, divisions, continuations, continuations-in-part, any patent issued with respect to any such patent applications, any reissue, reexamination, utility models or designs, renewal or extension (including any supplementary protection certificate) of any such patent, and any confirmation patent or registration patent or patent of addition based on any such patent, and all counterparts thereof in any country.

**1.63 “Patent Term Extension”** means any term extensions, supplementary protection certificates and equivalents thereof offering Patent protection beyond the initial term with respect to any issued Patents.

**1.64 “Person”** means any corporation, limited or general partnership, limited liability company, joint venture, trust, unincorporated association, governmental body, authority, bureau or agency, any other entity or body, or an individual.

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**1.65 “Phase IV Clinical Trials”** means certain post-marketing studies to delineate additional information about a pharmaceutical product’s risks, benefits, and optimal use, commenced after receipt of regulatory approval for a product in the indication for which such trial is being conducted.

**1.66 “PRC” or “China”** means the People’s Republic of China (for the purpose of this Agreement, excluding Hong Kong, Macau and Taiwan).

**1.67 “Pre-Marketing”** means marketing activities undertaken prior to and in preparation for the launch of the Product in the Territory. Pre-Marketing shall include market research, key opinion leader development, advisory boards, medical education, disease-related public relations, health care economic studies, sales force training and other pre-launch activities prior to the First Commercial Sale of the Product in the Territory.

**1.68 “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 competent Governmental Authority for sale in the United States and sold under either the Vascepa® trademark or another trademark Controlled by Amarin, or outside the United States and outside the Territory by or under license from Amarin, or as permitted under this Agreement to be approved and sold in the Field in the Territory. [\*\*\*]

**1.69 “Product Approval”** means the approval of a Governmental Authority necessary for the marketing and sale of the Product in a given country or regulatory jurisdiction, which may include the approval of an IDL, but which shall exclude any pricing or reimbursement approvals.

**1.70 “Product Complaint”** means any written, verbal or electronic expression of dissatisfaction regarding any Product sold by or on behalf of Licensee (or any of its Affiliates or wholesalers) in the Territory, including reports of actual or suspected product tampering, contamination, mislabeling or inclusion of improper ingredients.

**1.71 “Product Specifications”** means those Manufacturing, performance, quality-control, and Packaging and Labeling specifications for the Finished Product or Bulk Product, as applicable, in the Territory set forth in a schedule to the Quality Agreement, as such specifications may be amended from time to time pursuant to the terms of this Agreement and the Quality Agreement.

**1.72 “Promotional Materials”** means all written, printed, video or graphic advertising, promotional, educational and communication materials (other than the Product labels and package inserts) for marketing, advertising and promoting of the Product in the Field in the Territory, for use (i) by a Sales Representative, Medical Science Liaison, or other authorized employee or agent of Licensee, (ii) by a wholesaler, or (iii) in advertisements, web sites or direct mail pieces.

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**1.73 “Quality Agreement”** means each of the quality agreements between Licensee and Amarin relating to the Product for clinical and Commercial uses.

**1.74 “Regulatory Approvals”** 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 or reimbursement approvals.

**1.75 “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, in the Territory, the CFDA.

**1.76 “Regulatory Costs”** means the costs and expenses incurred by Licensee or its Affiliates attributable to, or reasonably allocable to, the preparation, obtaining or maintaining of Regulatory Materials and Regulatory Approvals for the Product (other than Manufacturing-related Regulatory Approvals), including any filing fees and such costs and expenses incurred by Amarin or its Affiliates to the extent requested by Licensee or required by this Agreement. “Regulatory Costs” shall include (i) Out-of-Pocket Costs and (ii) internal costs (*e.g.*, staff or administrative) that are specifically attributable to the preparation of Regulatory Materials, and obtaining or maintenance of Regulatory Approvals, for the Product in the Field in the Territory.

**1.77 “Regulatory Data”** means any and all research data, pharmacology data, chemistry, manufacturing and control data, preclinical data, clinical data and all other documentation submitted, or required to be submitted, to Regulatory Authorities in association with regulatory filings for the Product (including any applicable Drug Master Files (“DMFs”), Chemistry, Manufacturing and Control (“CMC”) data, or similar documentation).

**1.78 “Regulatory Materials”** means regulatory applications, submissions, notifications, communications, correspondence, registrations, Regulatory Approvals and/or other filings made to, received from or otherwise conducted with a Regulatory Authority that are necessary in order to Develop, Manufacture, obtain marketing authorization, market, sell or otherwise Commercialize the Product in a particular country or regulatory jurisdiction. Regulatory Materials include CTAs, Import Drug Licenses (“IDLs”), presentations, responses, and applications for other Product Approvals.

**1.79 “Royalty Term”** means, on a Product-by-Product basis in the Territory, the period of time beginning on the First Commercial Sale of such Product and ending upon the later of: (i) the date on which such Product (including, the use, sale, offer for sale, importation, development or manufacturing thereof) is no longer Covered by a Valid Claim, or (ii) the twelfth (12<sup>th</sup>) anniversary of the First Commercial Sale of such Product in the PRC.

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**1.80 “Sales Representative”** means an individual employed by Licensee 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 such 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.

**1.81 “Sublicense Income”** means any and all fees, or payments, of any kind or nature received by Licensee in consideration for, on account of, or in connection with, granting a Third Party (other than a contract sales organization) a sublicense under the Amarin Technology, including license fees (including upfront) and milestone payments (including development- or commercialization-related); provided, that, for clarity, Sublicense Income shall not include any payments made to Licensee solely on account of sales of the Product associated with such sublicense, which sales shall be considered Net Sales and subject to the Royalty Payments hereunder (for clarity, such excluded sales are solely for Royalty Payments purposes and any payments received by Licensee in connection with a Sublicensee achieving a commercialization/annual Net Sales type milestone shall be considered Sublicense Income).

**1.82 “Territory”** means the PRC, Hong Kong, Macau and Taiwan.

**1.83 “Territory Development Activities”** means those Development Activities consistent with the Development Plan that are (i) necessary solely for obtaining or maintaining Regulatory Approval for the Product in the Field in the Territory and (ii) post-Regulatory Approval-filing date Development Activities for the Product in the Field in the Territory. Notwithstanding the foregoing, in the event that Licensee requests that Amarin perform certain Development Activities, within the Territory, which are not necessary solely for obtaining Regulatory Approval in the Territory, and Amarin agrees at its sole discretion to perform such activities within the Territory, then such activities as are conducted in the Territory shall be deemed Territory Development Activities.

**1.84 “Territory-Specific Analytical Release Testing”** means all activities associated with carrying out the analytical testing and release of the Product which is necessary for delivery of the Product for Development or sale in the Field in the Territory, but which is not necessary for delivery of the Product for Development or sale in the Field in the U.S. Such activities shall include: transferring test methods, developing and validating new analytical tests required in the Territory, amending the release specifications to be in compliance with local Applicable Laws in the Territory, conducting the release testing of the Product and final release of the Product (including raw materials, intermediates, drug substance, and drug product). [\*\*\*]

**1.85 “Third Party”** means any Person other than Amarin or Licensee or their respective Affiliates.

**1.86 “U.S.”** means the United States of America and its possessions and territories.

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**1.87 “Valid Claim”** means a claim of an Amarin Patent, a Licensee Patent or a Joint Patent that (i) has not been rejected, revoked or held to be invalid or unenforceable by a court or other authority of competent jurisdiction, from which decision no appeal can be further taken or (ii) has not been finally abandoned, disclaimed or admitted to be invalid or unenforceable through reissue or disclaimer.

**1.88 “Very High Triglyceride” or “VHTG”** means the treatment of adult patients with very high triglycerides (TG >500 mg/dL) [\*\*\*]

**1.89 Interpretation.** Except where expressly stated otherwise in this Agreement, the following rules of interpretation apply to this Agreement: (i) “include”, “includes” and “including” are not limiting; (ii) “hereof”, “hereto”, “herein” and “hereunder” and words of similar import when used in this Agreement refer to this Agreement as a whole and not to any particular provision of this Agreement; (iii) “knowledge” of a Party means the actual knowledge of any officer of such Party involved in the negotiation of this Agreement, without the obligation to perform due inquiry; (iv) words of one gender include the other gender; (v) words using the singular or plural number also include the plural or singular number, respectively; (vi) references to a contract or other agreement mean such contract or other agreement as from time to time amended, modified or supplemented; (vii) references to a Person are also to its permitted successors and assigns; (viii) references to an “Article”, “Section”, “Exhibit” or “Schedule” refer to an Article or Section of, or an Exhibit or Schedule to, this Agreement, unless expressly stated otherwise; and (ix) references to a law include any amendment or modification to such law and any rules and regulations issued thereunder, whether such amendment or modification is made, or issuance of such rules and regulations occurs, before or after the Effective Date.

**1.90 Additional Definitions.** The following terms have the meanings set forth in the corresponding Sections of this Agreement:

<u>Term</u>	<u>Section</u>
“Abandoned Patents”	9.3.3(b)
“Abandoned Joint Inventions”	9.3.3(b)
“Agreement”	Preamble
“Amarin”	Preamble
“Amarin Ireland”	Preamble
“Amarin Pharma”	Preamble
“Bankrupt Party”	14.5
“Breaching Party”	13.2
“CMC”	1.77
“Combination Product”	1.68
“Commercialization Budget”	6.2.3(f)
“Commercialization Data”	6.11
“Commercialization Plan”	6.2.1
“Committee”	3.3
“Compliance Audit”	6.6

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<u>Term</u>	<u>Section</u>
“Confidential Disclosure Agreement”	12.1
“Confidential Information”	12.1
“Controlling Party”	9.4.1(a)
“Defect” or “Defective”	7.9.2(a)
“Development Budget”	4.3.1(c)
“Development Data”	4.6
“Development Plan”	4.3.1
“Disbanding Notice”	3.5
“Disclosing Party”	12.1
“DMFs”	1.77
“Effective Date”	Preamble
“Executive Officer”	15.2
“Financial Audit”	8.10
“Forecast”	7.6.1
“Forecast Date”	7.6.1
“Global Branding Strategy”	6.10
“ICH”	1.41
“IDL”	1.47
“Improvement Plan”	6.5.5
“Indemnitee”	11.3
“Infringement Claim”	9.4.1
“Initial Commercialization Plan”	6.2.1
“Initial Forecast Date”	7.6.1
“Joint Commercialization Committee” or “JCC”	3.2.1
“Joint Patents”	9.1.1
“Latent Defects”	7.9.2(b)
“Licensee”	Preamble
“Licensee Trade Dress”	6.9.1
“Licensee Trademark”	6.9.1
“Long Range Forecast”	7.6.2
“Losses”	11.1
“Manufacturing Certificate of Analysis and Compliance”	7.9.2(a)
“Milestone Notification Notice”	8.2
[***]	[***]
“Notice of Non-Conformance”	7.9.2(a)
“OOS”	7.9.3
“Packaging and Labeling”	7.5
“Party” or “Parties”	Preamble
“Patent Challenge”	9.7
“PRC”	1.66
“Product Trade Dress”	6.9.1

<u>Term</u>	<u>Section</u>
“Product Trademark”	6.9.1
“Provisions”	6.5.4
“Purchase Order”	7.6.3
“Purchase Order Acceptance Date”	7.6.4
“Receiving Party”	12.1
“Recovery”	9.4.2(c)(iv)
“Redacted Agreement”	12.5.2
“Representatives”	6.5.3
“Required Notice Date”	16.5
“Royalty Payments”	8.3.1
“Royalty Rates”	8.3.1
[***]	[***]
“Sublicense Income Payment”	8.3.2
“Sublicensee”	2.1.3
“Supply Price”	7.7.1
“Term”	13.1
“Third Party Claim”	11.1
“Upfront Payment”	8.1
“VAT”	8.5.1

## ARTICLE 2 LICENSES

### 2.1 Grant to Licensee.

**2.1.1 General Grant to Licensee.** Subject to the terms and conditions of this Agreement, Amarin hereby grants to Licensee during the Term an exclusive (even as to Amarin and its Affiliates), payment-bearing license with the right to sublicense solely in accordance with Section 2.1.3, under and with respect to the Amarin Technology, to (i) Develop the Product for Commercialization in the Field in the Territory and (ii) Commercialize the Product in the Field in the Territory.

**2.1.2 Additional Grant to Licensee.** Subject to the terms and conditions of this Agreement, including in particular Section 6.9, Amarin hereby grants to Licensee during the Term an exclusive (even as to Amarin and its Affiliates) license with the right to sublicense solely in accordance Section 2.1.3, to use the Product Trademark and Product Trade Dress solely to the extent necessary to (i) Commercialize the Product in the Field in the Territory and (ii) Package and Label the Product for Development or Commercialization in the Field in the Territory.

**2.1.3 Licensee’s Right to Sublicense.** Licensee shall have the right to sublicense those rights granted to it under Sections 2.1.1 and 2.1.2 to (i) Affiliates, subject to Licensee’s prior written notice to Amarin of the identity of such Affiliate and the purpose of such

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sublicense, and (ii) Third Parties, subject to first obtaining Amarin’s prior written consent (each of (i) and (ii), a “**Sublicensee**”); provided, however, that Licensee shall remain responsible for the performance by any of its Sublicensees and shall cause its Sublicensees to comply with the provisions of this Agreement in connection with such performance. Without limiting the foregoing, Licensee shall ensure that each of its Sublicensees accepts in writing all applicable terms and conditions of this Agreement, [\*\*\*] and shall terminate all relevant agreements with any such Sublicensee in the case of any breach of such terms and conditions by such Sublicensee. Each Sublicensee shall also be prohibited from further sublicensing. For the avoidance of doubt, (a) Licensee will remain directly responsible for all amounts owed to Amarin under this Agreement, and (b) each Sublicensee is subject to the negative covenants set forth in Section 2.5.1. Licensee hereby expressly waives any requirement that Amarin exhaust any right, power or remedy, or proceed against a subcontractor, for any obligation or performance hereunder prior to proceeding directly against Licensee.

**2.1.4 Performance by Affiliates and Subcontractors.** Licensee shall have the right to perform some or all of its obligations under this Agreement through Affiliates and/or Third Party subcontractors in the Territory; provided, however, that Licensee shall cause its Affiliates and subcontractors to accept the terms and conditions of this Agreement in connection with such performance.

## **2.2 Grant to Amarin.**

**2.2.1 General Grant to Amarin.** Subject to the terms and conditions of this Agreement, Licensee hereby grants to Amarin during the Term a non-exclusive, royalty-free license or sublicense, as applicable, with the right to sublicense, under and with respect to the Licensee Technology, to Develop, Manufacture or Commercialize the Product outside the Territory and, subject to Section , in the Territory.

**2.2.2 Additional Grant to Amarin.** Subject to the terms and conditions of this Agreement, Licensee hereby grants to Amarin a non-exclusive, paid-up, irrevocable, perpetual, worldwide license or sublicense, as applicable, with the right to sublicense, under and with respect to the Licensee Technology, to develop (including obtaining and maintaining regulatory approval), make, use, import, export, offer for sale and sell pharmaceutical products containing Drug Substance (other than the Product in the Field in the Territory) for sale anywhere in the world.

**2.2.3 Grants after Expiration or Termination.** Subject to the terms and conditions of this Agreement, Licensee hereby grants to Amarin from and after the expiration or termination of this Agreement (on a Product-by-Product basis) by Amarin pursuant to Section 13.2 or 13.3 or by Licensee pursuant to Section 13.4, a non-exclusive, paid-up, irrevocable, perpetual, license or sublicense, as applicable, with the right to sublicense, under and with respect to the Licensee Technology, to Develop, Manufacture or Commercialize such Product outside the Field (whether inside or outside the Territory) or in the Field (whether inside or outside the Territory) and to develop (including obtaining and maintaining regulatory approval), make, use, import, export, offer for sale and sell pharmaceutical products containing the Drug Substance for sale anywhere in the world.

### 2.3 Additional Licensing Provisions.

**2.3.1 Negative Covenant.** Each Party covenants that it will not use or practice any of the other Party’s Patent rights or other intellectual property rights licensed (or sublicensed, as applicable) to it under this ARTICLE 2 except for the purposes expressly permitted in the applicable license grant.

**2.3.2 No Implied Licenses; Retained Rights.** Except as explicitly set forth in this Agreement, neither Party grants any license, express or implied, under its intellectual property rights to the other Party, whether by implication, estoppel or otherwise.

### 2.4 [\*\*\*]

### 2.5 Restrictive Covenants.

#### 2.5.1 [\*\*\*]

(a) [\*\*\*]

(b) [\*\*\*]

#### 2.5.2 [\*\*\*]

**2.5.3 Jurisdictional Compliance.** It is the desire and intent of the Parties that the restrictive covenants contained in this Section 2.5 be enforced to the fullest extent permissible under the Applicable Laws and public policies applied in each jurisdiction in which enforcement is sought. Amarin and Licensee believe that the restrictive covenants in this Section 2.5 are valid and enforceable. However, if any restrictive covenant should for any reason become or be declared by a competent court or competition authority to be invalid or unenforceable in any jurisdiction, such restrictive covenant shall be deemed to have been amended to the extent necessary in order that such provision be valid and enforceable, such amendment shall apply only with respect to the operation of such provision of this Section 2.5 in the particular jurisdiction in which such declaration is made.

### ARTICLE 3 GOVERNANCE

#### 3.1 Joint Development Committee.

**3.1.1 Establishment and Responsibilities.** The Parties shall establish the JDC within [\*\*\*] after the Effective Date. The JDC shall perform the following functions:

- (a) Review, coordinate, discuss and approve the overall strategy for Developing the Product in the Field in the Territory, including reviewing, coordinating, discussing and approving the overall strategy for seeking Regulatory Approvals for the Product in the Field in the Territory and approving the Development Plan and each annual update and any material amendments thereto;
- (b) Review, coordinate, discuss and approve the design of the clinical trial protocols and endpoints and oversee the conduct of all clinical trials required as set forth in the Development Plan as well as discuss any Territory Development Activities to be conducted with respect to the Product in the Field;
- (c) Review any matters related to obtaining and maintaining Regulatory Approvals for the Product in the Field in the Territory, including being informed of the development and contents of all submissions to Regulatory Authorities in the Territory for Regulatory Approvals and all necessary filing and registration activities related thereto;
- (d) Review, coordinate, discuss and approve any Phase IV Clinical Trials in the Territory, investigator-sponsored studies in the Territory, and any other clinical studies to be conducted in the Territory that are not described in the Development Plan;
- (e) Facilitate the exchange of information between the Parties under this Agreement regarding the strategy for implementing the Development Activities in the Territory, including sharing Development Data created pursuant to this Agreement and establishing procedures for the efficient sharing of information and materials necessary or useful for the Development of the Product in the Field in the Territory;
- (f) Review and oversee issues regarding supply of Product for clinical trials and Phase IV Clinical Trials in the Territory under the Development Plan and for anticipated commercial needs;
- (g) Review and oversee issues regarding pharmacovigilance and safety both inside and outside the Territory; and
- (h) Have such other responsibilities as may be assigned to the JDC pursuant to this Agreement or as may be mutually agreed upon by the Parties in writing from time to time.

**3.1.2 Membership.** The JDC 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 JDC 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 JDC shall be preserving continuity. The JDC shall be co-chaired by a representative of each of Licensee and Amarin. One member of the JDC shall serve as secretary of the JDC at each JDC meeting, and the secretary shall alternate from meeting to meeting

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between a Licensee JDC member and an Amarin JDC member. The chairpersons shall be responsible for (i) calling meetings, (ii) preparing and issuing minutes of each such meeting within [\*\*\*] thereafter, and (iii) preparing and circulating an agenda for the upcoming meeting; provided, that the chairpersons shall consider including any agenda items proposed by either Party no less than [\*\*\*] prior to the next scheduled JDC meeting.

**3.1.3 Meetings.** The JDC shall hold at least [\*\*\*] until pre-launch Territory Development Activities for the Product in the Field in the Territory are completed, and thereafter, if the Parties mutually so decide, [\*\*\*]; provided, that the JDC shall meet more or less frequently as Licensee and Amarin mutually agree upon as appropriate. Meetings of the JDC shall be effective only if at least one (1) representative of each Party is present or participating. The JDC may meet either (i) in person at either Party’s facilities (alternating between the facilities of Licensee and Amarin) or at such locations as the Parties may otherwise agree or (ii) by audio or video teleconference; provided, that no less than [\*\*\*] of the JDC during each [\*\*\*] shall be conducted in person to the extent permissible under Applicable Laws. Other representatives of each Party involved with the Product may attend meetings as non-voting participants, subject to the confidentiality provisions set forth in ARTICLE 12. Additional meetings of the JDC may also be held with the consent of each Party, as required to resolve disputes, disagreements or deadlocks in the other Committees or as otherwise required under this Agreement, and neither Party shall unreasonably withhold its consent to hold such additional meetings.

**3.1.4 Decision-Making.** The JDC may make decisions with respect to any subject matter that is subject to the JDC’s decision-making authority and functions as set forth in Section 3.1. All decisions of the JDC shall be made by unanimous vote or written consent, with Licensee and Amarin each having, collectively, among its respective members, one (1) vote in all decisions. The JDC shall use Commercially Reasonable Efforts to resolve the matters within its roles and functions or otherwise referred to it. If the JDC cannot reach consensus on a given matter, then decision-making authority shall be allocated: (i) to [\*\*\*] to the extent the disagreement relates to Territory Development Activities (provided, however, that, to the extent [\*\*\*] reasonably determines that a given decision of [\*\*\*] with respect to the Territory Development Activities could materially and adversely affect Development and Commercialization of the Product in the Field outside the Territory, then [\*\*\*] shall, upon a prior written notification to [\*\*\*] of the grounds for its decision in reasonable detail, have the final decision making authority with respect to such matter); and (ii) [\*\*\*] with respect to any matter other than a Territory Development Activity-related matter.

### **3.2 Joint Commercialization Committee.**

**3.2.1 Establishment and Responsibilities.** At an appropriate and agreed time following the Effective Date, (but no later than [\*\*\*] prior to anticipated filing for Regulatory Approval in the Territory), the Parties shall establish a joint commercial committee (the “**Joint Commercialization Committee**” or “**JCC**”) to oversee Commercialization of the Product in the Territory, including reviewing and approving the Commercialization Plan (and the Commercialization Budget contained therein) and overseeing the implementation of such plan.

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**3.2.2 Membership.** The JCC shall consist of up to six (6) members (or such other number as may be agreed by the Parties in writing), three (3) of whom shall be representatives designated by Licensee, and three (3) of whom shall be representatives designated by Amarin. Each of Licensee and Amarin may replace any or all of its representatives on the JCC at any time upon written notice to the other Party. Such representatives shall include individuals who have commercial experience and expertise in pharmaceutical drug pre-launch, launch and other commercialization activities. A Party may designate a substitute to temporarily attend and perform the functions of such Party’s designee at any meeting of the JCC. The JCC shall be co-chaired by a representative of each of Licensee and Amarin. One Licensee member of the JCC shall serve as secretary of the JCC at each JCC meeting.

**3.2.3 Meetings.** Following formation, the JCC shall meet at least once every [\*\*\*], and in any case more or less frequently as Licensee and Amarin deem appropriate or as reasonably requested by either such Party, on such dates and at such places and times as the Parties shall agree. The JCC may meet either (i) in person alternating between the offices of Licensee and Amarin, or such other place as the Parties may agree or (ii) by audio or video teleconference. The members of the JCC also may convene or be polled or consulted from time to time by means of telecommunications, video conferences, electronic mail or correspondence, as deemed necessary or appropriate. Licensee and Amarin each may, on advance notice to the other Party, invite non-member employees of such Party to attend meetings of the JCC.

**3.2.4 Decision-Making.** The JCC may make decisions with respect to any subject matter that is subject to their decision-making authority and functions as set forth in Section 3.2. All decisions of the JCC shall be made by unanimous vote or written consent, with Licensee and Amarin each having collectively, among its respective members, one (1) vote in all decisions. If the JCC cannot reach consensus on a given matter, then decision-making authority shall be allocated to [\*\*\*]; provided, however, that, to the extent [\*\*\*] reasonably determines that a given decision of [\*\*\*] could materially and adversely affect Development and Commercialization of Product outside the Territory, then [\*\*\*] shall, upon a prior written notification to [\*\*\*] of the grounds for its decision in reasonable detail, have the final decision making authority with respect to such matter.

**3.3 Committees.** From time to time, the Parties may establish and delegate duties to other committees (each, a “Committee”) to oversee particular matters. Each such Committee shall be constituted and shall operate as the Parties reasonably and mutually determine as reflected in a written agreement between the Parties; provided, that each Committee shall have equal representation from each Party.

**3.4 Limits on Committee Authority.** The JDC, JCC and any other Committee shall have only the powers assigned expressly to it in this ARTICLE 3 and elsewhere in this Agreement, and shall not have any power to amend, modify or waive compliance with this Agreement. In furtherance thereof, each Party shall retain the rights, powers and discretion granted to it under this Agreement and no such rights, powers or discretion shall be delegated or vested in the JDC, JCC and any other Committee unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree in writing. Without

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limiting the generality of the foregoing, the JDC, JCC and any other Committee shall have no decision-making authority with respect to any matters related to (i) approving (or otherwise making decisions with respect to) matters related to obtaining, maintaining or enforcing Patent protection for the Product in the Field in the Territory (which matters shall be governed by ARTICLE 9), (ii) the Development of the Product outside the Field or outside of the Territory, (iii) the Commercialization of the Product outside the Field or outside of the Territory or (iv) the Manufacture of the Product.

**3.5 Disbanding the JDC and JCC.** At any time during the Term, and for any reason, Amarin shall have the right to disband the JDC and JCC (and any Committees existing as of such time) upon written notice to Licensee, which notice shall be effective immediately upon receipt (“**Disbanding Notice**”). Following the issuance of a Disbanding Notice and subject to this Section 3.5, (i) the JDC and JCC (and any Committees existing as of such time) shall immediately cease meeting and (ii) all decisions, obligations, rights and responsibilities within the purview of the JDC and JCC (and any Committees existing as of such time) shall henceforth be handled directly between the Parties with each Party maintaining its respective decision making authority in the event of any dispute. If, at any time following the issuance of a Disbanding Notice, Amarin wishes to reestablish the JDC and/or JCC, Amarin shall notify Licensee in writing and, thereafter, the JDC and/or JCC, as applicable, shall be reestablished and function in accordance with the provisions of this ARTICLE 3. For clarity, to the extent that the Development and/or Commercialization of the Product in the Territory are not adversely affected, the disbanding of the JDC and JCC (and any Committees existing as of such time) by Amarin under this Section 3.5 shall have no impact on the consideration provided for or due to Amarin under this Agreement.

**3.6 Actions.** In developing strategies, making decisions and exercising its rights under this Agreement (including acting through its representatives on any of the Committees), each Party shall act in good faith.

**3.7 Exchange of Information.** Licensee shall keep Amarin fully and promptly informed as to its progress and activities in material aspects relating to the Development and Commercialization of the Product in the Territory, including with respect to regulatory matters and meetings with Regulatory Authorities, by way of updates to appropriate Committees at their meetings or directly in writing in English in the event that the Committees are disbanded and as otherwise specified in this Agreement, or as reasonably requested from time to time by Amarin. In connection therewith, Licensee shall provide Amarin with such information regarding such progress and activities under the Development Plan or the Commercialization Plan, or otherwise relating to the Product, as Amarin may reasonably request from time to time.

**3.8 Minutes of Committee Meetings.** Definitive minutes of all Committee meetings shall be finalized no later than [\*\*\*] after each meeting. The minutes shall be approved by each Party not later than the first order of business at the immediately succeeding Committee meeting.

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**3.9 Expenses.** Each Party shall be responsible for all of its own expenses incurred in connection with participating in the JDC or JCC meetings or any of the other Committee meetings.

## **ARTICLE 4 DEVELOPMENT**

### **4.1 Overview.**

**4.1.1 Overview of Development.** Subject to the terms and conditions of this Agreement, Licensee shall conduct, in accordance with the Development Plan, the Territory Development Activities, including bridging studies, clinical studies, Phase IV Clinical Studies (and other post-Regulatory Approval studies). Licensee shall perform the Territory Development Activities (with the necessary assistance of Amarin to the extent such assistance is required by Applicable Laws in the Territory) so as to (i) enable obtaining Regulatory Approval in the Territory for Product in the Field and (ii) maximize the commercial potential for Product in the Field in the Territory.

**4.1.2 General Development Activities and Development Outside the Territory or Outside the Field; Regulatory Approvals Outside the Territory or Outside the Field.** The Parties hereby agree and acknowledge that nothing contained herein shall limit or otherwise restrict the ability of Amarin or its other licensees or sublicensees, as applicable, to (i) perform the General Development Activities as it sees fit and at its sole discretion, (ii) Develop the Product for use or sale outside the Territory (whether or not in the Field) and (iii) obtain or maintain Regulatory Approvals for the Product outside the Territory (whether or not in the Field). Without limiting the generality of the foregoing, the Development Plan shall not address (a) any General Development Activities, (b) any activities which are necessary solely for obtaining or maintaining Regulatory Approval for the Product in any country outside the Territory or (c) obtaining or maintaining Regulatory Approvals for the Product outside the Territory.

**4.1.3 Manufacturing Related Activities.** The Parties shall agree as to the allocation of responsibility with respect to the performance of the developmental aspects of Territory-Specific Analytical Release Testing; provided, that, for clarity, Licensee shall be solely responsible for any costs incurred by Licensee or Amarin in performing Territory-Specific Analytical Release Testing.

**4.1.4 Certain Additional Restrictions.** Licensee agrees and acknowledges that it and its Affiliates shall not conduct any Development of the Product except in accordance with the Development Plan established pursuant to this Agreement.

## 4.2 Objectives Under the Development Plan.

### 4.2.1 Development Activities.

(a) Licensee shall use Commercially Reasonable Efforts to carry out the Territory Development Activities set forth in the Development Plan in accordance with the time frames set forth therein and in a manner designed to achieve successful Development and Regulatory Approval for the VHTG indication in the Territory.

(b) Licensee shall use Commercially Reasonable Efforts to carry out the Territory Development Activities set forth in the Development Plan in accordance with the time frames set forth therein and in a manner designed to achieve successful Development and Regulatory Approval for [\*\*\*] in the Territory to the extent that (a) the competent Governmental Authorities have approved the Product in such indication for sale outside the Territory or (b) Amarin or its Affiliates or any of their respective licensees are Developing the Product for such indication outside the Territory.

**4.2.2 Specific Development Diligence.** [\*\*\*], Licensee shall (i) assuming the Regulatory Materials to be provided by Amarin hereunder are sufficient for submitting a CTA in the PRC, submit a CTA in the PRC [\*\*\*], (ii) subject to Amarin’s timely supply of required quantities of clinical samples and placebo, initiate clinical testing in the PRC within [\*\*\*] after obtaining CTA approval therefor, and (iii) file for IDL approval within [\*\*\*] after finalizing clinical testing in the PRC. [\*\*\*] the Parties shall meet with key opinion leaders, contract research organizations and other experts in such indication in order to generate a Development Plan [\*\*\*]

**4.2.3 Compliance.** Licensee shall conduct its Development Activities in accordance with sound and ethical business and scientific practices, and in compliance with all Applicable Laws, GCPs and GLPs. In addition, Licensee shall not use in any capacity, in connection with its Development (or Commercialization) of Product hereunder, any Person who has been debarred pursuant to Section 306 of the FD&C Act (or similar Applicable Laws outside of the U.S.), or who is the subject of a conviction described in such section, and Licensee shall inform Amarin in writing immediately if it or any Person who is performing services for Licensee hereunder is debarred or is the subject of a conviction described in Section 306 (or similar Applicable Laws outside of the U.S.), or if any action, suit, claim, investigation or legal administrative proceeding is pending or, to Licensee’s knowledge, is threatened, relating to the debarment of Licensee or any Person used in any capacity by Licensee in connection with its Development (or Commercialization) of Product hereunder.

## 4.3 Development Plan and Development Budget.

**4.3.1 General.** In connection with the Development of the Product for use in the Field in the Territory, Licensee shall conduct Territory Development Activities, if any, pursuant to a comprehensive development plan (the “**Development Plan**”). The Development Plan shall set forth, among other things, the following:

(a) any preclinical studies, toxicology studies, pharmaco-economic studies, and other clinical studies (including Phase IV Clinical Trials) necessary for obtaining and maintaining Regulatory Approval in the Territory, in each case, together with all protocols, endpoints and primary investigators conducting such studies, with respect to the Product in the Field in the Territory, including:

(i) for the VHTG indication, a timeline for commencement and completion of clinical trials;

(ii) for each of the HTG and Cardiovascular Risk Reduction indications in the Territory [\*\*\*] and

(iii) [\*\*\*]

(b) all regulatory plans and other elements of obtaining and maintaining Regulatory Approvals in the Field in the Territory, including the plans and timeline for preparing the necessary Regulatory Materials and for obtaining Regulatory Approval in the Field in the Territory;

(c) a detailed annual budget for all Development Costs and Regulatory Costs for the activities in the applicable Development Plan (the “**Development Budget**”); and

(d) summary plans and timeline for Territory-Specific Analytical Release Testing.

**4.3.2 Initial Development Plan.** The initial Development Plan for the Product is set forth as Schedule 4.3.2. To the extent that future “national meetings” with the Regulatory Authorities in the Territory provide guidance with respect to the risk management plan or Territory Development Activities, the Parties shall consider such guidance in updating and amending the Development Plan pursuant to Section 4.3.3.

**4.3.3 Updating and Amending Development Plan and Development Budget; Additional Development Activities.** [\*\*\*] during the Term, the JDC shall review, update and approve amendments to the Development Plan (including the Development Budget contained therein) which shall cover the Territory Development Activities to be conducted during the upcoming Calendar Year, and the JDC shall, on at least a [\*\*\*] basis, review and update, as appropriate, the then-current Development Plan (including the Development Budget) to reflect any material changes, reprioritizations of, or additions to the Development Plan. Notwithstanding the foregoing, from time to time during the Term, either Party may submit to the JDC any proposed expansion or other material amendment of the Development Plan to cover additional Territory Development Activities (or otherwise amend the Territory Development Activities) with respect to the Product for use in the Field in the Territory for the JDC’s review and approval. Once approved by the JDC, each amended Development Plan (including the Development Budget contained therein) shall become effective and supersede the previous Development Plan and Development Budget as of the date of such approval or at such other time as decided by the JDC.

#### **4.4 Development Costs.**

**4.4.1 Territory Development Activities.** Licensee shall be solely responsible for one hundred percent (100%) of all Development Costs incurred by: (i) Licensee; or (ii) to the extent approved by the JDC or included in a Development Plan and Development Budget, Amarin (except to the extent as described in the next sentence), with respect to any Territory Development Activities (including, for clarity, any given Development Activities which are deemed Territory Development Activities in accordance with Section 1.83). To the extent reasonably requested by Licensee, Amarin shall provide assistance [\*\*\*] in connection with the preparation and filing of the CTA application for the VHTG indication. In addition, in each Calendar Year, to the extent reasonably requested by Licensee, Amarin shall provide [\*\*\*] for the performance or implementation of Territory Development Activities necessary for Regulatory Approval of the Product in the Territory. However, any Out-of-Pocket Costs incurred by Amarin in performing or implementing such assistance, or the internal costs for any assistance by Amarin in excess of [\*\*\*], shall be borne by Licensee, and Amarin shall invoice Licensee for such Development Costs it incurs in connection with performing such Territory Development Activities, which invoices Licensee shall pay within [\*\*\*] of receipt thereof. Notwithstanding the foregoing, Product and placebo required for the purpose of performing one or more clinical trials (i.e., clinical trial material) for the VHTG indication in the Territory will be provided by Amarin [\*\*\*] to Licensee [\*\*\*] in the aggregate (and Product or placebo required in excess of such number of subjects or for other Territory Development Activities shall be supplied to Licensee at Licensee’s sole cost and expense in accordance with Article 7). For clarity, Licensee shall be responsible for all freight, shipping, handling, imported tax and duties, clinical packaging and labeling, distribution and returns associated with any such Product.

**4.4.2 Territory-Specific Analytical Release Testing.** Licensee shall be solely responsible for one hundred percent (100%) of all Development Costs incurred by Licensee or Amarin (to the extent as described in the next sentence) with respect to any Territory-Specific Analytical Release Testing. Amarin shall invoice Licensee for Development Costs it incurs in connection with performing Territory-Specific Analytical Release Testing, which invoices Licensee shall pay within [\*\*\*] of receipt thereof.

**4.4.3 General Development Activities.** Amarin shall be responsible for one hundred percent (100%) of all Development Costs incurred by Amarin with respect to any General Development Activities.

#### **4.5 Records, Reports and Information.**

**4.5.1 General.** Licensee shall, and shall cause each of its Affiliates and permitted Third Party subcontractors to, maintain current and accurate records of all work conducted by it under the Development Plan and all data and other information resulting from such work (which records shall include, as applicable, books, records, reports, research notes, charts, graphs, comments, computations, analyses, recordings, photographs, computer programs and documentation thereof (e.g., samples of materials and other graphic or written data generated in connection with the Development Activities)). Such records shall properly reflect all work done and results achieved in the performance of the Development Activities in sufficient detail and in good scientific manner appropriate for regulatory and patent purposes. Licensee shall

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document all preclinical studies and clinical trials to be conducted pursuant to the Development Plan in formal written study reports according to applicable national and international (*e.g.*, ICH, GCP and GLP) guidelines. Amarin shall be given an adequate opportunity, in any event not less than [\*\*\*], to comment on and approve the drafts of reports resulting from Territory Development Activities conducted under the Development Plan.

**4.5.2 Status Updates.** Licensee shall provide the JDC with reports detailing its respective Territory Development Activities and the results thereof at least [\*\*\*] prior to any JDC meeting, but in any event, on at least a Calendar Quarter basis. Without limiting the foregoing, Licensee shall promptly, but in any event within [\*\*\*] after receipt thereof, provide to Amarin copies of any material documents or correspondence received from any Regulatory Authority related to Territory Development Activities.

**4.5.3 Access to Records.** Amarin shall have the right to review all records under the Development Plan maintained by Licensee at reasonable times, upon written request.

**4.6 Ownership and Transfer of Development Data.** All data (including pre-clinical, clinical, technical, chemical, safety, and scientific data and information), know-how and other results generated by or resulting from or in connection with the conduct of Development Activities, including relevant laboratory notebook information, screening data, Regulatory Data and synthesis schemes, including descriptions in any form, data and other information (collectively, the “**Development Data**”), shall be owned solely and exclusively by the Party generating such data which shall be Confidential Information of such Party (and each Party shall require that all of its Affiliates and subcontractors assign any of such Affiliates’ and subcontractors’ right, title and interest in and to such Development Data to such Party). With respect to Development Data generated by a Party hereunder, such Party shall promptly provide the other Party with copies of reports and, if available, summaries thereof, in each case as such reports and summaries become available to such Party.

**4.7 Right to Audit.** Licensee shall ensure that Amarin’s authorized representatives and any Regulatory Authorities, to the extent permitted by Applicable Laws, may, during regular business hours and upon reasonable advance written notice, (i) examine and inspect its facilities or, subject to any Third Party confidentiality restrictions and other obligations, the facilities of any subcontractor or any investigator site used by Licensee in the performance of Development of the Product in the Field in the Territory hereunder, and (ii) subject to Applicable Laws and any Third Party confidentiality restrictions and other obligations, inspect all data, documentation and work product to the extent reasonably available to Licensee relating to the activities performed by it, the subcontractor or investigator site, including the medical records of any patient participating in any clinical study, in each case generated pursuant to the said Development. This right to inspect all data, documentation, and work product relating to the Product in the Field in the Territory may be exercised at any time during the Term upon reasonable notice, or such longer period as shall be required by Applicable Laws. The audit rights described in this Section 4.7 are without limitation of other audit rights described elsewhere in this Agreement.

## ARTICLE 5 REGULATORY

### 5.1 Regulatory Data and Regulatory Materials.

**5.1.1 Regulatory Data Generated by Amarin and Licensee.** Within [\*\*\*] after the Effective Date, Amarin and Licensee shall meet and agree upon the portion of Regulatory Materials and Regulatory Data which is in Amarin’s possession and that is necessary for Licensee to perform its obligations hereunder and Amarin shall thereafter use reasonable efforts to supply Licensee with such Regulatory Materials and Regulatory Data. During the Term, Amarin and Licensee shall each promptly provide to the other copies of any further Regulatory Materials and Regulatory Data that either may generate or otherwise acquire. For clarity, Regulatory Materials and Regulatory Data generated or acquired by Amarin’s sublicensees shall be included in such Regulatory Materials and Regulatory Data to be provided by Amarin to Licensee to the extent that such materials are accessible to and Controlled by Amarin.

**5.1.2 Use of Data by Licensee.** Licensee may only use the Regulatory Materials and Regulatory Data, and any other Development Data, provided by Amarin hereunder for the purposes of Developing and Commercializing the Product, and obtaining and maintaining Regulatory Approval for the Product, in the Field in the Territory pursuant to this Agreement. Amarin may use the Regulatory Materials and Regulatory Data, and any other Development Data, provided by Licensee hereunder for the purposes of Development and Commercialization of and obtaining and maintaining Regulatory Approval of the Product (a) outside the Territory (whether in the Field or outside Field) and (b) in accordance with Section , in the Territory.

**5.1.3 Regulatory Materials.** Each Party shall, as soon as reasonably practicable after the same become available, provide the other Party with copies of the core data sheet, approved local prescriber, and patient-directed, labeling that are proposed or approved for the Commercialization and Development of the Product in the Field in the Territory, with respect to Licensee, or outside the Field or outside the Territory, with respect to Amarin.

### 5.2 Regulatory Filings and Regulatory Approvals.

**5.2.1 General Responsibilities; Ownership of Regulatory Approvals.** Subject to Section 5.2.4, Licensee shall be responsible for the preparation of all Regulatory Materials necessary or desirable for obtaining and maintaining the Regulatory Approvals for the Product in the Field in the Territory (including in connection with Patient Information Leaflets, labeling and packaging for the Product in the Field in the Territory) and Licensee shall submit such Regulatory Materials, as applicable, to the applicable Governmental Authorities in the Territory. For clarity, to the extent allowed by Applicable Laws, all Regulatory Approvals for the Product in the Field in the Territory (other than those related solely to the Manufacture of the Bulk Product and Finished Product, if any, which it is agreed shall be held and owned by Amarin) shall be held and owned by Licensee in its name. In the event that the Applicable Law does not allow Licensee to be the holder of certain Regulatory Approval for the Product in the Territory,

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such Regulatory Approval shall be held by Amarin in its name with the intent to provide under this Agreement to Licensee the privileges of ownership of such Regulatory Approvals and related Regulatory Materials. In furtherance of the foregoing, (i) to the extent required by Applicable Laws or a Regulatory Authority (which requirement shall be notified in writing by Licensee to Amarin), at Amarin’s cost and expense, or (ii) at the reasonable request of Licensee, at Licensee’s cost and expense, then Amarin or its designee shall attend key meetings with the relevant Regulatory Authorities with respect to obtaining or maintaining the Product Approvals for the Product in the Field in the Territory; provided, that, to the extent the subject matter of such meeting makes it appropriate given the allocation of responsibilities herein (e.g., Amarin’s responsibility for Manufacturing the Bulk Product or the Finished Product), then Amarin or its designee may attend such meeting. Notwithstanding the foregoing, if changes during the Term in the activities performed by Licensee with respect to the Product, or in Applicable Laws, would permit any of the Regulatory Approvals for the Product in the Field in the Territory to be held by, and in the name of, Licensee, then Amarin shall transfer any such Regulatory Approvals to Licensee.

**5.2.2 Cost of Regulatory Activities.** All Regulatory Costs incurred in connection with the preparation by or on behalf of Licensee of Regulatory Materials for, and obtaining of, Product Approvals in the Field in the Territory for Product shall be borne solely by Licensee. Licensee shall be responsible for all Regulatory Costs involved in the maintenance of all Regulatory Approvals for Product in the Field in the Territory. Amarin shall invoice Licensee for Regulatory Costs it incurs in connection with the preparation of Regulatory Materials (including the performance of any Territory-Specific Analytical Release Testing associated therewith) for, and obtaining of Product Approvals in, the Field in the Territory for the Product to the extent that such Regulatory Costs to be incurred by Amarin are incurred in accordance with the Development Plan or have otherwise been approved by Licensee in writing, which invoices Licensee shall pay within [\*\*\*] of receipt thereof. [\*\*\*]

**5.2.3 Reporting and Review.** Licensee shall keep Amarin reasonably and regularly informed in connection with the preparation of all Regulatory Materials, Regulatory Authority review of Regulatory Materials, and Regulatory Approvals, in each case with respect to Product for sale in the Field in the Territory. Licensee shall provide Amarin, within [\*\*\*] to the extent material, and otherwise within [\*\*\*], with copies of all notices, questions, and requests for information in tangible form which it receives from a Regulatory Authority with respect to Product for sale in the Field; provided, however, that Licensee shall have the right to redact any information to the extent not related to Product.

**5.2.4 Consultation and Approval Prior to Regulatory Filings.** The Parties shall consult with each other on the strategy for pre-authorization activities (i.e., Regulatory Authority meetings and IDL filing) and post-authorization activities, with respect to Regulatory Approvals for the Product in the Field in the Territory prior to the filing. Without limitation of the foregoing, Licensee shall provide Amarin with a copy of all proposed Regulatory Materials in English for review and approval prior to filing, and Licensee shall incorporate any reasonable comments received from Amarin to the extent Amarin provides comments in a timely manner;

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provided, however, that Amarin shall have final decision-making authority on the content of all Regulatory Materials associated with the Product in the Field in the Territory in the event that Amarin, in accordance with Section 3.1.4, reasonably determines that such Regulatory Materials could materially and adversely affect Development and Commercialization of the Product in the Field outside the Territory; provided, further, that, if such Regulatory Materials are required in order to obtain Regulatory Approval for the Product in the Field in the Territory, then Licensee may submit such Regulatory Materials but shall revise them to the extent possible to take into account Amarin’s comments.

**5.3 Communications.** The Parties shall cooperate in communicating with any Regulatory Authority having jurisdiction regarding the Product in the Field whether within the Territory or outside the Territory and Licensee shall immediately notify Amarin in the event that Licensee (or any of its Affiliates, Sublicensees, subcontractors, wholesalers or distributors) communicates, or intends to communicate, either on its own initiative in accordance with this Agreement or as a result of such a Regulatory Authority initiating contact with such Person in connection therewith. Notwithstanding the foregoing, except as may be required by Applicable Laws, Licensee (and its Affiliates, Sublicensees, subcontractors, wholesalers and distributors) shall not, with respect to the Product, communicate with (i) any Regulatory Authority having jurisdiction outside the Territory regarding the Product or (ii) any Regulatory Authority with respect to the Product for use outside the Field, in each case, unless explicitly provided for in the Development Plan or requested or permitted in writing to do so by Amarin, or unless so ordered by such Regulatory Authority, in which case Licensee shall immediately notify Amarin of such order and shall, to the extent permitted by Applicable Laws, not take any further actions or communicate with such Regulatory Authority further until Amarin has provided instruction as to how to proceed, which instruction shall be given reasonably in advance of the deadline, if any. All communications with Regulatory Authorities regarding the Product in the Field in the Territory shall be undertaken as provided in this Agreement.

**5.4 No Other Regulatory Filings.** Except as otherwise expressly set forth in ARTICLE 5, Licensee (and its Affiliates) shall not file any Regulatory Materials or Regulatory Approvals for the Product or that are otherwise based on any Amarin Technology or any Joint Patents.

### **5.5 Rights of Reference.**

**5.5.1 Licensee’s Rights.** Amarin shall permit Licensee (and its Affiliates or permitted Sublicensees) to access, and shall provide Licensee (and its Affiliates or permitted Sublicensees) with sufficient rights to reference and use, in association with exercising Licensee’s rights and performing its obligations under this Agreement, Amarin’s Development Data, Regulatory Materials and Regulatory Approvals outside the Territory that are associated with the Product in the Field. Amarin shall transmit to the extent accessible to and Controlled by Amarin all necessary and appropriate letters to applicable Regulatory Authorities advising such applicable Regulatory Authorities of such rights of reference and use.

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**5.5.2 Amarin’s Rights.** Licensee shall permit Amarin (and its Affiliates or permitted Sublicensees) to access, and shall provide Amarin (and its Affiliates or permitted Sublicensees) with sufficient rights to reference and use, in association with exercising its rights and performing its obligations under this Agreement, Licensee’s Development Data, Regulatory Materials and Regulatory Approvals in the Territory that are associated with the Product. Licensee shall transmit to the extent accessible to and Controlled by Licensee all necessary and appropriate letters to applicable Regulatory Authorities advising such applicable Regulatory Authorities of such rights of reference and use.

**5.6 Adverse Event Reporting, Safety Data Exchange and Medical Inquiries.**

**5.6.1 Pharmacovigilance.** Subject to the terms of this Section 5.6.1, each Party shall be responsible for its respective pharmacovigilance obligations under Applicable Laws. Licensee, as the intended beneficiary under this Agreement of the privileges of ownership of the Product Approvals in the Field in the Territory, shall be responsible for the collection, review, assessment, tracking and filing of information related to adverse events associated with the Product in the Territory (whether or not Product Approval has been achieved), in each case in accordance with Applicable Laws and this Agreement (and Licensee shall ensure that, in the Development and Commercialization of the Product, it will record, investigate, summarize, notify, report and review all adverse events in accordance with Applicable Laws, including, for clarity, laws relating to adverse event reporting in both the U.S. and the Territory). Amarin (or its designee) shall be responsible for the collection, review, assessment, tracking and filing of information related to adverse events associated with the Product in the countries outside the Territory. The safety units from each of the Parties shall meet and agree upon a written pharmacovigilance agreement for exchanging adverse event and other safety information relating to the Product prior to Licensee’s first clinical activity or prior to the first Regulatory Approval in the Territory (whichever is first). Such written pharmacovigilance agreement shall ensure that adverse event associated with the Product and other safety information is exchanged according to a schedule that will permit each Party (and its designees or, solely with respect to Amarin, its sublicensees) to comply with Applicable Laws and regulatory requirements in their respective markets.

**5.6.2 Global Safety Database.** Amarin shall be responsible for maintaining the global safety database for Product. The written pharmacovigilance agreement prescribed by Section 5.6.1 shall ensure that adverse event and other safety information is exchanged according to a schedule that will permit Amarin (and each of its designees and sublicensees, as applicable) to comply with Applicable Laws and regulatory requirements in their respective markets. Amarin shall provide Licensee with reasonable access to such global safety database without any compensation to Amarin.

**5.6.3 Medical Inquiries for the Product.** Following the Effective Date, Licensee, as the intended beneficiary under this Agreement of the privileges of ownership of the Product Approvals in the Field in the Territory, shall be responsible for handling all medical questions or inquiries in the Territory, including all Product Complaints, with regard to any Product sold by or on behalf of Licensee (or any of its Affiliates), in each case in accordance

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with Applicable Laws and this Agreement. Amarin shall provide a copy of any standardized responses to medical inquiries to Licensee for Licensee’s use with respect to the Product in the Field in the Territory. Amarin shall immediately forward any and all medical questions or inquiries which it receives with respect to any Product sold by or on behalf of Licensee (or any of its Affiliates) in the Territory to Licensee in accordance with all Applicable Laws and Licensee shall immediately forward to Amarin any and all medical questions or inquiries that it receives with respect to Product (i) not sold by or on behalf of Licensee (or any of its Affiliates) in the Territory or (ii) outside of the Territory, in each case in accordance with all Applicable Laws. Notwithstanding the foregoing, Amarin shall be responsible for handling all Product Complaints other than those related to the Development and Commercialization of the Product in the Field in the Territory, and Licensee shall refer all such Product Complaints to Amarin. Licensee shall be responsible for handling all Product Complaints related to the Development and Commercialization of the Product in the Field in the Territory, and Amarin shall refer all such Product Complaints to Licensee.

#### **5.7 Regulatory Authority Communications Received by a Party.**

**5.7.1 General.** Each Party shall immediately inform the other Party of notification of any action by, or notification or other information which it receives (directly or indirectly) from, any Regulatory Authority whether inside the Territory or outside the Territory which (i) raises any material concerns regarding the safety or efficacy of the Product; (ii) indicates or suggests a potential material liability of either Party to Third Parties in connection with the Product; (iii) is reasonably likely to lead to a recall, market withdrawal or market notification with respect to the Product whether inside the Territory or outside the Territory; or (iv) relates to expedited and periodic reports of adverse events with respect to the Product whether inside the Territory or outside the Territory, or Product Complaints, and which may have an adverse impact on Regulatory Approval or the continued Commercialization of the Product whether inside the Territory or outside the Territory. Licensee shall be solely responsible for responding to any such communications relating to the Product in the Field in the Territory and the Parties shall reasonably cooperate with and assist each other in complying with regulatory obligations, including by Amarin providing to Licensee such information and documentation which is in Amarin’s possession as may be necessary or reasonably helpful for Licensee to prepare a response to an inquiry from a Regulatory Authority in the Territory with respect to the Product in the Field. Each Party shall also promptly provide the other Party with a copy of all correspondence received from a Regulatory Authority whether inside the Territory or outside the Territory specifically regarding the matters referred to above. Amarin (or its designee) shall be solely responsible for any communications relating to the Product outside of the Territory or outside the Field.

**5.7.2 Disclosures.** In addition to its obligations under this Agreement, each Party shall disclose to the other Party (and in the case of Amarin, Amarin shall have the right to subsequently disclose to its designees) the following regulatory information:

(a) all material information pertaining to actions taken by Regulatory Authorities, whether inside the Territory or outside the Territory, in connection with the

Product in the Field, including any notice, audit notice, notice of initiation by Regulatory Authorities of investigations, inspections, detentions, seizures or injunctions concerning the Product in the Field, notice of violation letter (i.e., an untitled letter), warning letter, service of process or other inquiry; provided, however, that a Party shall be entitled to redact those portions thereof to the extent not related to the Product in the Field. Without limiting the generality of the foregoing, each Party shall promptly, but in any event within [\*\*\*], inform the other Party of any inspections, proposed regulatory actions, investigations or requests for information or a meeting by any Regulatory Authority with respect to the Product in the Field whether inside the Territory or outside the Territory; and

(b) all information pertaining to notices from Regulatory Authorities, whether inside the Territory or outside the Territory, of non-compliance with Applicable Laws in connection with the Product, including receipt of a warning letter or other notice of alleged non-compliance from any Regulatory Authority relating to the Product; provided, however, that a Party shall be entitled to redact those portions thereof to the extent not related to the Product.

#### **5.8 Recall, Withdrawal, or Market Notification of Product.**

**5.8.1 Notification and Determination.** In the event that any Governmental Authority threatens or initiates any action to remove the Product from the market in the Field whether inside the Territory or outside the Territory (in whole or in part), the Party receiving notice thereof shall notify the other Party of such communication immediately, but in no event later than [\*\*\*], after receipt thereof. Notwithstanding the foregoing, in all cases Licensee, as the intended beneficiary under this Agreement of the privileges of ownership of the Product Approvals in the Field in the Territory, shall determine (and notify Amarin with respect to such determination) whether to initiate any recall, withdrawal or market notification of the Product in the Field in the Territory, and Amarin, acting as the holder of the Product Approval, shall act on behalf of Licensee in any recall, withdrawal and market notification of the Product. Amarin shall determine whether to initiate any such recall, withdrawal or market notification of the Product outside the Field in the Territory, or outside the Territory, including the scope of such recall or withdrawal (e.g., a full or partial recall, temporary or permanent recall, or “dear doctor” letter) or market notification; provided, however, that, before Licensee or Amarin (as the case may be) initiates a recall, withdrawal or market notification in the Territory, the Parties shall promptly meet and discuss in good faith the reasons therefor; provided, that such discussion shall not delay any action that is required to be taken under Applicable Laws in relation to any recall, withdrawal or market notification. In the event of any such recall, withdrawal or market notification in the Territory, Licensee or Amarin (as the case may be) shall determine the necessary actions to be taken, and shall implement such action, with the other Party providing reasonable input (which the first Party shall in good faith consider and incorporate into any recall, withdrawal or market notification strategy) and reasonable assistance, to conduct such recall, withdrawal or market notification. Without limiting the foregoing, Amarin shall have the right to propose that a Product recall, withdrawal or market notification should be initiated by Licensee in the Territory, and the Parties shall jointly make the decision as to whether or not the

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recall, withdrawal or market notification will be initiated; provided, however, that, in the event Licensee does not agree to initiate such recall, withdrawal or market notification, then Licensee shall indemnify Amarin under Section 11.2 with respect thereto. Licensee shall at all times utilize a batch tracing system which will enable the Parties to identify, on a prompt basis, customers within the Territory who have been supplied with Product of any particular batch, and to recall such Product from such customers as set forth in this Section 5.8.1.

**5.8.2 Cost Allocation.** [\*\*\*]

(a) [\*\*\*]

(b) [\*\*\*]

**ARTICLE 6  
COMMERCIALIZATION**

**6.1 Commercialization in the Field in the Territory.** During the Term, Licensee shall be solely responsible for Commercializing the Product in the Territory for use in the Field, which Commercialization shall be in accordance with the Commercialization Plan and this Agreement. Licensee shall be responsible for one hundred percent (100%) of the expenses (including Pre-Marketing and other Commercialization expenses) incurred in connection with the Commercialization of the Product in the Territory for use in the Field. Without limiting the foregoing, Licensee shall use Commercially Reasonable Efforts to Commercialize the Product for use in the Field in the Territory; provided, that Amarin is using Commercially Reasonable Efforts to comply with its obligations to supply Product in accordance with ARTICLE 7 of this Agreement.

**6.2 Commercialization Plan.**

**6.2.1 Initial Commercialization Plan.** On an annual basis commencing with the Calendar Year in which the first filing for Regulatory Approval in the Field in the Territory is expected to be made, Licensee shall prepare a commercialization plan with respect to the Commercialization of the Product in the Field in the Territory pursuant to this Agreement (the “**Commercialization Plan**”). The initial Commercialization Plan (i.e., for the Product for the Calendar Year in which the Regulatory Approval is expected to be received) will be prepared by Licensee (the “**Initial Commercialization Plan**”) at an appropriate and agreed time following the Effective Date [\*\*\*] and shall be subject to approval by the JCC in accordance with the provisions of Section 3.2.4.

**6.2.2 Updates to Commercialization Plan.** [\*\*\*] each Calendar Year (except as set forth in Section 6.2.1), Licensee shall create and submit to the JCC for its review, discussion and approval the Commercialization Plan for the following Calendar Year. From time to time during a given Calendar Year, Licensee may propose written updates to the Commercialization Plan for review, discussion and approval by the JCC. Licensee shall conduct all Commercialization of the Product in accordance with the Commercialization Plan and this Agreement.

**6.2.3 Contents of Commercialization Plan. [\*\*\*]**

- (a) [\*\*\*]
- (b) [\*\*\*]
- (c) [\*\*\*]
- (d) [\*\*\*]
- (e) [\*\*\*]
- (f) [\*\*\*]

**6.3 Licensee’s Performance.**

**6.3.1 Specific Commercialization Obligations.** Without limiting the generality of the provisions of Section 6.1, in connection with the Commercialization of the Product in the Territory for use in the Field by Licensee hereunder:

- (a) Licensee shall (i) use Commercially Reasonable Efforts to Commercialize Product for use in the Field in the Territory, (ii) maximize the commercial potential for Product in the Field in the Territory, (iii) represent Product accurately and fairly, (iv) Commercialize Product so as to reflect favorably on Product and the good name, goodwill and reputation of Amarin and (v) act in good faith to maximize the economic value of Product.
- (b) Licensee shall not (i) disparage, defame, discredit, or negatively comment to Third Parties in any way about or concerning the Product or Amarin (including Amarin’s activities, operations or other products) nor permit its employees, officers or directors to do so, (ii) utilize deceptive, misleading or unethical business practices, or (iii) take any action or inaction that would reasonably be likely to prejudice the value of Product.
- (c) Licensee shall be solely responsible for (i) receiving, accepting and filling orders for the Product in the Field in the Territory, (ii) handling all returns of the Product in the Field in the Territory, (iii) controlling invoicing, order processing and collection of accounts receivable for the sales of the Product in the Field in the Territory, and (iv) distributing and managing inventory of the Product in the Field in the Territory.
- (d) Licensee shall launch Product in the Territory within [\*\*\*] after all applicable Regulatory Approvals for Product have been obtained, and shall thereafter ensure that the Product remains commercially available in the Territory for the duration of the Royalty Term, subject to adequate supply of the Product in accordance with ARTICLE 7 of this Agreement.

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(e) As promptly as practicable, following the First Commercial Sale of the Product in the Field in the PRC, Licensee shall commit a dedicated team to maximize the market access of the Product in the Field in the PRC. During the [\*\*\*] period after the First Commercial Sale of the Product in the Field in the PRC, Licensee shall use Commercially Reasonable Efforts (1) to file applications to win the biddings in all core provinces in the PRC as agreed under the Commercialization Plan, (2) to submit for pricing approval and (3) for listing in the national drug reimbursement catalogue. [\*\*\*]

**6.3.2 Commercialization Plan.** Without limiting the obligations of Licensee under Sections 6.3.1, Licensee shall use Commercially Reasonable Efforts to carry out the Commercialization activities in the Commercialization Plan in accordance with the time frames set forth in the Commercialization Plan.

**6.4 Reports.** Without limiting Licensee’s quarterly reporting obligations under Section 8.4 with respect to Net Sales, Royalty Payments and Sublicense Income, Licensee shall (i) [\*\*\*], provide Amarin a reasonably detailed report regarding its significant Commercialization activities involving Product during the preceding Calendar Year, including number of sales representatives and details, and overall marketing expenditures; and (ii) [\*\*\*], provide Amarin the number of prescriptions written (aggregated by province) to the extent such number of prescriptions written can be provided by IMS (or a similar internationally recognized information service). In addition, Licensee shall update the JCC [\*\*\*] regarding its significant Commercialization activities involving the Product.

### **6.5 Compliance.**

**6.5.1 Reporting.** Licensee shall ensure that all government reporting (including price and gift reporting), and sales, marketing and promotional practices, in respect of the Product in the Territory meet the standards required by (i) the Drug Administration Law, (ii) the Anti-unfair Competition Law of the PRC, (iii) the Advertising Law of the PRC, the Standards for the Review and Publication of Drug Advertisement issued by the CFDA and the State Administration of Industry and Commerce, (iv) the Anti-Corruption Laws, and (v) other Applicable Laws. Each of Amarin and Licensee shall reasonably cooperate with the other Party to provide the other Party access to any and all information, data and reports required by the other in order to comply with the provisions of Applicable Laws required in the respective jurisdictions in which each Party sells the Product, including reporting requirements, in a timely and appropriate manner. Each Party shall ensure that its reporting under governmental healthcare programs in the Territory related to the Product is true, complete and correct in all respects; provided, however, that a Party shall not be held responsible for submitting erroneous reports if such deficiencies result from information provided by the other Party which itself was not true, complete and correct.

**6.5.2 Corporate Compliance Program.** Licensee shall maintain an effective comprehensive corporate compliance program that is compliant with Applicable Laws; provided, however, that, whether or not required by Applicable Laws, such compliance program will include a mechanism for its employees and the public to report, anonymously if they choose, any concerns about potential illegal activity relating to the Commercialization of the Product in the Field in the Territory. Such compliance program will require Licensee to investigate any such report of wrongdoing. At Amarin’s request, Licensee shall provide to Amarin written copies in English of any reports of any investigations initiated by Governmental Authorities in the Territory as to the knowledge of Licensee.

**6.5.3 General Compliance Obligations.** Licensee specifically agrees, on behalf of itself and its Affiliates, Sublicensees and subcontractors, and its and their respective officers, directors and employees (together with Licensee, the “**Representatives**”), to comply with Applicable Laws and, specifically, in connection with the subject matter of this Agreement:

(a) The Representatives shall not directly or indirectly pay, offer or promise to pay, authorize the payment of any money or give, offer or promise to give, or authorize the giving of anything else of value, to: (a) any Government Official in order to influence official action; (b) any individual or entity (whether or not a Government Official) (1) to influence such individual or entity to act in breach of a duty of good faith, impartiality or trust (“acting improperly”), (2) to reward such individual or entity for acting improperly or (3) where such individual or entity would be acting improperly by receiving the money or other thing of value; (c) any individual or entity (whether or not a Government Official) while knowing or having reason to know that all or any portion of the money or other thing of value will be paid, offered, promised or given to, or will otherwise benefit, the individuals or entities for the purposes listed in clauses (a) and (b) above.

(b) The Representatives shall not, directly or indirectly, solicit, receive or agree to accept any payment of money or anything else of value in violation of the Anti-Corruption Laws.

(c) The Representatives shall comply with the Anti-Corruption Laws and shall not take any action that will, or would reasonably be expected to, cause either Party or its Affiliates to be in violation of any such laws or policies.

(d) No Representative that will participate or support its performance of its obligations hereunder has, directly or indirectly, (i) paid, offered or promised to pay or authorized the payment of any money, (ii) given, offered or promised to give or authorized the giving of anything else of value or (iii) solicited, received or agreed to accept any payment of money or anything else of value, in each case ((i), (ii) and (iii)), in violation of the Anti-Corruption Laws during the three (3) years preceding the date of this Agreement.

(e) Each Representative shall have acquired all applicable licenses, permits, qualifications, approvals or authorizations by the competent Governmental Authority in each jurisdiction in which it operates, including the PRC Ministry of Commerce, the PRC State Administration of Industry and Commerce and the CFDA, in accordance with Applicable Laws.

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(f) Licensee shall promptly provide Amarin with written notice of the following events: (i) upon becoming aware of any actual or alleged breach or violation by Licensee or its Representative of any obligation in this Section 6.5 or (ii) upon receiving a formal notification that it is the target of an investigation by a governmental authority for a violation of the Anti-Corruption Laws or upon receipt of information from any of the Representatives connected with this Agreement that any of them is the target of an investigation by a governmental authority for a violation of the Anti-Corruption Laws.

Licensee shall be responsible for any breach of any obligation under this Section 6.5 or of the Anti-Corruption Laws by any of its Representatives.

**6.5.4 Non-Compliance.** On the occurrence of any of the following events:

(a) Amarin becomes aware of, whether or not through a Compliance Audit, that Licensee or any of its Representatives is in breach or violation of any obligation in this Section 6.5 or of the Anti-Corruption Laws; or

(b) notification is received under Section 6.5.3(f) relating to any suspected or actual violation of the Anti-Corruption Laws by Licensee or any of its Representatives,

then, in either case ((a) or (b)), Amarin shall have the right, in addition to any other rights or remedies under this Agreement or to which Amarin may be entitled in law or equity, to: (i) take such steps as are reasonably necessary in order to avoid a potential violation or continuing violation by Licensee or any of its Representatives of the Anti-Corruption Laws, including by requiring that Licensee agrees to such additional measures, including possible self-disclosures, representations, warranties, undertakings and other provisions as are reasonably necessary (“**Provisions**”); and (ii) terminate this Agreement in its entirety immediately: (A) in the event that the breach or violation by Licensee which is the subject of the notice to Amarin pursuant to Section 6.5.3(f)(i) is confirmed by an internal investigation of the compliance team of Licensee, and has not been cured to the reasonable satisfaction of Amarin within [\*\*\*] after receipt of such notice by Amarin (provided, that Amarin shall have the right in its sole discretion to challenge the finding of Licensee’s internal investigation and, upon exercising such right, the Parties agree to cooperate with, and submit any and all evidence in connection with such investigation to, an internationally recognized law firm mutually selected by the Parties in order to resolve such dispute within [\*\*\*] after such submission and the Parties agree to be bound by the final decision rendered in connection therewith); or (B) in the event that an investigation which is the subject of the notice by Licensee to Amarin pursuant to Section 6.5.3(f)(ii) is concluded with a finding that Licensee violated the Anti-Corruption Laws.

**6.5.5 Effective Date Status; Improvement Plan.** Licensee represents and warrants that (i) it has reviewed its internal programs in relation to compliance with Applicable Laws and the Anti-Corruption Laws in advance of the signing of this Agreement, and (ii) it and the other Representatives can and will continue to comply with such Applicable Laws and Anti-Corruption Laws in performance of its obligations hereunder. Should any measures be identified

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at meetings of the JCC that should be reasonably taken to improve the Representatives’ compliance with such Anti-Corruption Laws for the performance of its obligations hereunder (the “**Improvement Plan**”), Licensee shall implement such Improvement Plan within an agreed reasonable timeframe (which shall in any event not be in excess of [\*\*\*]) from the date the Improvement Plan is delivered to Licensee.

**6.5.6 Compliance Certification.** Within [\*\*\*] of each anniversary of the Effective Date (i.e., once per Calendar Year on the anniversary of the Effective Date), Licensee shall submit to Amarin a written certification by an appropriate corporate officer of Licensee, in a form acceptable to Amarin, regarding Licensee’s (and its Sales Representatives, as applicable) compliance with the terms of this Section 6.5.

**6.5.7 Disclaimer.** Licensee acknowledges that compliance with the Anti-Corruption Laws and other Applicable Laws in the Territory by it and its Representatives is the responsibility of Licensee under this Section 6.5, and Licensee agrees that Amarin shall have no liability to Licensee or any of its Representatives by reason of Amarin’s exercise (or failure to exercise) its rights or performance of its obligations under this Section 6.5.

**6.6 Compliance Audit.** For the Term, Licensee shall, for the purpose of auditing and monitoring the performance of its compliance with this Agreement and particularly its compliance obligations hereunder, permit Amarin and its Affiliates or its or the auditors of any of them to have once per Calendar Year (or more frequently upon a showing of good reason), upon reasonable notice, access to any premises of Licensee or its Affiliates used in connection with this Agreement (“**Compliance Audit**”). To the extent that any Compliance Audit by or on behalf of Amarin requires access and review of any commercially or strategically sensitive information of Licensee or its Affiliates relating to the business of Licensee or its Affiliates, such activity shall be carried out by a Third Party professional advisor appointed by Amarin and such professional advisor shall only report back to Amarin such information as is directly relevant to informing Amarin on Licensee’s compliance with the particular provisions of this Agreement being Compliance Audited (and shall enter into a commercially reasonable confidentiality agreement consistent with the foregoing). The costs and fees of any such Compliance Audit shall be paid by Amarin, except that, if a Compliance Audit reveals any material breach by Licensee of Section 6.5 as documented by such Third Party professional advisor, such costs and fees shall be paid by Licensee. Licensee shall bear its own costs of rendering assistance to the Compliance Audit. The audit rights described in this Section 6.6 are without limitation of other audit rights described elsewhere in this Agreement.

## **6.7 Provisions applicable to Sales Representatives and/or Medical Science Liaisons.**

**6.7.1 General.** Licensee shall, and shall cause its Sales Representatives to, conduct all details with respect to the Product and perform its other Commercialization activities under this Agreement in the Territory in adherence with Applicable Laws and Regulatory Approvals.

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**6.7.2 Compensation.** Licensee shall be solely responsible for (i) any compensation that is payable to its Sales Representatives (including with respect to any employee benefit plan), (ii) the payment or withholding of any contributions, payroll taxes, or any other payroll-related item by or on behalf of Licensee (or its Affiliates) or any of its Sales Representatives or Medical Science Liaisons, and (iii) any failure of Licensee (or its Affiliates) to withhold or pay required taxes or failure to file required forms with regard to compensation and benefits paid or extended by Licensee (or its Affiliates) to any of its Sales Representatives or Medical Science Liaisons.

**6.7.3 Training.** Licensee shall be solely responsible for training, and all costs associated with such training, its Sales Representatives and Medical Science Liaisons using Commercially Reasonable Efforts and in all cases in accordance with Applicable Laws, including timely reporting of any adverse events with respect to the Product. Such training will include, among other topics, CFDA requirements and other national and local regulations and industry guidelines, including those set forth in Section 6.5.1 above.

**6.7.4 Acts of Sales Representatives and Medical Science Liaisons.** For the avoidance of doubt, Licensee shall be solely responsible for any act or omission of its Sales Representatives and Medical Science Liaisons while interacting with healthcare professionals or performing any Commercialization activities (including any proceedings or claims for benefits that any Sales Representative or Medical Science Liaison may make under or with respect to any Amarin benefit plan). Licensee shall be solely responsible and liable for all probationary and termination actions taken by it with respect to its Sales Representatives and Medical Science Liaisons, as well as for the formulation, content and dissemination (including content) of all employment policies and rules (including written compliance policies, and probationary and termination policies) applicable to its employees and contractors. Licensee shall ensure that its policies require a clear delineation between the promotional and medical activities, including training both its Sales Representatives and Medical Science Liaisons on the differentiation of their roles under Applicable Laws. For clarity, Sales Representatives shall not engage in medical affairs activities (including receiving, approving or delivering grants) nor will they attend formulary committee meetings and no Medical Science Liaison shall serve as a Sales Representative.

## **6.8 Promotional Materials.**

**6.8.1 Creation of Promotional Materials.** Licensee will create and develop Promotional Materials for the Territory in accordance with the Regulatory Approvals and Applicable Laws and at Licensee’s sole cost and expense, in each case based (to the extent consistent with such Regulatory Approvals and Applicable Laws) on promotional materials used by Amarin in the U.S. (copies of which shall be provided by Amarin to Licensee at Licensee’s reasonable request). Prior to the First Commercial Sale of the Product, Licensee shall provide samples thereof to Amarin in English for its information and use prior to distributing such Promotional Materials (for clarity, such samples need only be submitted for each different type of Promotional Material, as opposed to each item of Promotional Material needing to be submitted). Any new samples of Promotional Material for the Territory made thereafter will be

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provided to Amarin for its information and use. To the extent Licensee includes any Amarin trademarks in the Promotional Materials for the Territory, Licensee shall comply with Amarin’s then current guidelines for trademark usage.

**6.8.2 Inclusion of Logos on Packaging and Promotional Materials.** To the extent permitted or required by Applicable Laws and subject to obtaining necessary Regulatory Authority approvals, with respect to Product to be sold by or on behalf of Licensee (or any of its Affiliates) in the Territory, the Amarin housemark and the Licensee housemark shall be given equal prominence on all package inserts utilized by Licensee. Amarin hereby grants to Licensee a non-exclusive, royalty-free right and license during the Term to utilize the Amarin housemark (including all trademarks, names and logos) in order to perform the Commercialization activities required to be performed by Licensee hereunder in accordance with the terms of this Agreement. Licensee hereby grants to Amarin a non-exclusive, royalty free right and license during the Term to utilize the Licensee housemark (including all trademarks, names and logos) in order to perform the Manufacturing and other activities to be performed by or on behalf of Amarin under the terms of this Agreement. Each Party shall only use the housemark of the other Party with the necessary trademark designations, and each Party shall use the other Party’s housemarks in a manner that does not derogate from such Party’s rights in its trademarks, names and logos. Each Party shall submit representative samples of its use of the other Party’s housemark for review by the JCC. Each Party will take no action that will interfere with or diminish the other’s rights in its respective trademarks, names and logos, and if a Party reasonably believes that the use of its trademarks, names and logos by the other Party hereunder is interfering with or diminishing its rights, such Party shall notify the other Party thereof in writing and such other Party shall promptly cease use of such trademarks, names or logos in such manner. Each Party agrees that all use of the other Party’s trademarks, names and logos will inure to the benefit of such other Party, including all goodwill in connection therewith.

**6.8.3 Licensee Ownership of Promotional Materials.** Subject to ARTICLE 14, Licensee shall own all right, title and interest in and to any Promotional Materials created by Licensee hereunder relating to the Product in the Field in the Territory including copyrights, but excluding trademarks (including the Product Trademark), names, logos and other marks owned by or on behalf of Amarin or its Affiliates.

**6.8.4 Use of Promotional Materials Exclusively for the Product.** The Promotional Materials, and any aspects of those uniquely tied to the Product, shall be used by Licensee (and its Affiliates, Sublicensees, subcontractors, wholesalers and distributors) in connection with the Commercialization of the Product in the Field in the Territory in accordance with the terms of this Agreement, and Licensee shall not use, or allow any other Person to use, any such Promotional Materials except in accordance with this Agreement.

## **6.9 Product Trademarks and Product Trade Dress.**

**6.9.1 Product Trademark.** Licensee shall Commercialize the Product in the Field in the Territory under the trademark VASCEPA™ (and logo) (as displayed on Schedule 6.9.1) and related trade dress (together, the “**Product Trademark**” and the “**Product Trade**

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**Dress**”, respectively). Notwithstanding the foregoing, based on a review of market research, regulatory research, legal searches, investigation results, and any other relevant information that may have been collected by either Party that is relevant to the clearance for use and registration of a trademark or for use and registration of a trade dress, Licensee shall register a trademark and trade dress in the local language in the Territory mutually agreeable to the Parties (the “**Licensee Trademark**” and the “**Licensee Trade Dress**”) to be used in the Commercialization of the Product in the Field in the Territory. Licensee shall bear all costs relating to the creation, legal clearance, filing, registration, and maintenance of any Licensee Trademark and Licensee Trade Dress and shall own and employ any such Licensee Trademarks or Licensee Trade Dress in the Territory. For clarity, the Parties acknowledge and agree that it is their mutual intention that Licensee Commercialize the Product in the Field in the Territory under the Product Trademark, the Product Trade Dress, the Licensee Trademark and the Licensee Trade Dress. Licensee shall bear all costs relating to the creation, legal clearance, filing, registration, and maintenance of any alternative trademark and trade dress. Licensee shall not employ any such alternative trademarks or trade dress without obtaining Amarin’s prior approval.

**6.9.2 Use and Ownership of Product Trademarks and Product Trade Dress.** All uses of the Product Trademark and Product Trade Dress by Licensee (and its Affiliates, Sublicensees, subcontractors, wholesalers and distributors) to identify and/or in connection with the Commercialization of the Product in the Field in the Territory shall be in accordance with Regulatory Approvals and all Applicable Laws, Amarin’s quality control guidelines for the Product Trademarks and the Product Trade Dress, as may be amended from time to time, and shall be subject to the approval of Amarin in its reasonable discretion. Licensee (and its Affiliates) shall only use the Product Trademark and Product Trade Dress pursuant to the terms of this Agreement to identify, and in connection with the Commercialization of, the Product in the Territory for use in the Field. Licensee shall not (and shall cause its Affiliates, Sublicensees, subcontractors, wholesalers and distributors not to) use such Product Trademark or Product Trade Dress to identify, or in connection with the marketing of, any other products. Amarin shall own and retain all rights to the Product Trademark and Product Trade Dress (in each case, together with all goodwill associated therewith throughout the Territory), and Licensee shall assign (and shall cause its Affiliates, Sublicensees, subcontractors, wholesalers and distributors to assign), and hereby does assign, to Amarin, all of its and their right, title and interest in and to such Product Trademark and Product Trade Dress. If Licensee filed and registered any such Product Trademark or Product Trade Dress at the request of Amarin, then Amarin shall reimburse all reasonable costs relating to the filing, registration, and maintenance of such Product Trademark or Product Trade Dress within forty-five (45) days of receipt of an invoice therefor. Amarin shall also own rights to any Internet domain names incorporating the Product Trademark or any variation or part of the Product Trademark as its URL address or any part of such address; and Licensee shall own rights to any Internet domain names incorporating the Licensee Trademark or any variation or part of the Licensee Trademark (and not the trademark VASCEPA™ (and logo) (as displayed on Schedule 6.9.1)) as its URL address or any part of such address. Licensee shall not establish any Internet domain name or URL incorporating the Product Trademark without the prior written consent of Amarin. The Parties hereby agree and acknowledge that nothing contained herein shall limit Amarin’s right to use the Product Trademark or Product Trade Dress outside the Field or outside the Territory.

**6.9.3 Maintenance of Product Trademark.** During the Term, Amarin shall use Commercially Reasonable Efforts to establish, maintain and enforce the Product Trademark in the Territory and shall bear all costs and expenses relating thereto.

**6.9.4 Infringement of the Product Trademark.** In the event that either Party becomes aware of any infringement of the Product Trademark by a Third Party in the Territory, such Party shall promptly notify the other Party and the Parties shall consult with each other in good faith with respect thereto. Licensee shall, at its sole discretion, have the first right to determine how to proceed with respect to such infringement, including by the institution of legal proceedings against such Third Party, in which case all costs and awards relating to such legal proceedings will be borne exclusively by Licensee. If requested to do so, Amarin shall reasonably cooperate with any and all action initiated by Licensee, including by joining legal proceedings as a party at Licensee’s reasonable expense. If Licensee elects not to take action or initiate legal proceedings against an instance of infringement to the Product Trademark in the Territory, Amarin shall have the right at its own and sole discretion to take action or initiate legal proceedings against such instance of infringement to the Product Trademark in the Territory, in which case all costs and awards relating to such legal proceeding will be borne exclusively by Amarin. If requested to do so, Licensee shall reasonably cooperate with any and all action initiated by Amarin in connection therewith, including, by joining legal proceedings as a party at Amarin’s reasonable expense.

**6.9.5 Trademark Acknowledgments.** Each Party acknowledges the sole ownership by the other Party and validity of all copyright, trademarks, trade dress, logos and slogans owned by the other Party and used or intended to be used in connection with the Commercialization of the Product for the Field in the Territory. Each Party agrees that it will not at any time during or after the Term assert or claim any interest in, or do anything which may adversely affect the validity or enforceability of, any copyright, trademark, trade dress, logo or slogan owned by the other Party and used or intended to be used on or in connection with the marketing or sale of the Product. Neither Party will register, seek to register or cause to be registered any copyrights, trademarks, trade dress, logos or slogans owned by the other Party and used or intended to be used on or in connection with the marketing or sale of the Product or any variation thereof, under any Applicable Laws providing for registration of copyrights, trademarks, service marks, trade names or fictitious names (including as an Internet domain name) or similar Applicable Laws, without the other Party’s prior written consent (in its sole discretion).

**6.10 Global Branding Strategy.** Amarin shall have the right, from time to time during the Term, to implement (and thereafter modify and update) a global branding strategy, including global messaging, for the Product for use in the Field throughout the world (the “**Global Branding Strategy**”). To the extent Amarin determines to utilize such Global Branding Strategy, Licensee shall use Commercially Reasonable Efforts to adhere to the Global Branding Strategy in its Commercialization of the Product, including with respect to any

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Promotional Materials; provided, that, in the event that Licensee believes that the application of the Global Branding Strategy in the Territory would be inappropriate whether because of linguistic or cultural particularities, because it is against the Applicable Laws of the Territory or because Licensee reasonably determines it would be inconsistent with Licensee’s obligation to use Commercially Reasonable Efforts to Commercialize the Product in the Territory, Licensee shall present such concern to Amarin, and the Parties shall discuss whether appropriate revisions to the Global Branding Strategy may make it appropriate for use in the Territory. Nothing in this Section 6.10 shall be construed to derogate from Licensee’s ultimate right and responsibility to use Commercially Reasonable Efforts to Commercialize the Product in the Territory in accordance with the terms and conditions of this Agreement.

**6.11 Commercialization Data.** Licensee shall own all marketing and sales data and information resulting from its Commercialization of the Product in the Field in the Territory (the “**Commercialization Data**”). Upon request from Amarin, Licensee shall provide to Amarin a copy of the Commercialization Data, including promotional materials, marketing strategies, market research data and customer lists. Amarin shall have the right and license to use all such Commercialization Data (and the right to grant its Affiliates and Third Parties the right to use such Commercialization Data) in connection with its commercialization of the Product in the Field outside the Territory, which right and license shall survive the expiration or termination of this Agreement. Notwithstanding the foregoing, Licensee’s obligation to provide Commercialization Data and Amarin’s right to use such data shall be performed, or exercised, respectively, in all instances in accordance with all Applicable Laws, including, without limiting the foregoing, any data privacy laws.

## **ARTICLE 7 SUPPLY**

**7.1 General.** Amarin shall use Commercially Reasonable Efforts to Manufacture (or have Manufactured) and supply all quantities of the Finished Product or Bulk Product, as applicable, duly forecasted and ordered by Licensee pursuant to this ARTICLE 7 for clinical and commercial use in the Field in the Territory, in each case in accordance with the terms of this ARTICLE 7 and the Quality Agreement.

**7.2 Development Supply.** Amarin shall use Commercially Reasonable Efforts to Manufacture, or arrange for a Third Party to Manufacture, and supply all of Licensee’s requirements of the Finished Product for Territory Development Activities to be performed by it in accordance with the Development Plan, which supply shall be in accordance with the terms of this ARTICLE 7 and the applicable Quality Agreement. The Finished Product shall be ordered and supplied for Territory Development Activities in accordance with the procedures set forth in this ARTICLE 7; provided, that Amarin shall have no obligation to supply Product hereunder unless and until the Parties have (i) executed the Quality Agreement, and (ii) agreed as to an appropriate forecasting mechanism for Development supply of Product (either through including such forecasts in the Development Plan or some other mechanism) reasonably in advance of any orders therefor from Licensee.

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**7.3 Commercial Supply.** Amarin shall use Commercially Reasonable Efforts to Manufacture, or arrange for a Third Party to Manufacture, and supply all of Licensee’s requirements of the Finished Product or Bulk Product, as applicable, for commercial sale in the Field in the Territory pursuant to this Agreement, which supply shall be in accordance with the terms of this ARTICLE 7 and the applicable Quality Agreement. Licensee shall notify Amarin when its Manufacturing Facility and analytical laboratory(ies) in the Territory are qualified and ready for commercial production, and upon such notification, Amarin shall provide the Bulk Product to Licensee, and Licensee shall be responsible for qualifying and obtaining approval for its Facility and the subsequent packaging, labeling and release activities in the Territory. Amarin shall have the right to audit such Manufacturing Facility as set forth *mutatis mutandis* in Section 7.9.4.

**7.4 Exclusivity.** [\*\*\*]

**7.5 Packaging and Labeling; Certain Other Manufacturing Activities.**

**7.5.1 Finished Product.** Notwithstanding anything to the contrary contained herein, in accordance with the procedures set forth in the Quality Agreement, with respect to the supply of Finished Product, Amarin or its designated Third Party shall be responsible (at its sole cost and expense, which shall be included in the Cost of Goods and Supply Price) for all final product labeling and packaging (whether in commercial or clinical packaging presentation, and, if not already qualified by Amarin’s existing stability program, including a new stability program, which shall be included in Cost of Goods and Supply Price), including insertion of materials such as patient inserts, patient medication guides, professional inserts and any other written, printed or graphic materials accompanying the Product, considered to be part of the Finished Product, and handling, storage, quality control, quality assurance, and the testing and release aspects of Territory-Specific Analytical Release Testing and related activities, of the Finished Product in connection with the foregoing (collectively, **“Packaging and Labeling”**). With respect to the supply of Finished Product, Amarin or its designated Third Party shall ensure that all such Packaging and Labeling shall comply with Applicable Laws, GMPs and the Regulatory Approvals for the Product in the Territory, including the Product Specifications; provided, that Licensee shall be responsible for compliance with Applicable Laws, GMPs and the Regulatory Approvals with respect to approved and camera-ready artwork for such Packaging and Labeling and all other printed components and materials, which camera-ready artwork Licensee shall prepare and deliver to Amarin (in electronic files in a native electronic format) at least [\*\*\*] prior to issuing a firm Purchase Order.

**7.5.2 Bulk Product.** Notwithstanding anything to the contrary contained herein, in accordance with the procedures set forth in the Quality Agreement, with respect to the supply of Bulk Product, Licensee shall be responsible (at its sole cost and expense) for all Packaging and Labeling. With respect to the supply of Bulk Product, Licensee shall ensure that all such Packaging and Labeling shall comply with Applicable Laws, GMPs and the Regulatory Approvals for the Product in the Territory, including the Product Specifications.

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**7.5.3 General.** Amarin or its designated Third Party shall also be responsible for performing the testing and release aspects of Territory-Specific Analytical Release Testing of the Finished Product or Bulk Product, as applicable, and Licensee shall provide reasonable assistance to Amarin in connection therewith, all as more particularly set forth in the Quality Agreement. For clarity, if Amarin provides Bulk Product and Licensee performs Packaging and Labeling, then Licensee or its designated Third Party shall be responsible for performing the testing and release aspects of the Finished Product.

## **7.6 Forecasting and Ordering.**

**7.6.1 Forecast.** Licensee shall furnish the first forecast under this Section 7.6 no less than [\*\*\*] before the anticipated commencement of Territory Development Activities or Commercialization activities, as applicable (the “**Initial Forecast Date**”). [\*\*\*] ([\*\*\*] a “**Forecast Date**”), Licensee shall furnish Amarin a forecast of quantities of Finished Product or Bulk Product, as applicable, that Licensee expects to be delivered [\*\*\*] (each a “**Forecast**”), with [\*\*\*] being binding, [\*\*\*] being permitted to vary in subsequent Forecasts by up to [\*\*\*] being permitted to vary in subsequent Forecasts by up to [\*\*\*], and the remainder of each Forecast being a good faith estimate for informational and planning purposes. If Licensee wishes to make a firm, binding order for the Product, it must provide Amarin with a Purchase Order for the Product [\*\*\*]. All Forecasts shall (i) be specified for Finished Product or Bulk Product, as applicable, on a [\*\*\*] basis and (ii) be for full production batches [\*\*\*] of Finished Product or Bulk Product, as applicable. In the event that the foregoing Forecasts change over time based on commercial or regulatory developments or other factors, the Parties shall meet to discuss in good faith the reasonable ability of Amarin to accommodate any such change and an equitable allocation between the Parties of any resulting costs and expenses.

**7.6.2 Long Range Capacity Planning; Supply Chain Improvements.** Concurrent with the Initial Forecast, for the purposes of discussion and planning of manufacturing capacity Licensee shall provide a non-binding forecast of Finished Product and Bulk Product needs for the [\*\*\*] following that specified in the then current Forecast as described in Section 7.6.1 (“**Long Range Forecast**”). In the event Amarin projects a shortfall in capacity based on the Long Range Forecast, the Parties will jointly discuss alternatives to increase such capacity, and the Parties shall promptly meet to discuss a reasonable manner of proceeding. Unless otherwise agreed to by the Parties during the Term, the Long Range Forecast shall be updated by Licensee and reviewed with Amarin on an annual basis.

**7.6.3 Orders.** On each Forecast Date, in addition to the Forecast specified in Section 7.6.1, Licensee shall for the Term deliver to Amarin a firm purchase order or orders specifying the quantities of the Finished Product or Bulk Product, as applicable, for delivery [\*\*\*] (each a “**Purchase Order**”). Each such Purchase Order shall provide for aggregate quantities for delivery [\*\*\*] provided, however, that, to the extent a Purchase Order sets forth quantities that are no less than [\*\*\*] and no more than [\*\*\*] of the quantities contained in such Forecast, then Amarin will use Commercially Reasonable Efforts to accommodate such amounts. [\*\*\*]

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**7.6.4 Receipt and Acceptance.** Subject to the terms and conditions of this Agreement, Amarin shall use Commercially Reasonable Efforts to supply, and Licensee shall purchase, all Finished Product or Bulk Product, as applicable, ordered and specified in a Purchase Order. Purchase Orders may be delivered electronically or by other means to such location as Amarin shall designate and shall be in a form reasonably acceptable to Amarin. Amarin shall provide written confirmation of such Purchase Order to Licensee within [\*\*\*] of receipt of such Purchase Order (the date of such written confirmation, the **“Purchase Order Acceptance Date”**). If Amarin fails to provide the written confirmation of such Purchase Order in a timely manner, such Purchase Order shall be deemed to have been duly accepted by Amarin and become legally binding upon the Parties on the [\*\*\*] after receipt by Amarin. Amarin shall accept any Purchase Order for Finished Product or Bulk Product, as applicable, that does not exceed the applicable maximum provided for in the most recent Forecast. If a Purchase Order, whether or not accepted, exceeds such applicable maximum, the Parties shall seek to agree on a reasonable manner of proceeding. Amarin shall use Commercially Reasonable Efforts to supply any amount of Finished Product or Bulk Product, as applicable, that Licensee orders pursuant to Section 7.6.3 in excess of the maximum amount deliverable under the ordering and forecasting procedures specified herein, but, in any event, such efforts shall not be construed as an obligation hereunder and in no event shall Amarin be deemed in breach of this Agreement by means of a failure to provide Finished Product or Bulk Product, as applicable, in excess of the Forecasted amount. Nothing in any such Purchase Order or written acceptance shall supersede the terms and conditions of this Agreement or the Quality Agreement, and in the event of a conflict between the terms such Purchase Order (or written acceptance, as applicable) and the terms of this Agreement (or the Quality Agreement, as applicable), the terms of this Agreement (or the Quality Agreement, as applicable) shall control. All Purchase Orders, written acceptances of Purchase Orders and other notices contemplated under this Section 7.6 shall be sent to the attention of such persons as each Party may identify to the other in writing from time to time in accordance with Section 16.3. In addition, (i) Amarin shall not be liable for any delays related to changes or other matters applicable to any camera-ready artwork or other materials or information provided by Licensee, and (ii) the Parties acknowledge that delivery times for clinical quantities may vary.

### **7.7 Supply Price, Invoicing, and Cost of Goods Audit.**

**7.7.1 Clinical and Commercial Supply.** Subject to Sections 4.4.1 and 5.2.2, the Finished Product or placebo supplied for Development in the Territory shall be invoiced [\*\*\*] To the extent that placebo requested by Licensee is different from placebo used by Amarin, then, in addition to the foregoing, Licensee shall reimburse Amarin for any additional costs incurred by Amarin to develop, Manufacture, qualify or obtain such placebo. The Finished Product or Bulk Product, as applicable, supplied for Commercialization in the Territory shall be invoiced at [\*\*\*]

**7.7.2 Invoice.** Each delivery of Finished Product hereunder for Development shall be accompanied by an invoice setting forth the Cost of Goods for such shipment, and each delivery of Finished Product or Bulk Product, as applicable, hereunder for Commercialization shall be accompanied by an invoice setting forth the Supply Price for such shipment. Licensee

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will make payment against each invoice, within the earlier of (a) [\*\*\*] after obtaining the affirmative drug testing report at the destination port for the Product covered by a given invoice (provided, that Licensee shall deliver a copy of such drug testing report in English to Amarin within such [\*\*\*] time period) or (b) [\*\*\*] after the Product arrives at the destination port.

**7.7.3 Cost of Goods Audit.** Licensee shall have the right to audit the calculation of Amarin’s Cost of Goods. Such audit shall be carried out in the same manner as the audit provisions of Section 8.10 which shall apply *mutatis mutandis* to both Parties to facilitate such right of audit.

## **7.8 Shipping and Delivery.**

**7.8.1 Delivery.** Subject to the terms and conditions of this Agreement, Amarin shall ship (or have shipped) to Licensee in accordance with this Section 7.8 the quantity of the Finished Product or Bulk Product, as applicable, specified in each accepted Purchase Order within [\*\*\*] from the Purchase Order Acceptance Date or otherwise as agreed to by the Parties. Notwithstanding anything to the contrary contained herein, (i) Amarin will notify Licensee of the anticipated [\*\*\*] (Incoterms 2010) [\*\*\*] at least [\*\*\*] prior to such [\*\*\*] (Incoterms 2010) [\*\*\*] date, which [\*\*\*] (Incoterms 2010) [\*\*\*] date may occur as many as [\*\*\*] from the Purchase Order Acceptance Date, and such shipment shall be deemed to have been shipped on a timely basis hereunder, and (ii) in order to allow for Finished Product or Bulk Product, as applicable, Manufacturing variances, Amarin shall be entitled to ship quantities of Finished Product or Bulk Product, as applicable, [\*\*\*] specified by Licensee in the applicable Purchase Order, and such shipment shall be deemed to have been shipped in satisfaction of Amarin’s obligations hereunder. Licensee shall purchase all such Finished Product or Bulk Product, as applicable, so shipped. The Finished Product or Bulk Product, as applicable, delivered by Amarin or its designee shall have at least [\*\*\*] shelf life upon arrival at the destination port in the Territory, subject to delays caused by customs and other Governmental Authorities.

**7.8.2 Shipment Terms.** Finished Product or Bulk Product, as applicable, shall be supplied to Licensee [\*\*\*] (Incoterms 2010) [\*\*\*]. Delivery shall occur, and title and risk of loss will pass to Licensee, when the Product is shipped to Licensee’s carrier. Finished Product or Bulk Product, as applicable, shall be shipped at Licensee’s expense via a carrier identified by Licensee in the applicable Purchase Order; provided, that (i) such carrier shall be one that can transport and maintain such Finished Product or Bulk Product, as applicable, in accordance with Product Specifications (e.g., controlled room temperature [\*\*\*] as per Product storage requirements), and (ii) in the event that Licensee fails to identify a carrier, Amarin may choose a carrier at its own reasonable discretion, at Licensee’s expense.

**7.8.3 Retention.** Unless the Parties agree otherwise, Amarin will maintain or cause to be maintained analytical samples of each Finished Product or Bulk Product, as applicable, in storage for a time period based upon Amarin’s sample retention policy.

## 7.9 Quality and Compliance.

**7.9.1 Quality Agreements.** The Quality Agreements will set forth the Parties’ quality and compliance obligations with respect to Manufacture of the Finished Product or Bulk Product, as applicable, and Amarin’s quality and compliance obligations with respect to Manufacture of the Drug Substance used in the Finished Product or Bulk Product, as applicable. Licensee and Amarin agree to comply with the requirements and provisions set forth in the Quality Agreements. The Quality Agreements will set forth in greater detail many of the responsibilities and obligations set forth herein. In the event of a conflict between the terms of the Quality Agreements and the terms of this Agreement, the terms of this Agreement shall prevail. The Parties shall execute the Quality Agreements within [\*\*\*] of the Effective Date, or such other time-frame as otherwise agreed between the Parties.

### 7.9.2 Notice of Non-Conformance.

(a) Amarin shall supply to Licensee the applicable batch number for the Finished Product or Bulk Product, as applicable, delivered as well as such other information as the Parties may set forth in the Quality Agreement with respect to the Manufacture of the Product (a “**Manufacturing Certificate of Analysis and Compliance**”) for all Finished Product or Bulk Product, as applicable, shipped to Licensee hereunder. Licensee shall promptly on receipt of each shipment of Finished Product or Bulk Product, as applicable, hereunder inspect, or cause to have inspected, each shipment of such Product for any damage, Defect or shortage, and cause to be tested by the qualified drug testing institution at the destination port in the Territory of each shipment of such Product for any quality issues, within a reasonable period of time and give Amarin written notice of any such damaged, defective or short shipment or any shipment of such Product with quality issues (a “**Notice of Non-Conformance**”). All testing shall be conducted in accordance with the Product Specifications and the Quality Agreement. “**Defect**” and “**Defective**” refer to Finished Product or Bulk Product, as applicable, that fails to meet the representations and warranties set forth in Section 10.2(j) as of the date of delivery.

(b) Latent Defects shall be communicated to Amarin, together with appropriate detail, via a Notice of Non-Conformance, without undue delay after such Latent Defect is first discovered by Licensee (or Licensee otherwise is notified of such Latent Defect), but in all cases within [\*\*\*] of the date on which such Latent Defect was first discovered by Licensee or was notified to Licensee by the relevant Person discovering the defect, and thereafter such Latent Defect shall be handled as set forth in the remainder of this Section 7.9 and/or the Quality Agreement, as applicable. For purposes of this Section 7.9.2(b), “**Latent Defects**” shall mean those defects that could not be discovered by inspection or testing by Licensee or its designee as described in Section 7.9.2(a). Notwithstanding the foregoing, Licensee must submit a Notice of Non-Conformance, if at all, with respect to Finished Product or Bulk Product, as applicable, no later than [\*\*\*] from the date of delivery of such Finished Product or Bulk Product, as applicable.

**7.9.3 Notification of Significant Quality Issues.** As set forth in the Quality Agreements, the Parties shall notify each other of the occurrence of a confirmed out-of specification or out-of-trend (“**OOS**”) result or major process deviation relating to the Product

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and/or Drug Substance in the Territory. The Parties agree to consult on all quality decisions regarding any OOS result or major process deviations involving the Finished Product or Bulk Product, as applicable, and/or Drug Substance that is intended for the Territory.

**7.9.4 Audits.** Licensee shall have access to Amarin’s or its Third Party manufacturer’s Facilities associated with the Finished Product or Bulk Product, as applicable, or Drug Substance at a mutually agreeable time for the sole purpose of auditing the Facilities for operational compliance with cGMPs and the content of the respective Quality Agreement for Finished Product or Bulk Product, as applicable, and Drug Substance. The right to audit also includes any testing Facility related to the Finished Product or Bulk Product, as applicable, or Drug Substance; provided, that, to the extent a Third Party’s Facilities are the subject of an audit pursuant to this Section 7.9.4, Licensee shall (a) perform such audit in conjunction with Amarin (and any other licensees of Amarin desiring to so audit), (b) bear any costs charged by such Third Party associated with such audit, and (c) abide by any applicable terms and conditions regarding such audit as Amarin’s agreement with such Third Party may provide (including any limitations on the number of such audits as may be conducted in a given a time-frame). For clarity, Amarin shall have the right to accompany Licensee on any such audit of a Third Party’s Facility. The audit rights described in this Section 7.9.4 are without limitation of other audit rights described elsewhere in this Agreement. The audit rights described herein may be exercised by Licensee [\*\*\*]. Notwithstanding anything in this Section 7.9.4 to the contrary, Licensee shall only have the right to audit a Third Party to the extent that Amarin has such right and such Third Party consents to Licensee accompanying Amarin on such audit.

## **7.10 Disputes and Remedies.**

**7.10.1 Disputes.** If Licensee timely delivers a Notice of Non-Conformance in respect of all or any part of a shipment of the Finished Product or Bulk Product, as applicable, and Amarin does not agree with Licensee’s determination that the Finished Product or Bulk Product, as applicable, fails to meet the Product Specifications (or there is a short shipment), the Parties shall in good faith attempt to resolve such dispute. Amarin and Licensee shall have [\*\*\*], unless otherwise agreed in writing by the Parties, from the date of Amarin’s receipt of a Notice of Non-Conformance to resolve such dispute regarding whether all or any part of such shipment of Finished Product or Bulk Product, as applicable, was Manufactured in conformance with the Product Specifications (or there is otherwise a short shipment). In the event of such a dispute, Licensee shall retain samples of such Finished Product or Bulk Product, as applicable, and make such samples available to Amarin at Amarin’s reasonable request. If the dispute regarding whether all or any part of a shipment of Finished Product or Bulk Product, as applicable, rejected by Licensee was Manufactured in conformance with the Product Specifications (or there is a short shipment) is not resolved in such [\*\*\*] period, then the Parties shall submit the samples of such Finished Product or Bulk Product, as applicable, to the drug testing institution in the Territory for re-testing. The results of the drug testing qualified institution’s re-testing shall be final and binding on the Parties, and if such Finished Product or Bulk Product, as applicable, is determined to meet the Product Specifications (or is otherwise determined not to be a short shipment, as applicable), then Licensee shall pay for the costs of such drug re-testing; otherwise Amarin shall pay for such costs.

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**7.10.2 Remedies.** In the event any shipment of Finished Product or Bulk Product, as applicable, is timely rejected pursuant to this Section 7.10 solely as a result of such Finished Product or Bulk Product, as applicable, being Defective, then (i) Licensee shall, at the direction of Amarin, either (a) destroy such rejected Finished Product or Bulk Product, as applicable, at Amarin’s reasonable expense (in accordance with Applicable Laws) or (b) return such Finished Product or Bulk Product, as applicable, to Amarin, at a location designated by Amarin and at Amarin’s reasonable expense, and (ii) Amarin, at no expense to Licensee, shall (in Amarin’s sole discretion) either (a) use its Commercially Reasonable Efforts to replace such non-conforming Finished Product or Bulk Product, as applicable, or short shipment, or (b) give Licensee a credit in an amount equal to the amount paid or payable by Licensee with respect to such rejected Finished Product or Bulk Product, as applicable, or short shipment. In the event that any shipment of Finished Product or Bulk Product, as applicable, is not timely rejected or is rejected for any reason other than being Defective, Amarin shall have no liability to Licensee in connection therewith, and Licensee shall, at its sole cost, destroy such rejected Finished Product or Bulk Product, as applicable, in compliance with Applicable Laws. SUBJECT TO SECTION 11.1, AMARIN’S LIABILITY IN RESPECT OF ANY REJECTION (INCLUDING ANY SHORT SHIPMENT) SHALL BE LIMITED TO THE REMEDIES PROVIDED IN THIS SECTION 7.10.2. For clarity, a shipment of Finished Product or Bulk Product, as applicable, that is a short shipment shall not be subject to return by Licensee.

**7.11 Shortages.** In the event that Amarin anticipates the materials and/or Manufacturing capacity of Amarin or its Third Party manufacturer required to Manufacture and deliver the Finished Product or Bulk Product, as applicable, to Licensee is to be in short supply, Amarin shall promptly notify Licensee of such shortage and the Parties shall promptly meet to discuss the shortage. Amarin shall provide a written plan of action stating in reasonable detail the identifiable cause of the shortage and proposed measures to remedy the shortage and the date such shortage is expected to end. Within [\*\*\*] after the occurrence of any shortage event, Amarin shall allocate its inventory of the Product, if any, among Licensee and Amarin, and its Affiliates, licensees and/or business partners for the Product world-wide, on a *pro-rata* basis, based upon market share and order volumes for the prior [\*\*\*] period until the Purchase Orders from Licensee can be adequately fulfilled. Upon the occurrence of a shortage event as described above, Amarin shall, for the limited purpose of complying with its inventory allocation obligations set forth above, provide Licensee with reports setting forth its annual world-wide sales of the Product within [\*\*\*] after the end of each Calendar Year. Notwithstanding anything to the contrary contained herein, the situation where the commercial success of the Product in the Territory is the reason for such shortage shall not constitute a “shortage” or mean that Amarin is “unable to supply” for purposes of this Section 7.11 (provided, that Amarin is using Commercially Reasonable Efforts to supply all of Licensee’s Purchase Orders in accordance with this Agreement, including the allocation set forth in this Section 7.11). Amarin shall use its Commercially Reasonable Efforts to minimize the duration of any shortage. Licensee shall maintain reasonable safety stock of Finished Product or Bulk Product, as applicable, of at least [\*\*\*] of safety stock of the Product based on [\*\*\*] binding portion of the most recent Forecast.

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**7.12 Product Specification and Manufacturing Changes.** Neither Party shall make any Product Specification changes and/or Drug Substance Specification changes as it pertains to the Product to be supplied in the Field in the Territory without prior written consent of the other Party, such consent not to be unreasonably withheld. In the event of such consent, the Parties shall enter into a written supplemental agreement with respect to the division of responsibilities for obtaining Regulatory Approvals of such changes and the cost to be assumed by each Party in connection therewith. Amarin shall notify Licensee in writing (i) [\*\*\*] before it changes the Facility used to Manufacture the supply of the Product in the Field in the Territory and any Product Specification for the Product in the Field in the Territory applicable to the Regulatory Materials filed with CFDA, or (ii) [\*\*\*] before it makes any changes within the Facility for the Product in the Field in the Territory applicable to the Regulatory Materials filed with CFDA. Each Party shall provide the other Party with all necessary documentation and information required for preparing the applicable Regulatory Materials with CFDA; provided, that all applicable Regulatory Materials shall be prepared and filed by the Parties in accordance with the provisions of ARTICLE 5 and each Party shall bear its respective costs and expenses incurred in connection therewith. Notwithstanding the foregoing and the forecasting and ordering provisions under Section 7.6, Amarin shall use Commercially Reasonable Efforts to ensure the sufficient supply of Product to Licensee during the transitional period for the changes set forth in this Section 7.12. Amarin and Licensee shall discuss means to ensure supply throughout this transition period and the Parties may be required to hold a safety stock of Product at each of their respective sites to mitigate any supply shortages that may occur as a result of such changes. For clarity, changes made with respect to the Facilities or other sites that are applicable to the supply of Product outside the Field or outside the Territory, or otherwise not applicable to the Regulatory Materials filed with CFDA with respect to the supply of the Product in the Field in the Territory, will not be subject to this Section 7.12.

**7.13 Termination of Supply Obligations.** Notwithstanding anything to the contrary contained herein, the obligations of Amarin under this ARTICLE 7, including the obligations to Manufacture and supply Finished Product or Bulk Product, as applicable, to Licensee hereunder, and Licensee’s obligations to purchase solely from Amarin, shall continue during the Royalty Term and, so long as Amarin desires to continue supplying the Finished Product or Bulk Product, as applicable, shall continue after the end of the Royalty Term, upon reasonable terms and conditions to be agreed between the Parties. [\*\*\*]

## **ARTICLE 8 PAYMENTS**

**8.1 Upfront Payment.** On the Effective Date, Licensee shall pay to Amarin an upfront amount equal to fifteen million Dollars (\$15,000,000) (the “Upfront Payment”) by wire transfer of immediately available funds into an account designated in writing by Amarin. The Upfront Payment shall be nonrefundable and noncreditable against any other payments due hereunder.

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**8.2 Milestone Payments.** Licensee shall pay to Amarin the milestone payments described in this Section 8.2 following achievement (first occurrence) of the corresponding milestone event. A Party shall promptly notify the other Party in writing of, but in no event later than [\*\*\*] after, the achievement (first occurrence) of each such milestone event (each, a “**Milestone Notification Notice**”) achieved by it. Licensee shall pay the applicable milestone payment by wire transfer of immediately available funds into an account designated by Amarin within [\*\*\*] after the date of the Milestone Notification Notice; provided, however, that in no event shall a failure to deliver a Milestone Notification Notice relieve Licensee of its obligation to pay Amarin the milestone payments described in this Section 8.2. Each such milestone payment shall be payable only once regardless of how many times the milestone event is achieved. Each such milestone payment is nonrefundable and noncreditable against any other payments due hereunder.

<u>Milestone Event</u>	<u>Milestone Payment</u>
<b>Regulatory Milestones</b>	
Very High Triglycerides	
[***]	[***]
[***]	[***]
High Triglycerides	
[***]	[***]
[***]	[***]
Cardiovascular Risk Reduction*	
[***]	[***]
[***]	[***]
[***]	[***]
Sales Based Milestones	
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
<b>Total Possible Milestone Event Payments:</b>	<b>One Hundred Fifty Four Million Dollars (\$154,000,000)</b>

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### 8.3 Royalty Payments; Sublicense Income.

**8.3.1 Royalty Payments.** As further consideration for the rights granted to Licensee under this Agreement, Licensee shall pay to Amarin tiered payments (“**Royalty Payments**”) at the following rates (the “**Royalty Rates**”) based on aggregate annual Net Sales of Product in the Territory for all or any portion of the Calendar Year falling within the Royalty Term for such Product:

<u>Calendar Year Net Sales</u>	<u>Royalty Rate</u>
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

**8.3.2 Sublicense Income.** In addition to other amounts due under this Section 8.3, Licensee will pay Amarin [\*\*\*] of all Sublicense Income received during a given [\*\*\*] (“**Sublicense Income Payment**”).

**8.4 Royalty Reports and Payment Procedures.** Licensee shall calculate all (i) Royalty Payments with respect to Net Sales, and (b) Sublicense Income, payable to Amarin pursuant to Section 8.3 at the end of each [\*\*\*], which amounts shall be converted to Dollars at such time in accordance with Section 8.6. Licensee shall provide a written estimate of Sublicense Income received and Net Sales during the just ended [\*\*\*] within [\*\*\*] of the end of such [\*\*\*]. Thereafter, Licensee shall pay to Amarin the Royalty Payment due for Net Sales, and Sublicense Income Payment due for Sublicense Income, during a given [\*\*\*] within [\*\*\*] following the end of such [\*\*\*]. Each Royalty Payment and Sublicense Income Payment due to Amarin shall be accompanied by (i) a statement of the amount of gross sales of the Product in the Territory, and gross Sublicense Income received, during the applicable [\*\*\*] (such amounts expressed in local currency and in Dollars converted at the relevant time in accordance with Section 8.6), (ii) an itemized calculation of Net Sales in the Territory, showing each deduction provided for in the definition of “Net Sales” during such [\*\*\*], and (iii) a calculation of the amount of the Royalty Payment due on such Net Sales, and the Sublicense Income Payment due on such Sublicense Income, for such [\*\*\*]. Without limiting the generality of the foregoing, Licensee shall require its Affiliates and Sublicensees (if any) to account for its Net Sales and to provide such reports with respect thereto as if such sales were made by Licensee.

**8.5 Taxes and Withholding.** Each of the Parties, respectively, shall pay and/or withhold taxes in accordance with Applicable Laws.

**8.5.1 VAT.** The Parties agree to cooperate with one another and use reasonable efforts to ensure that value added tax or similar payment (“**VAT**”) in respect of any payments made by Licensee to Amarin under this Agreement does not represent an unnecessary cost in respect of payments made under this Agreement. For purposes of clarity, all sums payable under this Agreement shall be exclusive of VAT. In the event that any VAT is owing in any jurisdiction in respect of any such payment, Licensee shall pay such VAT, and (i) if such VAT is owing as a result of any action by Licensee, including any assignment or sublicense (including assignment to, or payment hereunder by, another Licensee-related entity or Affiliate), or any failure on the part of Licensee or its Affiliates to comply with applicable tax laws or filing or

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record retention requirements, that has the effect of modifying the tax treatment of the Parties hereto, then the payment in respect of which such VAT is owing shall be made without deduction for or on account of such VAT to ensure that Amarin receives a sum equal to the sum which it would have received had such VAT not been due or (ii) otherwise, such payment shall be made after deduction of such VAT. For the sake of clarity, any increase in payments to Amarin under this Section 8.5 shall reflect only the incremental increase in VAT directly resulting from clause (i) above. In the event that any VAT is owing in any jurisdiction in respect of any such payment, Amarin will provide to Licensee tax invoices showing the correct amount of VAT in respect of such payments hereunder.

**8.6 Withholding Tax.** If Licensee is required to make a payment to Amarin that is subject to a deduction of tax or withholding tax under the Applicable Laws, the sum payable by Licensee to Amarin shall be net of any such deduction or withholding tax and any amount so deducted or withheld by Licensee shall be remitted in accordance with the Applicable Laws. Any such deduction or withholding tax required to be paid or withheld by Licensee under the Applicable Laws shall be an expense of, and borne solely by, Amarin. Licensee shall not change its methodology or procedures for payments under this Agreement without the prior written consent of Amarin. For clarity, any business tax due under Applicable Laws in the Territory shall be borne by Licensee as an Indirect Tax in accordance with Section 8.6.2.

**8.6.1 Tax Cooperation.** To the extent Licensee is required to deduct and withhold taxes on any payments to Amarin, Licensee shall pay the amounts of such taxes to the proper Governmental Authority in a timely manner and promptly transmit to Amarin an official tax certificate or other evidence of such withholding sufficient to enable Amarin to claim such payments of taxes. Amarin shall provide to Licensee any tax forms that may be reasonably necessary in order for Licensee not to withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. Amarin shall use reasonable efforts to provide any such tax forms to Licensee at least [\*\*\*] prior to the due date for any payments for which Amarin desires that Licensee apply a reduced withholding rate. Each Party shall provide the other with reasonable assistance to enable the recovery, as permitted by Applicable Laws, of withholding taxes, VAT, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding tax or VAT.

**8.6.2 Indirect Tax.** All payments to be made by Licensee to Amarin pursuant to the terms of this Agreement are stated exclusive of Indirect Taxes. If any Indirect Taxes are chargeable in respect of such payments, Licensee shall pay such Indirect Taxes.

**8.7 Currency Conversion.** All payments hereunder shall be made in Dollars. For the purpose of calculating any sums due under, or otherwise reimbursable pursuant to, this Agreement (including the calculation of Net Sales expressed in currencies other than Dollars), any amount expressed in a foreign currency shall be converted into Dollars based on the applicable exchange rate quoted on “[www.oanda.com](http://www.oanda.com)” for the last day of the relevant [\*\*\*] or the date that a milestone is achieved.

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**8.8 General Payment Procedures.** Unless otherwise expressly payable in certain time frames as provided in this Agreement (including Section 7.7.1), the receiving Party shall invoice the paying Party for all amounts due to such receiving Party under this Agreement, and such payments shall be made within [\*\*\*] following the receipt by the paying Party of an invoice from the receiving Party specifying the amount due.

**8.9 Late Payments.** Any amount required to be paid by a Party hereunder which is not paid within [\*\*\*] after the date due shall bear interest at a rate equal to the [\*\*\*]. Such interest shall be computed on the basis of a year of [\*\*\*] for the actual number of days payment is delinquent. Interest charged and paid with respect to any late payments will not limit any other remedies that may be available to a Party.

**8.10 Financial Records and Audit.** Licensee (and its Affiliates and Sublicensees) shall keep full, true and accurate records and books of account containing all particulars that may be necessary for the purpose of confirming the accuracy of, and calculating, as applicable, all Royalty Payments, Sublicense Income Payments and other amounts payable to Amarin hereunder (including records of Net Sales and Sublicense Income), for a minimum period of [\*\*\*] or such longer period as required by Applicable Laws. Amarin shall have a right to request an audit of Licensee by an independent, internationally recognized accounting firm in order to confirm the accuracy of the foregoing (a “**Financial Audit**”). Upon the written request by Amarin to Licensee to conduct a Financial Audit, Amarin shall have the right to engage an independent, internationally recognized accounting firm to perform a review as is reasonably necessary to enable such accounting firm to calculate or otherwise confirm the accuracy of any of the foregoing for the Calendar Year(s) requested by Amarin; provided, that (i) such accountants shall be given access to, and shall be permitted to examine and copy such books and records of Licensee upon [\*\*\*] prior written notice to Licensee, (ii) prior to any such examination taking place, such accountants shall enter into a confidentiality agreement with Licensee reasonably acceptable to Licensee in order to keep all information and data contained in such books and records strictly confidential and shall not disclose such information or copies of such books and records to any third person including Amarin, but shall only use the same for the purpose of the reviews and/or calculations which they need to perform in order to determine any amounts being reviewed, and (iii) such accountants shall use reasonable efforts to minimize any disruption to Licensee’s business. Licensee shall make personnel reasonably available during regular business hours to answer queries on all such books and records required for the purpose of the Financial Audit. The accountants shall deliver a copy of their findings to each of the Parties within [\*\*\*] of the completion of the review, and, in the absence of fraud or manifest error, the findings of such accountant shall be final and binding on each of the Parties. Any underpayments by Licensee shall be paid to Amarin within [\*\*\*] of notification of the results of such inspection. Any overpayments made by Licensee shall be refunded by Amarin within [\*\*\*] of notification of the results of such inspection. The cost of the accountants shall be the responsibility of [\*\*\*] unless the accountants’ calculation shows that the actual royalties payable, Net Sales, Sublicense Income and/or any other applicable amount audited hereunder to be different, by more than [\*\*\*]. Without limitation of the foregoing, Licensee shall have the right to audit the calculation of any costs incurred by Amarin and with respect to which Amarin is

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seeking reimbursement from Licensee hereunder, on the same terms and conditions as Amarin may audit Licensee’s records under this Section 8.10 (substituting references to “Amarin” for “Licensee”, and vice versa, and substituting references to “Development Costs” or “Regulatory Costs”, as the case may be, for “Net Sales”). The audit rights described in this Section 8.10 are without limitation of other audit rights described elsewhere in this Agreement.

## ARTICLE 9 INTELLECTUAL PROPERTY MATTERS

### 9.1 Ownership of Intellectual Property.

**9.1.1 General.** Subject to the provisions of this Section 9.1.1 and except as expressly set forth otherwise in this Agreement, (i) Amarin shall solely own, and it alone shall have the right to apply for, Amarin Patents within and outside of the Territory, and (ii) Licensee shall solely own, and it alone shall have the right to apply for, Licensee Patents within and outside of the Territory. With respect to any Patents Covering any Joint Invention (“**Joint Patents**”), Licensee shall assign (and shall cause its Affiliates, Sublicensees and subcontractors to assign), and hereby does assign, any and all of Licensee’s (and its Affiliates’, Sublicensees’ and subcontractors’) right, title and interest in and to such Joint Patents, to Amarin, such that Amarin shall solely own such Joint Patents, and thereafter any Confidential Information contained therein shall be deemed “Confidential Information” of Amarin. Each Party shall promptly disclose to the other Party all Amarin Inventions, Licensee Inventions and Joint Inventions, as applicable, made by it during the Term. The determination of inventorship for such Inventions shall be made in accordance with Applicable Laws relating to inventorship set forth in the patent Applicable Laws of the United States (Title 35, United States Code). Licensee agrees that it shall not grant any license or other right with respect to the Licensee Inventions to any Third Party without the prior written consent of Amarin.

**9.1.2 Employees.** Each Party will require all of its and its Affiliates’ employees to assign all Inventions that are developed, made or conceived by such employees according to the ownership principles described in Section 9.1.1 free and clear of all liens, encumbrances, charges, security interests, mortgages or other similar restrictions. Each Party will also use its Commercially Reasonable Efforts to require any agents or independent contractors performing an activity pursuant to this Agreement to assign all Inventions that are developed, made or conceived by such agents or independent contractors to Amarin and/or Licensee according to the ownership principles described in Section 9.1.1 free and clear of all liens, encumbrances, charges, security interests, mortgages or other similar restrictions.

**9.2 Disclosures; Disputes Regarding Inventions.** Each Party shall, before filing a new Patent application (including provisionals and continuations-in-part) claiming or covering an Invention, promptly disclose such Invention to the other Party and shall provide the other Party with a copy of the proposed patent application at least [\*\*\*] before filing such application or such shorter time as may be required to preserve Patent rights, including the avoidance of a statutory bar or prior publication. If the non-filing Party believes that the filing Party’s

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proposed Patent application discloses Confidential Information of the non-filing Party, the non-filing Party shall so notify the filing Party within such [\*\*\*] after receipt thereof, and the filing Party shall amend its proposed application to comply with the confidentiality provisions of this Agreement. If the Parties are in agreement as to the designation of the Invention as an Amarin Invention, Joint Invention or Licensee Invention, as applicable, they can continue as set forth in Section 9.3. If the Parties disagree as to whether an Invention is an Amarin Invention, Joint Invention or Licensee Invention, and are unable to reach agreement within thirty (30) days after commencing discussions, then the provisions of ARTICLE 15 shall apply to such dispute.

### **9.3 Patent Filings, Prosecution and Maintenance.**

#### **9.3.1 Amarin Patents.**

(a) Subject to, and without limiting Licensee’s rights under, Section 9.4 of this Agreement, Amarin shall have the first right to prepare, file, prosecute and maintain all Amarin Patents, at its own cost and expense. Amarin shall keep Licensee informed of the status of Amarin Patents and will provide Licensee with copies of all substantive documentation submitted to, or received from, the patent offices in connection therewith. With respect to any substantive submissions that Amarin is required to or otherwise intends to submit to a patent office in the Territory with respect to an Amarin Patent, Amarin shall provide a draft of such submission to Licensee at least [\*\*\*] (or such time as is possible) prior to the deadline for, or the intended filing date of, such submission, whichever is earlier (or as soon as reasonably possible if Amarin has less than [\*\*\*] notice of a deadline for submission). Licensee shall have the right to review and comment upon any such submission by Amarin to a patent office in the Territory, and will provide such comments within [\*\*\*] after receiving such submission (provided, that if no comments are received within such [\*\*\*] period, then Amarin may proceed with such submission). Amarin shall consider in good faith any suggestions or recommendations of Licensee concerning the preparation, filing, prosecution and maintenance thereof.

(b) If, during the Term, Amarin (a) intends to allow any Amarin Patent to which Licensee has a license under this Agreement to expire or intends to otherwise abandon any such Amarin Patent, or (b) decides not to prepare or file patent applications covering Amarin Inventions in the Territory to which Licensee would otherwise have a license under this Agreement, Amarin shall notify Licensee of such intention or decision at least [\*\*\*] (or as soon as possible if less than [\*\*\*]) prior to any filing or payment due date, or any other date that requires action, in connection with such Amarin Patent or Amarin Inventions, and Licensee shall thereupon have the right, but not the obligation, to assume responsibility for the preparation, filing, prosecution or maintenance thereof at its sole cost and expense, in the name of Licensee.

### 9.3.2 Joint Patents.

(a) Subject to, and without limiting Licensee’s rights under, Section 9.4 of this Agreement, Amarin shall have the first right to prepare, file, prosecute and maintain Joint Patents. Amarin shall keep Licensee informed of the status of Joint Patents and will provide Licensee with copies of all substantive documentation submitted to, or received from, the patent offices in connection therewith. With respect to any substantive submissions that Amarin is required to or otherwise intends to submit to a patent office with respect to a Joint Patent, Amarin shall provide a draft of such submission to Licensee at least [\*\*\*] (or such time as is possible) prior to the deadline for, or the intended filing date of, such submission, whichever is earlier (or as soon as reasonably possible if Amarin has less than [\*\*\*] notice of a deadline for submission). Licensee shall have the right to review and comment upon any such submission by Amarin to a patent office, and will provide such comments within [\*\*\*] after receiving such submission (provided, that if no comments are received within such [\*\*\*], then Amarin may proceed with such submission). Amarin shall consider in good faith any suggestions or recommendations of Licensee concerning the preparation, filing, prosecution and maintenance thereof.

(b) If, during the Term, Amarin (i) intends to allow any Joint Patent to expire or intends to otherwise abandon any such Joint Patent (“**Abandoned Patents**”), or (ii) decides not to prepare or file patent applications covering Joint Inventions (“**Abandoned Joint Inventions**”) Amarin shall notify Licensee of such intention or decision at least [\*\*\*] (or as soon as possible if less than [\*\*\*]) prior to any filing or payment due date, or any other date that requires action, in connection with such Abandoned Patent or Abandoned Joint Invention, and Licensee shall thereupon have the right, but not the obligation, to assume responsibility for the preparation, filing, prosecution or maintenance thereof at its sole cost and expense, in the name of Licensee.

### 9.3.3 Licensee Patents.

(a) Licensee shall have the first right to prepare, file, prosecute and maintain all Licensee Patents, at its own cost and expense. Licensee shall keep Amarin informed of the status of Licensee Patents and will provide Amarin with copies of all substantive documentation submitted to, or received from, the patent offices in connection therewith. With respect to any substantive submissions that Licensee is required to or otherwise intends to submit to a patent office with respect to a Licensee Patent, Licensee shall provide a draft of such submission to Amarin at least [\*\*\*] (or such time as is possible) prior to the deadline for, or the intended filing date of, such submission, whichever is earlier (or as soon as reasonably possible if Licensee has less than [\*\*\*] notice of a deadline for submission). Amarin shall have the right to review and comment upon any such submission by Licensee to a patent office, and will provide such comments within [\*\*\*] after receiving such submission (provided, that if no comments are received within such [\*\*\*], then Licensee may proceed with such submission). Licensee shall consider in good faith any suggestions or recommendations of Amarin concerning the preparation, filing, prosecution and maintenance thereof.

(b) With respect to the Licensee Patents outside of the Territory, Licensee shall notify Amarin before entering such Licensee Patent into national phase filings, and if Amarin notifies Licensee that Amarin desires to prepare, file, prosecute and

maintain (at its own expense) such Licensee Patent, said patent will be assigned, after completion of national phase filing, to Amarin at Amarin’s expense, without any compensation to Licensee, and Amarin shall have the right at Amarin’s expense to prepare, file, prosecute and maintain such Licensee Patent as assigned to Amarin. If Amarin does not notify Licensee that Amarin desires to do so, then such Licensee Patent may be abandoned.

(c) If, during the Term, Licensee (a) intends to allow any Licensee Patent to which Amarin has a license under this Agreement to expire or intends to otherwise abandon any such Licensee Patent, or (b) decides not to prepare or file patent applications covering Licensee Know-How or Licensee Inventions to which Amarin would otherwise have a license under this Agreement, Licensee shall notify Amarin of such intention or decision at least thirty (30) days (or as soon as possible if less than thirty (30) days) prior to any filing or payment due date, or any other date that requires action, in connection with such Licensee Patent or Licensee Inventions, and Amarin shall thereupon have the right, but not the obligation, to assume responsibility for the preparation, filing, prosecution or maintenance thereof at its sole cost and expense, in the name of Amarin, and, to the extent such Licensee Patent Covers a Licensee Invention, Licensee shall, and hereby does, assign to Amarin Licensee’s entire right, title and interest in and to any such Licensee Patents (rendering, for clarity, such Licensee Patent an Amarin Patent hereunder).

**9.3.4 Cooperation.** The Parties agree to reasonably cooperate in the preparation, filing, prosecution and maintenance of all Patents under this Section 9.3, including obtaining and executing necessary powers of attorney and assignments by the named inventors, providing relevant technical reports to the filing Party concerning the Invention disclosed in such Patent, obtaining execution of such other documents which are needed in the filing and prosecution of such Patent, and, as requested by a Party, updating each other regarding the status of such Patent, and shall cooperate with the other Party so far as reasonably necessary with respect to furnishing all information and data in its possession reasonably necessary to obtain or maintain such Patents.

**9.3.5 Patent Expenses.** Any expenses incurred by a Party in connection with the preparation, filing, prosecution and maintenance of any Amarin Patents, Joint Patents or Licensee Patents, as applicable, shall be borne by the Party incurring such expenses.

#### **9.4 Defense and Enforcement of Patents.**

**9.4.1 Infringement of Third Party Patents.** Each of the Parties shall promptly, but in any event no later than [\*\*\*] after receipt of notice thereof, notify the other Party in writing in the event of any claims by a Third Party of alleged patent infringement by Licensee or Amarin or any of their respective Affiliates or sublicensees (in the case of Amarin) or Sublicensees (in the case of Licensee) with respect to the research, development, manufacture, use, sale, offer for sale or importation of a Product (each, an “**Infringement Claim**”). With respect to any Infringement Claim in the Field in the Territory, the Parties shall attempt to negotiate in good faith a resolution with respect thereto. If the Parties cannot settle such Infringement Claim with the appropriate Third Parties within [\*\*\*] after the receipt of the notice pursuant to this Section 9.4.1, then the following shall apply:

(a) In the case of any such Infringement Claim, in respect of a patent owned by Licensee, then Licensee shall be deemed to be the “**Controlling Party**” for purposes of such Infringement Claim. In the case of any Infringement Claim, in respect of a patent owned by Amarin, then Amarin shall be deemed to be the “**Controlling Party**” for purposes of such Infringement Claim. Each Party shall reasonably assist the other in its role as the Controlling Party.

(b) The Controlling Party shall assume control of the defense of such Infringement Claim. The non-Controlling Party, upon request of the Controlling Party, agrees to join in any such litigation at the Controlling Party’s expense, and in any event to reasonably cooperate with the Controlling Party at the Controlling Party’s expense. The non-Controlling Party will have the right to consult with the Controlling Party concerning such Infringement Claim and to participate in and be represented by independent counsel in any litigation in which such non-Controlling Party is a party at its own expense. The Controlling Party shall have the exclusive right to settle any Infringement Claim without the consent of the other Party, unless such settlement shall have a material adverse impact on the other Party (in which case the consent of such other Party shall be required). For purposes of this Section 9.4.1(b), any settlement that would involve the waiver of rights (including the rights to receive payments) of such other Party shall be deemed a material adverse impact and shall require the consent of such other Party, such consent not to be unreasonably withheld.

(c) If a Party shall become engaged in or participate in any suit described in this Section 9.4.1, the other Party shall cooperate, and shall cause its and its Affiliates’ employees to cooperate, with such Party in all reasonable respects in connection therewith, including giving testimony and producing documents lawfully requested, and using its reasonable efforts to make available to the other, at no cost to the other (other than reimbursement of actually incurred, reasonable Out-of-Pocket Costs associated with travel and lodging), such employees who may be helpful with respect to such suit, investigation, claim or other proceeding.

#### **9.4.2 Prosecution of Infringers.**

(a) **Notice.** If either Party (i) receives notice of any patent nullity actions, any declaratory judgment actions or any alleged or threatened infringement of patents or patent applications or misappropriation of intellectual property in the Territory comprising the (w) Joint Inventions or Joint Patents, (x) Amarin Patents, Amarin Inventions or Amarin Know-How or (y) Licensee Patents, Licensee Inventions or Licensee Know-How, or (ii) learns that a Third Party is infringing or allegedly infringing any Patent within the Amarin Patents, Joint Patents or Licensee Patents in each case, in the Territory, or if any Third Party claims that any such Patent is invalid or unenforceable, in each case, with respect to the Field in the Territory, it shall promptly notify the other Party thereof, including providing evidence of infringement or the claim of invalidity or unenforceability reasonably available to such Party.

**(b) Enforcement of Patents.**

(i) As between Amarin and Licensee, Amarin shall have the first right (but not the obligation) to take the appropriate steps to enforce or defend any Patent within the Amarin Patents and Joint Patents against infringement by a Third Party that is conducting the manufacture, sale, use, offer for sale or import of any pharmaceutical product in the Field in the Territory. Amarin may take steps including the initiation, prosecution and control of any suit, proceeding or other legal action by counsel of its own choice. Amarin shall bear the costs of such enforcement or defense, as applicable. Notwithstanding the foregoing, Licensee will have the right, at its own expense, to be represented in any such action by counsel of its own choice.

(ii) If, pursuant to Section 9.4.2(b)(i), Amarin fails to institute such litigation or otherwise take steps to remedy the infringement of an Amarin Patent or a Joint Patent within [\*\*\*] of the date one Party has provided notice to the other Party pursuant to Section 9.4.2(a) of such infringement or claim, then Licensee shall have the right (but not the obligation), at its own expense, to bring any such suit, action or proceeding by counsel of its own choice and Amarin will have the right, at its own expense, to be represented in any such action by counsel of its own choice. Notwithstanding anything to the contrary contained herein, in no event shall Licensee have any right to bring any suit, action or proceeding with respect to any matter involving infringement of an Amarin Manufacturing Patent, or a Patent outside the Territory or outside the Field.

**(c) Cooperation; Damages.**

(i) If one Party brings any suit, action or proceeding under Section 9.4.2(b), the other Party agrees to be joined as party plaintiff if necessary to prosecute the suit, action or proceeding and to give the first Party reasonable authority to file and prosecute the suit, action or proceeding; provided, however, that neither Party will be required to transfer any right, title or interest in or to any property to the other Party or any other party to confer standing on a Party hereunder.

(ii) The Party not pursuing the suit, action or proceeding hereunder will provide reasonable assistance to the other Party, including by providing access to relevant documents and other evidence and making its employees available, subject to the other Party's reimbursement of any Out-of-Pocket Costs incurred by the non-enforcing or defending Party in providing such assistance.

(iii) Licensee shall not, without the prior written consent of Amarin (in its sole discretion), enter into any compromise or settlement relating to any claim, suit or action that it brought under Section 9.4.2 involving an Amarin Patent or a Joint Patent, that admits the invalidity or unenforceability of any Amarin Patent or any Joint Patent, or requires Amarin to pay any sum of money, or otherwise adversely affects the rights of Amarin with respect to such Patents, the Product or Amarin's rights hereunder (including the rights to receive payments).

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(iv) Any settlements, damages or other monetary awards (a “**Recovery**”) recovered pursuant to a suit, action or proceeding brought pursuant to Section 9.4.2(b) will be allocated first to the costs and expenses of the Party taking such action, and second, to the costs and expenses (if any) of the other Party, with any remaining amounts (if any) to be allocated as follows: (i) to the extent that such Recovery is a payment for lost sales of the Product in the Field in the Territory, (a) if Licensee is the Party taking such action, then Licensee shall pay a Royalty Payment to Amarin pursuant to Section 8.3 with respect to the imputed loss in Net Sales out of any such Recovery or (b) if Amarin is the Party taking such action, then any such Recovery shall be shared equally by Amarin and Licensee and (ii) all remaining Recoveries shall be payable to the Party taking such action to the extent such remaining Recoveries relate solely to the Product in the Field in the Territory (and, for purposes of clarity, all remaining Recoveries related to the Product outside the Field or outside the Territory shall be payable to Amarin).

(d) **Infringement and Defense of Amarin Patents Outside of the Territory or Outside the Field.** For clarity, with respect to any and all infringement or defense of any Patent Controlled by Amarin (including a Joint Patent) anywhere outside of the Territory or any Amarin Patent outside the Field, Amarin (or its designee) shall have the sole and exclusive right to bring an appropriate suit or other action against any Person engaged in such infringement or defense of any such Patents (including any Joint Patents), in its sole discretion and Licensee shall have no rights with respect thereto.

**9.5 Patent Term Extensions.** As between Amarin and Licensee, Amarin shall have the exclusive right, but not the obligation, to seek, in Licensee’s name if so required, Patent Term Extensions (including any supplemental protection certificates and the like available under Applicable Laws) in the Territory in relation to the Amarin Patents (including Joint Patents). Licensee and Amarin shall cooperate in connection with all such activities. Amarin, its agents and attorneys will give due consideration to all suggestions and comments of Licensee regarding any such activities, but in the event of a disagreement between the Parties, Amarin shall have the final decision making authority.

**9.6 Patent Marking.** Licensee shall mark the Product marketed and sold by Licensee (or its Affiliate, wholesaler or distributor) hereunder with appropriate patent numbers or indicia, as long as it is required by Applicable Laws.

**9.7 Patent Challenge.** Amarin will be permitted to terminate this Agreement upon written notice to Licensee, effective upon receipt, if Licensee (or of its Affiliates, Sublicensees, subcontractors, wholesalers or distributors), directly or indirectly, (i) initiate or request an interference or opposition proceeding with respect to, or (ii) make, file or maintain any claim, demand, lawsuit or cause of action to challenge the validity or enforceability of, or, to the extent applicable, oppose any extension of, or the grant of a supplementary protection certificate with respect to, any Amarin Patent or Amarin Manufacturing Patent (each of clause (i) or (ii), a “**Patent Challenge**”).

**ARTICLE 10**  
**REPRESENTATIONS, WARRANTIES AND COVENANTS**

**10.1 Mutual Representations and Warranties.** Each Party hereby represents, warrants, and covenants (as applicable) to the other Party as follows, as of the Effective Date:

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

(c) 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.

(d) Except with respect to Regulatory Approvals for the Development, Manufacturing or Commercialization of the Product or as otherwise described in this Agreement, (i) all necessary consents, approvals and authorizations of, and (ii) all notices to, and filings by such Party with, all Governmental Authorities and other Persons required to be obtained or provided by such Party as of the Effective Date in connection with the execution, delivery and performance of this Agreement have been obtained and provided, except for those approvals, if any, not required at the time of execution of this Agreement.

(e) In the course of the Development of Products, such Party has not used prior to the Effective Date and shall not use, during the Term, any employee, agent or, to its knowledge, independent contractor who has been debarred by any Regulatory Authority, or, to such Party's knowledge, is the subject of debarment proceedings by a Regulatory Authority.

**10.2 Additional Representations, Warranties and Covenants of Amarin.** Amarin hereby represents, warrants and covenants (as applicable) to Licensee that:

(a) As of the Effective Date, Amarin has not filed any Imported Drug License with a Governmental Authority in the Territory for the sale of the Finished Product or Bulk Product in the Territory, and, to the knowledge of Amarin, no application for Product Approval for any Competing Product has been filed with the CFDA by any Third Party which would block the application for Product Approval for the Product in the Territory.

(b) As of the Effective Date, Amarin is the owner or licensee of, and has the right to license, the Amarin Patents, Amarin Know-How, necessary to make, use and sell the Product in the Field in the Territory.

(c) As of the Effective Date, neither Amarin nor its Affiliates, nor, to the knowledge of Amarin, its subcontractors nor sublicensees, has received written notice of any proceedings pending before or threatened by any Regulatory Authority with respect to the Product or any Facility where the Product is Manufactured.

(d) As of the Effective Date, to the knowledge of Amarin, no Third Party (i) is infringing any Amarin Patents or Amarin Manufacturing Patents or has misappropriated any Amarin Technology or Amarin Manufacturing Know-How or (ii) has challenged the scope, duration, validity, enforceability, priority, or Amarin’s right to use or license any Amarin Technology, Amarin Manufacturing Patent or Amarin Manufacturing Know-How.

(e) As of the Effective Date, Amarin (or its Affiliate) is the exclusive owner of the trademark registrations for VASCEPA™ as displayed on Schedule 6.9.1.

(f) As of the Effective Date, the knowledge of Amarin, Amarin nor its Affiliates have received any written warning that any Patent, trademark or other intellectual property right owned by a Third Party would be infringed by research, development manufacture, use, sale, offer for sale, or import of the Product in the Field in the Territory.

(g) As of the Effective Date, Amarin has obtained assignments from the inventors of all inventorship rights relating to the Amarin Patents which are owned by Amarin, and, to the knowledge of Amarin, all such assignments of inventorship rights relating to such Amarin Patents are valid and enforceable.

(h) As of the Effective Date, to the knowledge of Amarin, Amarin has complied with all Applicable Laws, in all material respects, including any disclosure requirements, in connection with the filing, prosecution and maintenance of the Amarin Patents owned by Amarin.

(i) During the Term, Amarin shall use Commercially Reasonable Efforts to maintain valid Regulatory Approvals for the Product in the U.S.

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(j) During the Term, the Finished Product or Bulk Product, as applicable, furnished by Amarin to Licensee under this Agreement:

(i) shall be manufactured, handled, stored and shipped by Amarin, in accordance with, and shall conform to, the applicable Product Specifications;

(ii) shall be manufactured, handled and stored by or on behalf of Amarin in compliance with all Applicable Laws, including GMPs; and

(iii) shall be manufactured using Drug Substance which is manufactured, handled, stored and shipped by or on behalf of Amarin in accordance with, and conforms to, the applicable Drug Substance Specifications and in compliance with all Applicable Laws, including GMPs.

**10.3 Additional Representations, Warranties and Covenants of Licensee.** Licensee hereby represents, warrants and covenants (as applicable) to Amarin that:

(a) As of the Effective Date, Licensee is solvent and has the ability to pay and perform all of its obligations as and when such obligations become due, including payment obligations and other obligations under this Agreement.

(b) As of the Effective Date, Licensee’s compensation programs for its Sales Representatives do not, and during the Term will not with respect to the Product, provide financial incentives for the promotion, sales, and marketing in violation of any Applicable Laws or any professional requirements.

(c) During the Term, Licensee’s medical, regulatory or legal teams will review all training materials and programs prior to use by Licensee to ensure that such training materials and programs are in accordance with the Commercialization Plan and the Regulatory Approvals and in compliance with Applicable Laws.

(d) During the Term, all Product used in Development Activities, or Commercialized, by, or under authority of, Licensee:

(i) shall be packaged, labeled, handled, stored and shipped by Licensee, in accordance with, and shall conform to, the applicable Product Specifications;

(ii) shall be packaged, labeled, handled, stored and shipped by Licensee in compliance with all Applicable Laws, including GMPs; and

(iii) shall, from and after the time shipped by Amarin hereunder, not contain any material that would cause the Product to be adulterated or misbranded within the meaning of Applicable Laws.

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(e) As of the Effective Date, no claim or demand of any Person has been asserted in writing to Licensee arising out of Licensee’s development, regulatory or commercialization activities with respect to any other products that could reasonably be expected to impact Licensee’s ability to perform any of its obligations under this Agreement, and no investigations are pending or, to the knowledge of Licensee, threatened relating to such activities.

(f) As of the Effective Date, to the knowledge of Licensee, Licensee has complied with all Applicable Laws in all material respects.

(g) As of the Effective Date, Licensee has obtained assignments from the inventors of all inventorship rights relating to the Licensee Patents which are owned by Licensee, and, to the knowledge of Licensee, all such assignments of inventorship rights relating to such Licensee Patents are valid and enforceable.

**10.4 Disclaimer.** Subject to the regulatory and commercial status of the Product in the U. S. as of the Effective Date, Licensee understands that the Product is the subject of ongoing clinical research and development and that Amarin cannot ensure the safety or usefulness of the Product or that the Product will receive Regulatory Approvals. In addition, Amarin makes no warranties except as set forth in this ARTICLE 10 concerning the Amarin Technology.

**10.5 No Other Representations or Warranties.** EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, ARE MADE OR GIVEN BY OR ON BEHALF OF A PARTY. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.

## **ARTICLE 11 INDEMNIFICATION**

**11.1 Indemnification by Amarin.** Amarin hereby agrees to save, indemnify, defend and hold Licensee, its Affiliates, and their respective directors, officers, agents and employees harmless from and against any and all losses, damages, liabilities, costs and expenses (including reasonable attorneys’ fees and expenses) (collectively, “**Losses**”) arising in connection with any and all charges, complaints, actions, suits, proceedings, hearings, investigations, claims, demands, judgments, orders, decrees, stipulations or injunctions by a Third Party (each a “**Third Party Claim**”) resulting or otherwise arising from (i) any breach by Amarin or its Affiliates, sublicensees or subcontractors of any of Amarin’s representations, warranties, covenants or obligations pursuant to this Agreement, (ii) the negligence or willful misconduct by Amarin or its Affiliates, sublicensees or subcontractors or their respective officers, directors, employees, agents or consultants in performing any obligations under this Agreement or (iii) any matter related to the Development and Manufacturing of the Product hereunder (including, for clarity, product liability Losses resulting therefrom) by Amarin or its Affiliates, sublicensees or subcontractors or their respective officers, directors, employees, agents or consultants.

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**11.2 Indemnification by Licensee.** Licensee hereby agrees to save, indemnify, defend and hold Amarin, its Affiliates, and their respective directors, agents and employees harmless from and against any and all Losses arising in connection with any and all Third Party Claims resulting or otherwise arising from (i) any breach by Licensee (or by any of its Affiliates, Sublicensees, subcontractors, wholesalers or distributors) of any of Licensee’s representations, warranties, covenants or obligations pursuant to this Agreement, (ii) the negligence or willful misconduct by Licensee (or by any of its Affiliates, Sublicensees, subcontractors, wholesalers or distributors) or their respective officers, directors, employees, agents or consultants in performing any obligations under this Agreement, (iii) any matter related to the Development, Packaging and Labeling (or Manufacturing to the extent permitted under this Agreement), or Commercialization of the Product hereunder (including, for clarity, any product liability Losses resulting therefrom) by Licensee (or by any of its Affiliates, Sublicensees, subcontractors, wholesalers or distributors) or their respective officers, directors, employees, agents or consultants, or (iv) the failure by Licensee to initiate a Product recall, withdrawal or market notification that is proposed by Amarin under Section 5.8.1.

**11.3 Indemnification Procedures.** The obligations to indemnify and defend set forth in Sections 11.1 and 11.2 shall be contingent upon the Party seeking indemnification (the “**Indemnatee**”): (a) notifying the indemnifying Party of a claim, demand or suit within [\*\*\*] of receipt of same (provided, however, that Indemnatee’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 Third Party Claim, (c) using its Commercially Reasonable Efforts to cooperate with the indemnifying Party and/or its insurers in the defense of such Third Party Claim at the indemnifying Party’s expense, and (d) agreeing not to settle or compromise any Third Party Claim without prior written authorization of the indemnifying Party. Indemnatee shall have the right to participate in the defense of any such Claim referred to in this Section 11.3 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) as long as such settlement, compromise or termination includes an unconditional release of, and does not include an admission of liability by, each indemnified Party from all liability in respect of such Third Party Claim.

**11.4 Limitation of Liability.** NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY CONSEQUENTIAL, INCIDENTAL, OR INDIRECT DAMAGES ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 11.4 IS

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INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 11.1 or 11.2, OR DAMAGES AVAILABLE FOR A PARTY’S BREACH OF CONFIDENTIALITY OBLIGATIONS UNDER ARTICLE 12.

**11.5 Insurance.** Each Party shall procure and maintain insurance that is available on commercially reasonable terms, including general liability, clinical trial insurance, product liability insurance and other insurance as necessary, adequate to cover its obligations hereunder and which is consistent with normal business practices of prudent companies similarly situated at all times during which Product is being clinically tested in human subjects or commercially distributed or sold by a Party pursuant to this Agreement, and such insurance coverage shall be, in no event less than, in amounts per loss occurrence and in the aggregate as are customary in the industry in the Territory. It is understood that such insurance shall not be construed to create a limit of either Party’s liability with respect to its indemnification obligations under this ARTICLE 11. Each Party shall provide the other Party with written evidence of such insurance upon request of the other Party and upon expiration of any one coverage. Each Party shall provide the other Party with written notice at least [\*\*\*] prior to the cancellation, nonrenewal or material change in such insurance which materially adversely affects the rights of the other Party hereunder. Without limiting the foregoing, Licensee shall cause its insurance policies to name Amarin as an additional insured without cost to Amarin.

## **ARTICLE 12 CONFIDENTIALITY**

**12.1 Confidential Information.** As used in this Agreement, the term “**Confidential Information**” means all information, whether it be written or oral, including all production schedules, lines of products, volumes of business, processes, new product developments, product designs, formulae, technical information, patent information, Know-How, trade secrets, financial and strategic information, marketing and promotional information and data, and other material relating to any products, projects or processes of one Party (the “**Disclosing Party**”) that is provided to, or otherwise obtained by, the other Party (the “**Receiving Party**”) in connection with this Agreement (including information exchanged prior to the date hereof in connection with the transactions set forth in this Agreement, including any information disclosed by either Party pursuant to the Confidentiality and Nondisclosure Agreement between the Parties dated August 21, 2014 (the “**Confidential Disclosure Agreement**”). Notwithstanding the foregoing sentence, Confidential Information shall not include any information or materials that:

- (a) were already known to the Receiving Party (other than under an obligation of confidentiality), at the time of disclosure by the Disclosing Party, to the extent such Receiving Party has documentary evidence to that effect;
- (b) were generally available to the public or otherwise part of the public domain at the time of disclosure thereof to the Receiving Party;

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(c) became generally available to the public or otherwise part of the public domain after disclosure or development thereof, as the case may be, and other than through any act or omission of a Party in breach of such Party’s confidentiality obligations under this Agreement; or

(d) were independently discovered or developed by or on behalf of the Receiving Party without the use of the Confidential Information belonging to the other Party, to the extent such Receiving Party has documentary evidence to that effect.

**12.2 Confidentiality Obligations.** Each of Licensee and Amarin shall keep all Confidential Information received from or on behalf of the other Party with the same degree of care with which it maintains the confidentiality of its own Confidential Information, but in all cases no less than a reasonable degree of care. Neither Party shall use such Confidential Information for any purpose other than in performance of this Agreement, or exercise of rights under this Agreement, or disclose the same to any other Person other than to such of its and its Affiliates’ directors, managers, employees, independent contractors, agents, consultants or, solely with respect to Amarin, its sublicensees, who have a need to know such Confidential Information to implement the terms of this Agreement or enforce its rights under this Agreement; provided, however, that a Receiving Party shall advise any of its and its Affiliates’ directors, managers, employees, independent contractors, agents, consultants or, solely with respect to Amarin, its sublicensees, who receives such Confidential Information of the confidential nature thereof and of the obligations contained in this Agreement relating thereto, and the Receiving Party shall ensure (including, in the case of a Third Party, by means of a written agreement with such Third Party having terms at least as protective as those contained in this ARTICLE 12) that all such directors, managers, employees, independent contractors, agents, consultants or, solely with respect to Amarin, its sublicensees comply with such obligations. Upon termination of this Agreement, the Receiving Party shall return or destroy all documents, tapes or other media containing Confidential Information of the Disclosing Party that remain in the possession of the Receiving Party or its directors, managers, employees, independent contractors, agents, consultants or, solely with respect to Amarin, its sublicensees, except that the Receiving Party may keep one copy of the Confidential Information in the legal department files of the Receiving Party, solely for archival purposes. Such archival copy shall be deemed to be the property of the Disclosing Party, and shall continue to be subject to the provisions of this ARTICLE 12.

**12.3 Permitted Disclosure and Use.** Notwithstanding Section 12.2, (i) either Party may disclose Confidential Information belonging to the other Party only to the extent such disclosure is reasonably necessary to: (a) comply with or enforce any of the provisions of this Agreement; or (b) comply with Applicable Laws; and (ii) Amarin may disclose Confidential Information belonging to Licensee related to the Product only to the extent such disclosure is reasonably necessary to obtain or maintain Regulatory Approval of the Product, as applicable, to the extent such disclosure is made to a Governmental Authority. If a Party deems it necessary to disclose Confidential Information of the other Party pursuant to this Section 12.3, such Party shall give reasonable advance written notice of such disclosure to the other Party to permit such other Party sufficient opportunity to object to such disclosure or to take measures to ensure

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confidential treatment of such information, including seeking a protective order or other appropriate remedy. Notwithstanding Section 12.2, Amarin may also disclose Confidential Information belonging to Licensee related to the Product to Third Parties in connection with the development or commercialization of the Product outside of the Field or outside of the Territory (provided, that such Third Parties are bound by written agreements having terms at least as protective as those contained in this ARTICLE 12 with respect to keeping such Confidential Information confidential).

**12.4 Notification.** The Receiving Party shall notify the Disclosing Party promptly upon discovery of any unauthorized use or disclosure of the Disclosing Party’s Confidential Information, and will cooperate with the Disclosing Party in any reasonably requested fashion to assist the Disclosing Party to regain possession of such Confidential Information and to prevent its further unauthorized use or disclosure.

#### **12.5 Publicity; Filing of this Agreement.**

**12.5.1 Publicity.** The press release to be issued in connection with this Agreement and the transactions described herein is set forth on Schedule 12.5.1. Except as otherwise provided in this Section 12.5, each Party shall maintain the confidentiality of all provisions of this Agreement, and without the prior written consent of the other Party, which consent shall not be unreasonably withheld, neither Party nor its respective Affiliates shall make any press release or other public announcement of or otherwise disclose the provisions of this Agreement to any Third Party, except for: (i) disclosure to those of its directors, officers, employees, accountants, attorneys, underwriters, lenders and other financing sources, potential strategic partners, advisors, agents and, solely with respect to Amarin, its sublicensees, whose duties reasonably require them to have access to this Agreement; provided, that such directors, officers, employees, accountants, attorneys, underwriters, lenders and other financing sources, advisors, agents or, solely with respect to Amarin, sublicensees, are required to maintain the confidentiality of this Agreement;(ii) disclosures required by The NASDAQ Stock Market or any securities exchanges, in which case the disclosing Party shall provide the non-disclosing Party with at least [\*\*\*] notice, but in any event no later than the time the disclosure required by such NASDAQ Stock Market or any securities exchange is made;(iii) disclosures as may be required by Applicable Laws, in which case the disclosing Party shall provide the non-disclosing Party with prompt advance notice of such disclosure and cooperate with the non-disclosing Party to seek a protective order or other appropriate remedy, including a request for confidential treatment in the case of a filing with the U.S. Securities and Exchange Commission;(iv) the report on Form 8-K, which may be filed by Amarin or an Affiliate of Amarin setting forth the press release referred to above, and/or this Agreement in redacted form (i.e., Redacted Agreement) as provided in Section 12.5.2 and/or a summary thereof;(v) disclosures that are consistent with or complementary to those described in clause (iv) but which do not contain any Confidential Information of the other Party; and (vi) other disclosures for which consent has previously been given. A Party may publicly disclose without regard to the preceding requirements of this Section 12.5 any information that was previously publicly disclosed pursuant to this Section 12.5, so long as the context of such disclosure is substantially similar to the context in which the initial disclosure was made.

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**12.5.2 Required Filings.** Notwithstanding Section 12.5.1, 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. (“**Redacted Agreement**”); provided, that Amarin shall advise Licensee of such intended disclosures and provide Licensee 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 Licensee, and Licensee shall have the right to review and comment with respect to the Redacted Agreement or Licensee’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 or Section 12.5.1, if Amarin desires to make a public announcement concerning the material terms of this Agreement, milestones achieved under this Agreement or Licensee’s Confidential Information, then Amarin shall give reasonable prior advance notice of the proposed text of such announcement to Licensee for its prior review and approval (except as otherwise provided herein), such approval not to be unreasonably withheld, conditioned or delayed; provided, that Licensee 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 Licensee to provide comments within such time period shall be deemed to constitute Licensee’s consent to such public announcement). In relation to Licensee’s review of such an announcement, Licensee 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 Licensee to disclose any information already disclosed or otherwise in the public domain, provided such information remains accurate.

**12.6 Publication.** Licensee shall submit copies in English of each proposed academic, scientific, medical and other publication or presentation that contains or refers to the Amarin Patents, Amarin Know-How or otherwise relates to the Product or any research or Development Activities under this Agreement to Amarin at least [\*\*\*] in advance of submitting such proposed publication or presentation to a publisher or other Third Party. Amarin shall have the right to review, comment on and consent to each such proposed publication or presentation at its sole discretion. Amarin shall have the right to remove any of its Confidential Information prior to submission for publication or presentation. Licensee shall redact or otherwise modify the proposed publication or presentation to remove any such Confidential Information of Amarin. In addition, in the event that the document includes data, information or material generated by Amarin’s scientists, and professional standards for authorship would be consistent with including Amarin’s scientists as co-authors of the document, the names of such scientists will be included as co-authors.

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**12.7 Use of Names.** Except as otherwise set forth in this Agreement, neither Party shall use the name of the other Party in relation to this transaction in any public announcement, press release or other public document without the written consent of such other Party, which consent shall not be unreasonably withheld; provided, however, that subject to Section 12.5, either Party may use the name of the other Party in any document filed with any Regulatory Authority or Governmental Authority, including the Securities and Exchange Commission.

**12.8 Survival.** The obligations and prohibitions contained in this ARTICLE 12 as they apply to Confidential Information shall survive the expiration or termination of this Agreement for a period of [\*\*\*].

### ARTICLE 13 TERM AND TERMINATION

**13.1 Term.** This Agreement shall become effective on the Effective Date and, unless earlier terminated pursuant to this ARTICLE 13, shall remain in effect, on a Product-by-Product basis, until the expiration of the Royalty Term for such Product in the Territory (the “**Term**”).

**13.2 Termination for Breach.** In the event that either Party reasonably anticipates the occurrence of an event which may result in a material breach in the performance of its obligations under this Agreement, the Parties shall first consult with each other in good faith and use Commercially Reasonable Efforts to amicably resolve the disputed subject matter prior to the other Party invoking its termination rights under this Section 13.2. Subject to the foregoing, either Party may, without prejudice to any other remedies available to it at law or in equity, terminate this Agreement upon written notice to the other Party in the event that the other Party (the “**Breaching Party**”) shall have materially breached or defaulted in the performance of its obligations under this Agreement in a manner that materially diminishes the value or essential characteristics of the collaboration hereunder between the Parties taken as a whole. For clarity, (i) any of Licensee’s obligations under the second full sentence of Section 2.1.3, Sections 2.5.1, 4.2, 5.2, 6.3, 6.5, 8.1, 8.2, 8.3, or 9.7 or ARTICLE 12, in case of a breach by Licensee, or (ii) any of Amarin’s obligations under Sections 7.1, 7.13, and 10.2 (b), (e), (i), and (j), in case of a breach by Amarin, shall be deemed a material breach of this Agreement giving rise to Amarin’s or Licensee’s (as applicable) right to terminate under this Section 13.2. The Breaching Party shall have [\*\*\*] ([\*\*\*] in the event of payment) after written notice thereof was provided to the Breaching Party by the non-breaching Party to remedy such default. Unless the Breaching Party has cured any such breach or default prior to the expiration of such [\*\*\*] period ([\*\*\*] in the event of payment), such termination shall become effective upon the end of the [\*\*\*] period ([\*\*\*] in the event of payment). In the event of any dispute as to whether or not a material breach has been committed under this Section 13.2, the Parties shall first consult with each other in good faith and use Commercially Reasonable Efforts to settle such dispute. Should the Parties fail to agree on the settlement of any such dispute, the matter shall be submitted to and finally resolved by arbitration in accordance with Section 15.3 (provided, however, that referral to the Executive Officers shall not be applicable, and the time period for a decision under Section 15.3.2 shall be [\*\*\*] following selection of the arbitrators). For the avoidance of doubt, if Licensee is entitled to terminate this Agreement in accordance with the

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foregoing, it is agreed that Licensee shall also have the right not to terminate this Agreement. In the case that Licensee chooses not to terminate this Agreement, Licensee shall have the right to claim damages arising out of Amarin’s material breach; provided, however, that it is understood and agreed that Licensee shall remain subject to its payment obligations as set forth in ARTICLE 8.

**13.3 Termination as a Result of Bankruptcy.** Each Party shall have the right to terminate this Agreement upon written notice as a result of the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party; provided, that such termination shall be effective only if such proceeding is not dismissed within [\*\*\*] after the filing thereof.

**13.4 Termination by Licensee.** At any time during the Term following the third (3rd) anniversary of the First Commercial Sale of the Product in the PRC, Licensee has the right to immediately terminate this Agreement with or without cause upon twelve (12) months prior written notice to Amarin.

#### **ARTICLE 14 EFFECTS OF TERMINATION AND EXPIRATION**

**14.1 Termination Not Involving Amarin’s Fault.** Without limiting any other legal or equitable remedies that a Party may have, if this Agreement is terminated by either Party and for any reason prior to its natural expiration, then the following provisions shall apply:

**14.1.1 Termination of Licenses.** All rights and licenses granted to Licensee hereunder shall immediately terminate and be of no further force and effect and Licensee shall cease Developing, Commercializing and Packaging and Labeling the Product (except as otherwise set forth in Section 14.1.3).

**14.1.2 Assignments.** Licensee will promptly, in each case within [\*\*\*] after receipt of Amarin’s request, and at Licensee’s cost and expense (except in the case of termination by Licensee under Section 13.2, in which case it will be at Amarin’s cost and expense):

(a) at Amarin’s election, assign to Amarin or its designee all of Licensee’s right, title and interest in and to any agreements (or portions thereof) between Licensee and Third Parties that relate to the Development or Commercialization of the Product, or terminate such agreements;

(b) assign to Amarin or its designee all of Licensee’s right, title and interest in and to any (i) Licensee Technology (including all of Licensee’s right, title and interest in and to any and all Development Data and Commercialization Data Controlled by Licensee for the Product), (ii) Joint Patents, (iii) Promotional Materials and copyrights and trademarks, including any goodwill associated therewith, and any registrations and design patents for the foregoing, and (iv) any Licensee Trademark and Licensee Trade Dress, and

any Internet domain name registrations for such trademarks and slogans, all to the extent solely related to the Product; provided, however, in the event Amarin exercises such right to have assigned such Promotional Materials, Licensee shall grant, and hereby does grant, to Amarin a royalty-free right and license to any housemarks, trademarks, names and logos of Licensee contained therein for a period of [\*\*\*] in order to use such Promotional Materials in connection with the Commercialization of the Product. In furtherance of the foregoing, Licensee shall execute, and shall cause its Affiliates to execute, any documents reasonably required to confirm Amarin’s sole ownership of Licensee Technology, Joint Patents and Internet domain names, and any documents required to apply for, maintain and enforce any Patent or other right in the Licensee Technology or Joint Patents;

(c) at Amarin’s sole discretion, (i) assign to Amarin or its designee the management and continued performance of any clinical trials for the Product ongoing hereunder as of the effective date of such termination in respect of which Amarin shall assume full financial responsibility from and after the effective date of such termination, (ii) continue performing such activities (in accordance with applicable terms and conditions of this Agreement) at Amarin’s reasonable cost and expense, except in the event that Amarin has terminated this Agreement under Section 13.2 in connection Licensee’s breach, in which case at Licensee’s cost and expense, or (iii) wind-down the performance of such activities at Licensee’s cost and expense;

(d) transfer to Amarin or its designee any and all of Licensee’s right, title and interest in and to any and all regulatory filings, Regulatory Approvals and other Regulatory Materials for the Product in respect of which Amarin shall assume full financial responsibility; and

(e) provide a copy of (i) the material tangible embodiments of the foregoing and (ii) any other material books, records, files and documents Controlled by Licensee solely to the extent related to the Product, and, to the extent applicable, in accordance with Section 14.1.3; provided, that such materials may be redacted to exclude Confidential Information of Licensee that is unrelated to the Product;

provided, however, that to the extent that any agreement or other asset described in this Section 14.1.2 is not assignable by Licensee, then such agreement or other asset will not be assigned, and upon the request of Amarin, Licensee will take such steps as may be reasonably necessary to allow Amarin or its designee to obtain and to enjoy the benefits of such agreement or other asset. For purposes of clarity, (1) Amarin shall have the right to request that Licensee take any or all of the foregoing actions in whole or in part, or with respect to all or any portion of the assets set forth in the foregoing provisions and (2) to the extent Amarin requests Licensee to transfer its right, title and interest in the items set forth in this Section 14.1.2 to Amarin or its designee, Licensee shall also cause its Affiliates to transfer and assign to Amarin or its designee all of such Affiliates’ right, title and interest in and to the foregoing items set forth in this Section 14.1.2.

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**14.1.3 Delivery of Licensee Technology.** Licensee will promptly transfer to Amarin or its designee copies of any physical embodiment of any Licensee Know-How, to the extent then used in connection with the Development or Commercialization of Product; such transfer shall be effected by the delivery of material documents, to the extent such Licensee Know-How is embodied in such documents, and to the extent that Licensee Know-How is not fully embodied in such documents, Licensee shall make its employees and agents who have knowledge of such Licensee Know-How, in addition to that which is embodied in such documents, available to Amarin or its designee for interviews, demonstrations and training to effect such transfer in a manner sufficient to enable Amarin or its designee to practice such Licensee Know-How but only in a manner as set out as follows in this Section 14.1.3. The appropriate technical teams at Amarin (or its designee) and Licensee will meet to plan transfer for the Licensee Know-How as follows: (i) Licensee’s designated representative(s) for Product will meet with representatives from Amarin or its designee to answer questions with respect to the Licensee Know-How and establish a plan for the transfer for such Licensee Know-How; (ii) Licensee will allocate adequate appropriately qualified representatives to work with Amarin or its designee to review the Licensee Know-How to enable the completion of the transfer within [\*\*\*] of the completion of the initial transfer planning meetings to the extent reasonable, but in any event no longer than [\*\*\*] thereafter.

**14.1.4 Disposition of Inventory.** In the event that this Agreement is terminated other than by Amarin under Section 13.2 in connection with Licensee’s breach, Licensee and its Affiliates will be entitled, during the period ending on [\*\*\*] following the effective date of such termination, to sell any inventory of Product affected by such termination that remains on hand as of the effective date of the termination, so long as Licensee pays to Amarin the Royalty Payments and other amounts payable hereunder (including milestones) applicable to said subsequent sales, with respect to sales in the Territory, as applicable, in accordance with the terms and conditions set forth in this Agreement and otherwise complies with the terms set forth in this Agreement. In the event this Agreement is terminated by Amarin under Section 13.2 in connection with Licensee’s breach, Amarin shall have the option to purchase any inventory of Product affected by such termination at the Cost of Goods therefor.

**14.1.5 Disposition of Commercialization Related Materials.** Licensee will promptly deliver to Amarin or its designee in electronic, sortable form (a) a list identifying all wholesalers and other distributors involved in the Commercialization of the Product in the Territory as well as any customer lists (e.g., purchasers) related to the Commercialization of the Product in the Territory, and (b) all Promotional Materials as well as any items bearing the Product Trademark and/or any trademarks or housemarks of Amarin otherwise associated with the Product.

**14.1.6 Termination other than for Breach.** Except for termination by Licensee pursuant to Section 13.2, upon termination of this Agreement, in addition to the effects of termination set forth in this ARTICLE 14, the following obligations shall apply: (i) Licensee shall remain responsible for all of Licensee’s accrued but unpaid Development and Commercialization costs until the effective date of termination for [\*\*\*] after notice of termination; (ii) Licensee shall remain responsible to conduct any on-going clinical trials or other Development activities in the Territory until such clinical trials or other activities can be wound

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down in compliance with Applicable Laws and appropriate ethical standards prevailing in the industry or effectively transferred to Amarin; and (iii) Licensee shall not take any action that is intended or reasonably likely to materially adversely affect or impair the further Development or Commercialization of the Product by Amarin.

#### **14.2 Expiration of this Agreement.**

**14.2.1** Upon expiration of this Agreement pursuant to Section 13.1 (as opposed to termination of this Agreement), the licenses granted to Licensee under Section 2.1 shall become fully paid-up, royalty-free, perpetual and non-exclusive licenses; provided, however, that if, pursuant to Section 7.13, Amarin is not continuing to Manufacture the Product for Licensee, then such license shall not include any rights with respect to the Product Trade Name or Product Trade Dress.

**14.2.2** Licensee may use the Regulatory Materials and Regulatory Data provided by Amarin hereunder or generated by Licensee hereunder, and any other Development Data and Commercialization Data, for the purposes of maintaining Regulatory Approval for the Product in the Field in the Territory.

**14.3 Accrued Rights.** Termination or expiration of this Agreement for any reason will be without prejudice to any rights that will have accrued to the benefit of a Party prior to the effective date of such termination. Such termination will not relieve a Party from obligations that are expressly indicated to survive the termination or expiration of this Agreement.

**14.4 Survival.** Notwithstanding anything to the contrary contained herein, the following provisions shall survive any expiration or termination of this Agreement: Articles: 11, 12, 14, 15, and 16 and Sections: 2.2.3, 4.5.3, 5.3, 5.5.2, 6.3.1(b), 6.5.7, 6.7.2, 6.7.4, 7.13, 8.10, 9.1, 9.2, 9.3, 9.4 and 9.5. Except as set forth in this ARTICLE 14 or otherwise expressly set forth herein, upon termination or expiration of this Agreement all other rights and obligations of the Parties shall cease.

**14.5 Rights in Bankruptcy.** All rights and licenses granted under or pursuant to this Agreement by Amarin and Licensee are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code (and of any similar provisions of Applicable Laws under any other jurisdiction), licenses of right to “intellectual property” as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that each Party, as licensee of certain rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code and under any similar provisions of Applicable Laws under any other jurisdiction. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against a Party (such Party, the “**Bankrupt Party**”) under the U.S. Bankruptcy Code or under any similar provisions of Applicable Laws under any other jurisdiction, (a) the other Party shall be entitled to a complete duplicate of (or complete access to, as appropriate) any intellectual property licensed to such other Party and all embodiments of such intellectual property, which, if not already in such other Party’s possession, shall be promptly delivered to it (x) upon any such commencement of a bankruptcy proceeding upon such other Party’s written

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request therefor, unless the Bankrupt Party elects to continue to perform all of its obligations under this Agreement or (y) if not delivered under clause (x), following the rejection of this Agreement by the Bankrupt Party upon written request therefor by the other Party and (b) the Bankrupt Party shall not unreasonably interfere with the other Party’s rights to intellectual property and all embodiments of intellectual property, and shall assist and not unreasonably interfere with the other Party in obtaining intellectual property and all embodiments of intellectual property from another entity. The “embodiments” of intellectual property includes all tangible, intangible, electronic or other embodiments of rights and licenses hereunder, including all compounds and products embodying intellectual property, Products, filings with Regulatory Authorities and related rights and Amarin Know-How in the case that Amarin is the Bankrupt Party and Licensee Know-How in the case Licensee is the Bankrupt Party.

## ARTICLE 15 DISPUTE RESOLUTION

**15.1 Disputes.** The Parties recognize that, from time to time during the Term, disputes may arise as to certain matters 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 15 to resolve any controversy or claim arising out of, relating to or in connection with any provision of this Agreement (other than a dispute addressed in Section 3.1.4).

**15.2 Arising Between the Parties.** With respect to all disputes arising between the Parties and not from the JDC, including any alleged failure to perform, or breach, of this Agreement, or any issue relating to the interpretation or application of this Agreement, if the Parties are unable to resolve such dispute within [\*\*\*] after such dispute is first identified by either Party in writing to the other, the Parties shall refer such dispute to the Chief Executive Officers of each of the Parties, or a designee from senior management with decision-making authority (the Chief Executive Officer or such designee, the “**Executive Officer**”) for attempted resolution by good-faith negotiations within [\*\*\*] after such notice is received by the Executive Officers of each of the Parties.

**15.3 Dispute Resolutions.** If the Executive Officers are not able to resolve such dispute referred to them under Section 15.2 within such [\*\*\*] period, then either Party shall have right to refer such dispute for binding arbitration administered in [\*\*\*]. The language of the arbitration shall be English. Any situation not expressly covered by this Agreement shall be decided in accordance with the [\*\*\*]. Notwithstanding the foregoing, any dispute, controversy or claim relating to the scope, validity, enforceability or infringement of any patent rights covering the manufacture, use or sale of any Product or of any trademark rights relating to any Product shall be subject to Section 15.4 and not this Section 15.3

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**15.3.1 Arbitrator.** The tribunal shall consist of three (3) arbitrators. Each Party shall appoint one (1) arbitrator respectively and the third arbitrator shall be appointed by the Chairman of the [\*\*\*]. The arbitrators may, in the award, allocate all or part of the costs of the arbitration, including the fees of the arbitration and the reasonable attorneys’ fees of the prevailing Party.

**15.3.2 Decision.** A written decision shall be rendered by the arbitrators following a full comprehensive hearing, no later than [\*\*\*] following the selection of the arbitrators as provided for in Section 15.3.1.

**15.3.3 Award.** Any award rendered by the arbitrators may be entered in any court having jurisdiction thereof. Such 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 Laws, be charged against the Party resisting enforcement. Such award may include an appropriate allocation of the prevailing Party’s attorneys’ fees. Each Party agrees to abide by the award rendered in any arbitration conducted pursuant to this Section 15.3. The award shall include interest from the date of the award until paid in full, at a rate fixed by the arbitrators and the arbitrators may, in their discretion, award pre-judgment interest. With respect to money damages, nothing contained herein shall be construed to permit the arbitrators or any court or any other forum to award punitive or exemplary damages. Pursuant to this Agreement, the Parties expressly waive any claim for punitive or exemplary damages.

**15.3.4 Costs.** Except as set forth in Section 15.3.3, each Party shall bear its own legal fees. The arbitrators shall assess their 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 arbitrators shall divide his or her fees, costs and expenses according to their sole discretion.

**15.3.5 Injunctive Relief.** Provided a Party has made a sufficient showing under the rules and standards set forth in Applicable Laws, the arbitrators 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 Section 15.3 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.

**15.3.6 Confidentiality.** The arbitration proceeding shall be confidential and the arbitrators 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 U.S. Securities Exchange Commission, The NASDAQ Stock Market or any securities exchanges, no Party shall make (or instruct the arbitrators to make) any public announcement with respect to the proceedings or decision of the arbitrators 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 arbitrators, except as required in connection with the enforcement of such award or as otherwise required by Applicable Laws.

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

**15.4 Patent and Trademark Dispute Resolution.** Any dispute, controversy or claim relating to the scope, validity, enforceability or infringement of any patent rights covering the manufacture, use or sale of any Product or of any trademark rights relating to any Product shall be submitted to a court of competent jurisdiction in the region in which such patent or trademark rights were granted or arose.

**15.5 Injunctive Relief.** Nothing herein may prevent either Party from seeking a preliminary injunction or temporary restraining order, in any court of competent jurisdiction, so as to prevent any Confidential Information from being disclosed in violation of this Agreement.

## **ARTICLE 16 MISCELLANEOUS**

**16.1 Entire Agreement; Amendment.** This Agreement and all Schedules attached hereto 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.

**16.2 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.

**16.3 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, or by facsimile transmission, 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 facsimile transmission, on the day when sent by facsimile as confirmed

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by automatic transmission report coupled with overnight courier service receipt proving delivery, 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 Licensee:**

Name: Eddingpharm (Asia) Macao Commercial Offshore Limited  
Street: Unit 1505, 15/F, AIA Tower,  
Nos 251A-301, AvenidaComercial De Macau  
City: Macau  
Country: PR China  
Attn: Chief Executive Officer  
[\*\*\*]

**With a copy to:**

Name: Eddingpharm (Asia) Macao Commercial Offshore Limited  
Street: Unit 1505, 15/F, AIA Tower,  
Nos 251A-301, AvenidaComercial De Macau  
City: Macau  
Country: PR China  
Attn: Chief Executive Officer  
[\*\*\*]

**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  
Facsimile: [\*\*\*]

**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  
Facsimile: [\*\*\*]

**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  
Facsimile: Not valid notice

**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  
Facsimile: [\*\*\*]

**16.4 No Strict Construction; Interpretation.** This Agreement has been prepared jointly and shall not be strictly construed against either Party. Ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision. The headings of each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section.

**16.5 Assignment.** Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other, except that Amarin may make such assignment without Licensee’s consent to an Affiliate or a successor to all or substantially all of the business of Amarin to which this Agreement relates. Any permitted assignment shall be binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this Section 16.5 shall be null, void and of no legal effect. [\*\*\*]

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.

**16.6 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 Laws, then such terms or provisions shall be deemed to be modified to conform with such Applicable Laws 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 Laws. In the event that the terms and conditions of this Agreement are materially altered as a result of this Section 16.6, the Parties shall renegotiate the terms and conditions of this Agreement to resolve any inequities and to achieve the original intent of the Parties.

**16.7 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.

**16.8 Partnership or Joint Venture.** Amarin and Licensee shall be independent contractors and the relationship between the Parties hereunder shall not constitute a partnership, joint venture or agency. Neither Amarin nor Licensee 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.

**16.9 English Language; Governing Law.** This Agreement was prepared in the English language, which language shall govern the interpretation of, and any dispute regarding, the terms of this Agreement. All notices, reports and other documents contemplated by this Agreement to be delivered by a Party to the other Party shall be in the English language. This Agreement and all disputes arising out of or related to this Agreement or any breach hereof shall be governed by and construed under the laws of the State of New York, without giving effect to any choice of law principles that would require the application of the laws of a different jurisdiction.

**16.10 Execution in Counterparts.** This Agreement may be executed in counterparts, each of which shall be deemed an original but which together shall constitute one 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.

*[No Further Text on This Page]*

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

**EDDINGPHARM (ASIA) MACAO COMMERCIAL  
OFFSHORE LIMITED**

By: /s/ Xin Ni  
Name: Xin Ni  
Title: Chief Executive Officer

**AMARIN PHARMACEUTICALS IRELAND LIMITED**

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

**AMARIN PHARMA, INC.**

By: /s/ John F. Thero  
Name: John F. Thero  
Title: President and Chief Executive Officer

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.

**Schedule 1.8**

Amarin Patents

<b>Family</b>	<b>App. No.</b>	<b>Status</b>
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

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**Schedule 4.3.2**

**A) Initial China Development Plan**

[\*\*\*]

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[\*\*\*]

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[\*\*\*]:

- 1 [\*\*\*]
- 2 [\*\*\*]
- 3 [\*\*\*]
- 4 [\*\*\*]
- 5 [\*\*\*]
- 6 [\*\*\*]
- 7 [\*\*\*]
- 8 [\*\*\*]
- 9 [\*\*\*]

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**B) Initial Hong Kong / Macau Development Plan**

[\*\*\*]

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**C) Initial Taiwan Development Plan**

[\*\*\*]

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**Schedule 6.9.1**

Product Trademark

[\*\*\*]

United States:

VASCEPA – Registered 11/6/2012

Registration No. 4238272

Use Class: Pharmaceutical preparations

for the treatment of cardiovascular conditions

VASCEPA and Design

Application filing date 10/26/2012

Status: Allowed

Application no. 85764517

Use class: Pharmaceutical preparations

for the treatment of cardiovascular conditions

The logo for Vascepa, featuring the word "Vascepa" in a blue, serif font with a registered trademark symbol (®) to the upper right of the letter 'a'.

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**Schedule 7.6**

**FORECAST AND ORDERING METHODOLOGY**

[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]

- [\*\*\*]
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  - [\*\*\*]
  - [\*\*\*]
  - [\*\*\*]
  - [\*\*\*]
- [\*\*\*]

**Schedule 12.5.1**

Press Release

[\*\*\*]

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## 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 8, 2015

/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 8, 2015

/s/ Michael J. Farrell

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Michael J. Farrell  
Vice President, Finance  
(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, 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, Vice President, Finance (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, 2015, 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 8, 2015

/s/ John F. Thero

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

Date: May 8, 2015

/s/ Michael J. Farrell

Michael J. Farrell  
Vice President, Finance (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.