

AMARIN CORP PLC\UK  
Form 10-Q  
November 03, 2016  
Table of Contents

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

**FORM 10-Q**

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

**For the quarterly period ended September 30, 2016**

**OR**

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

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

**Commission File No. 000-21392**

**Amarin Corporation plc**  
**(Exact Name of Registrant as Specified in its Charter)**

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

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

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

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

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

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

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

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

Large accelerated filer  Accelerated filer

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

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

268,067,924 shares held as American Depositary Shares (ADSs), each representing one Ordinary Share, 50 pence par value per share, and 1,884,965 ordinary shares, were outstanding as of November 1, 2016.

**Table of Contents**

**INDEX TO FORM 10-Q**

	<b>Page</b>
<b><u>PART I Financial Information</u></b>	
Item 1. Financial Statements (unaudited):	
<u>Condensed Consolidated Balance Sheets as of September 30, 2016 and December 31, 2015</u>	3
<u>Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2016 and 2015</u>	4
<u>Condensed Consolidated Statement of Changes in Stockholders' Equity (Deficit) for the nine months ended September 30, 2016</u>	5
<u>Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2016 and 2015</u>	6
<u>Notes to Condensed Consolidated Financial Statements</u>	7
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	31
Item 3. <u>Quantitative and Qualitative Disclosures about Market Risk</u>	51
Item 4. <u>Controls and Procedures</u>	51
<b><u>PART II Other Information</u></b>	
Item 1. <u>Legal Proceedings</u>	52
Item 1A. <u>Risk Factors</u>	52
Item 6. <u>Exhibits</u>	80
<u>SIGNATURES</u>	81

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

	<b>September 30, 2016</b>	<b>December 31, 2015</b>
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 117,562	\$ 106,961
Restricted cash	600	600
Accounts receivable, net	17,504	13,826
Inventory	19,773	18,985
Prepaid and other current assets	5,741	3,152
Total current assets	161,180	143,524
Property, plant and equipment, net	102	243
Deferred tax assets	23,006	19,872
Other long-term assets	682	174
Intangible asset, net	8,933	9,417
<b>TOTAL ASSETS</b>	<b>\$ 193,903</b>	<b>\$ 173,230</b>
<b>LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIT)</b>		
Current Liabilities:		
Accounts payable	\$ 6,864	\$ 10,832
Accrued expenses and other current liabilities	38,334	24,226
Current portion of exchangeable senior notes, net of discount	15,273	2,266
Current portion of long-term debt from royalty-bearing instrument	13,471	12,476
Deferred revenue, current	1,172	923
Total current liabilities	75,114	50,723
Long-Term Liabilities:		
Exchangeable senior notes, net of discount		136,734
Long-term debt from royalty-bearing instrument	88,645	91,512
Long-term debt derivative liabilities		8,170
Deferred revenue, long-term	14,236	13,308
Other long-term liabilities	731	335
Total liabilities	178,726	300,782

Commitments and contingencies (Note 7)		
Stockholders' Equity (Deficit):		
Series A Convertible Preferred Stock, £0.05 par, unlimited authorized; 328,184,640 shares issued and outstanding as of September 30, 2016 and December 31, 2015 (equivalent to 32,818,464 ordinary shares upon future consolidation and redesignation at a 10:1 ratio)	24,364	24,364
Common stock, £0.50 par, unlimited authorized; 269,952,889 issued, 269,181,463 outstanding as of September 30, 2016; 183,577,765 issued, 183,403,263 outstanding as of December 31, 2015	207,023	149,978
Additional paid-in capital	961,691	816,171
Treasury stock; 771,426 shares as of September 30, 2016; 174,502 shares as of December 31, 2015	(1,350)	(411)
Accumulated deficit	(1,176,551)	(1,117,654)
Total stockholders' equity (deficit)	15,177	(127,552)
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>	<b>\$ 193,903</b>	<b>\$ 173,230</b>

See notes to condensed consolidated financial statements.

**Table of Contents**

## AMARIN CORPORATION PLC

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

	Three months ended September 30,		The months ended September 30,	
	2016	2015	2016	2015
Product revenue, net	\$ 32,441	\$ 21,320	\$ 90,563	\$ 54,585
Licensing revenue	293	163	825	538
<b>Total revenue, net</b>	<b>32,734</b>	<b>21,483</b>	<b>91,388</b>	<b>55,123</b>
Less: Cost of goods sold	8,451	7,478	24,208	19,486
<b>Gross margin</b>	<b>24,283</b>	<b>14,005</b>	<b>67,180</b>	<b>35,637</b>
Operating expenses:				
Selling, general and administrative	26,061	26,727	80,147	77,522
Research and development	13,490	13,092	39,798	37,715
<b>Total operating expenses</b>	<b>39,551</b>	<b>39,819</b>	<b>119,945</b>	<b>115,237</b>
Operating loss	(15,268)	(25,814)	(52,765)	(79,600)
Gain (loss) on change in fair value of derivative liabilities	3,610	(230)	8,170	(366)
Interest expense, net	(5,051)	(5,061)	(16,253)	(14,753)
Other expense, net	(78)	(102)	(381)	(135)
Loss from operations before taxes	(16,787)	(31,207)	(61,229)	(94,854)
Benefit from income taxes	1,015	532	2,332	1,541
Net loss	(15,772)	(30,675)	(58,897)	(93,313)
Preferred stock purchase option				(868)
Preferred stock beneficial conversion features		(1,646)		(32,987)
<b>Net loss applicable to common shareholders</b>	<b>\$ (15,772)</b>	<b>\$ (32,321)</b>	<b>\$ (58,897)</b>	<b>\$ (127,168)</b>
Loss per share:				
Basic	\$ (0.08)	\$ (0.18)	\$ (0.31)	\$ (0.71)
Diluted	\$ (0.08)	\$ (0.18)	\$ (0.31)	\$ (0.71)
Weighted average shares:				
Basic	209,149	183,245	192,618	179,780
Diluted	209,149	183,245	192,618	179,780

See notes to condensed consolidated financial statements.



**Table of Contents**

## AMARIN CORPORATION PLC

**CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)**

(Unaudited, in thousands, except share amounts)

	Preferred Shares	Common Shares	Treasury Shares	Preferred Stock	Common Stock	Additional Paid- in Capital	Treasury Stock	Accumulated Deficit	Total
<b>December 31, 2015</b>	<b>328,184,640</b>	<b>183,577,765</b>	<b>(174,502)</b>	<b>\$ 24,364</b>	<b>\$ 149,978</b>	<b>\$ 816,171</b>	<b>\$ (411)</b>	<b>\$ (1,119,293)</b>	<b>\$ (129,192)</b>
cumulative-effect adjustment								1,639	1,639
<b>January 1, 2016</b>	<b>328,184,640</b>	<b>183,577,765</b>	<b>(174,502)</b>	<b>\$ 24,364</b>	<b>\$ 149,978</b>	<b>\$ 816,171</b>	<b>\$ (411)</b>	<b>\$ (1,117,654)</b>	<b>\$ (127,552)</b>
issuance of common stock, net of transaction costs		24,265,000			15,712	48,902			64,614
exchange of exchangeable senior notes, net of transaction costs		60,311,188			40,062	87,375			127,437
exercise of stock options		94,272			67	69			130
vesting of restricted stock units		1,704,664	(596,924)		1,204	(1,211)	(939)		(940)
stock-based compensation expense for the period						10,385		(58,897)	10,385
<b>September 30, 2016</b>	<b>328,184,640</b>	<b>269,952,889</b>	<b>(771,426)</b>	<b>\$ 24,364</b>	<b>\$ 207,023</b>	<b>\$ 961,691</b>	<b>\$ (1,350)</b>	<b>\$ (1,176,551)</b>	<b>\$ 15,177</b>

See notes to condensed consolidated financial statements.



**Table of Contents**

## AMARIN CORPORATION PLC

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

(Unaudited, in thousands)

	<b>Nine Months Ended September 30,</b>	
	<b>2016</b>	<b>2015</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (58,897)	\$ (93,313)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	114	125
Loss on sale of fixed assets	48	
Stock-based compensation	10,376	10,177
Stock-based compensation warrants		(9)
Amortization of debt discount and debt issuance costs	7,246	5,654
Amortization of intangible asset	484	484
(Gain) loss on change in fair value of derivative liabilities	(8,170)	366
Deferred income taxes	(3,134)	(1,582)
Changes in assets and liabilities:		
Accounts receivable	(3,678)	(3,397)
Inventories	(788)	(5,971)
Prepaid and other current assets	(2,589)	(2,056)
Other non-current assets	(508)	529
Accrued interest payable	(4,730)	(1,399)
Deferred revenue	1,177	14,461
Accounts payable and other current liabilities	10,149	14,902
Other non-current liabilities	396	222
Net cash used in operating activities	(52,504)	(60,807)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchase of equipment	(21)	(10)
Net cash used in investing activities	(21)	(10)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from issuance of preferred stock, net of transaction costs		57,666
Proceeds from issuance of common stock, net of transaction costs	64,614	
Proceeds from exercise of stock options, net of transaction costs	136	31
Proceeds from exercise of warrants, net of transaction costs		2,713
Transaction costs related to exchange of exchangeable senior notes	(678)	
Taxes paid related to stock-based awards	(946)	(151)
Payments under capital leases		(5)
Net cash provided by financing activities	63,126	60,254

NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	10,601	(563)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	106,961	119,539
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 117,562	\$ 118,976
Supplemental disclosure of cash flow information:		
Cash paid during the year for:		
Interest	\$ 13,839	\$ 10,225
Income taxes	\$ 1,093	\$ 526
Non-cash transactions:		
Exchange of exchangeable senior notes into common stock	\$ 128,115	\$
Transfer of preferred stock purchase option derivative liability to equity	\$	\$ 868
Conversion of Series A Convertible Preferred Stock into common stock	\$	\$ 4,804
Accretion of preferred stock beneficial conversion features	\$	\$ 32,987

See notes to condensed consolidated financial statements.

---

**Table of Contents**

**AMARIN CORPORATION PLC**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

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

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

**Nature of Business**

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

The Company s lead product, Vascepa® (icosapent ethyl) capsules, is approved by the U.S. Food and Drug Administration, or FDA, for use as an adjunct to diet to reduce triglyceride levels in adult patients with severe (TG  $\geq$ 500 mg/dL) hypertriglyceridemia. Vascepa is available in the United States by prescription only. In January 2013, the Company began selling and marketing Vascepa in the United States. In August 2015, in addition to marketing Vascepa for severe hypertriglyceridemia, the Company commenced marketing Vascepa for use in adult patients with mixed dyslipidemia, as an adjunct to diet and an add-on to statin therapy in patients who despite statin therapy have high triglycerides (TGs  $\geq$ 200 mg/dL and  $<$ 500 mg/dL), which the Company also refers to as persistently high triglycerides. This expanded promotion of Vascepa commenced pursuant to a federal court order and is continuing pursuant to an agreement among the Company, the FDA and the U.S. government. 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 or its customers, that in turn resell Vascepa to retail pharmacies for subsequent resale to patients and healthcare providers. The Company markets Vascepa through its sales force of approximately 150 sales professionals, including sales representatives and their managers. In May 2014, Kowa Pharmaceuticals America, Inc. commenced co-promotion of Vascepa in accordance with a co-promotion agreement with the Company. Kowa Pharmaceuticals America, Inc. co-promotes Vascepa through its no less than 250 sales representatives who now devote a substantial portion of their time to promoting Vascepa in conjunction with the promotion of Kowa Pharmaceutical America, Inc. s primary product, a branded statin for patients with high cholesterol. The Company operates in one business segment.

The Company is also developing Vascepa for FDA approval of potential additional indications for use. In particular, the Company is conducting a cardiovascular outcomes study of Vascepa, titled REDUCE-IT (Reduction of Cardiovascular Events with EPA Intervention Trial). The REDUCE-IT study, which commenced in 2011 and completed patient enrollment and randomization of 8,175 individual patients in 2016, 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, 2015, or the 2015 Form 10-K, filed with the SEC. The consolidated balance sheet amounts at December 31, 2015 in this report were derived from the Company's audited 2015 consolidated financial statements included in the 2015 Form 10-K.

The condensed consolidated financial statements reflect all adjustments of a normal and recurring nature that, in the opinion of management, are necessary to present fairly the Company's financial position, results of operations and cash flows for the periods indicated. The preparation of the Company's condensed consolidated financial statements in conformity with U.S. Generally Accepted Accounting Principles ( GAAP ) requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. The results of operations for the three and nine months ended September 30, 2016 and September 30, 2015, respectively, are not necessarily indicative of the results for the entire fiscal year or any future period.

Certain numbers presented throughout this document may not add precisely to the totals provided due to rounding. Absolute and percentage changes are calculated using the underlying amounts in thousands. Certain prior period balances have been reclassified to conform to the current period presentation due primarily to the Company's adoption of recent accounting pronouncements related to the presentation of debt issuance costs and excess tax benefits. These reclassifications do not have a material impact on the Company's condensed consolidated financial statements.

---

**Table of Contents**

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.

As of September 30, 2016, the Company had current assets of \$161.2 million, including cash and cash equivalents of \$117.6 million. Cash and cash equivalents as of September 30, 2016 includes net proceeds of approximately \$64.6 million resulting from the issuance of 24,265,000 American Depositary Shares, or ADSs, as part of a public offering completed in August 2016 (see Note 8 Equity). The Company's condensed consolidated balance sheets also include long-term debt from royalty-bearing instrument and exchangeable senior notes. The outstanding January 2012 exchangeable senior notes, or the 2012 Notes, may be redeemed by the Company on or after January 19, 2017 and may be put back to the Company by the holders on each of January 19, 2017, 2022 and 2027 for cash equal to 100% of the principal amount of \$15.1 million plus any accrued and unpaid interest. The 2012 Notes are exchangeable under certain circumstances into cash, ADSs, or a combination of cash and ADSs, at the Company's election. Accordingly, the 2012 Notes represent a potential short-term claim on the liquid assets of the Company. In September 2016, the Company mandatorily exchanged the aggregate principal amount of \$118.7 million of the May 2014 exchangeable senior notes, or the 2014 Notes, and the aggregate principal amount of \$31.3 million of the November 2015 exchangeable senior notes, or the 2015 Notes, into ADSs such that they were retired in full, and derecognized the related derivative liabilities (see Note 6 Debt).

The Company believes its cash and cash equivalents will be sufficient to fund its projected operations for at least the next twelve months. Depending on the level of cash generated from operations, additional capital may be required to sustain operations, fund debt obligations or expand promotion of Vascepa as contemplated following anticipated successful results of the REDUCE-IT study. The Company anticipates that quarterly net cash outflows in future periods will be variable.

**(2) Significant Accounting Policies****Principles of Consolidation**

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

**Use of Estimates**

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

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

The use of forecasted financial information is inherent in many of the Company's accounting estimates including, but not limited to, determining the estimated fair values of derivatives, debt instruments and intangible assets, and

evaluating the need for valuation allowances for deferred tax assets. Such forecasted financial information is comprised of numerous assumptions regarding the Company's future revenues, cash flows, and operational results. Management believes that its financial forecasts are reasonable and appropriate based upon current facts and circumstances. Because of the inherent nature of forecasts, however, actual results may differ from these forecasts. Management regularly reviews the information related to these forecasts and adjusts the carrying amounts of the applicable assets prospectively, if and when actual results differ from previous estimates.

**Revenue Recognition**

The Company sells Vascepa principally to a limited number of major wholesalers, as well as selected regional wholesalers and specialty pharmacy providers, or collectively, its Distributors or its customers, that in turn resell Vascepa to retail pharmacies for subsequent resale to patients and healthcare 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 has contracts with its primary Distributors and delivery generally 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. In order to

---

**Table of Contents**

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 generally based on the wholesale acquisition cost that the Company charges its Distributors for Vascepa. The Company estimates its net product revenues by deducting from its gross product revenues (a) trade allowances, such as invoice discounts for prompt payment and distributor fees, (b) estimated government and private payor rebates, chargebacks and discounts, such as Medicaid reimbursements, (c) reserves for expected product returns and (d) estimated costs of incentives offered to certain indirect customers, including patients.

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

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

*Product Returns:* The Company's Distributors have the right to return unopened unexpired Vascepa during the 18-month period beginning six months prior to the labeled expiration date and ending twelve months after the labeled expiration date. The expiration date for Vascepa is three years after it has been converted into capsule form, which is the last step in the manufacturing process for Vascepa and generally occurs within a few months before Vascepa is delivered to Distributors. 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 tables summarize activity in each of the net product revenue allowance and reserve categories described above for the nine months ended September 30, 2016 and 2015:

<b>In thousands</b>	<b>Trade Allowances</b>	<b>Rebates, Chargebacks and Discounts</b>	<b>Product Returns</b>	<b>Other Incentives</b>	<b>Total</b>
<b>Balance as of December 31, 2015</b>	<b>\$ 4,296</b>	<b>\$ 9,881</b>	<b>\$ 535</b>	<b>\$ 1,084</b>	<b>\$ 15,796</b>
Provision related to current period sales	15,823	46,553	403	8,539	71,318
Provision related to prior period sales	(87)	(402)			(489)
Credits/payments made for current period sales	(11,086)	(22,236)		(6,788)	(40,110)
Credits/payments made for prior period sales	(4,180)	(8,492)	(247)	(1,284)	(14,203)
<b>Balance as of September 30, 2016</b>	<b>\$ 4,766</b>	<b>\$ 25,304</b>	<b>\$ 691</b>	<b>\$ 1,551</b>	<b>\$ 32,312</b>



**Table of Contents**

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

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

*Multiple-Element Arrangements and Licensing Revenue*

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

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

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

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

*Milestones*

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

See Note 10 Development, Commercialization and Supply Agreement for further information regarding licensing revenue and milestones primarily related to the Company's multiple-element arrangement with Eddingpharm (Asia) Macao Commercial Offshore Limited.

**Table of Contents****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 and Restricted Cash**

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

**Accounts Receivable, net**

Accounts receivable, net, comprised of trade receivables, are generally due within 30 days and are stated at amounts due from customers. The Company recognizes an allowance for losses on accounts receivable in an amount equal to the estimated probable losses net of any recoveries. The allowance is based primarily on assessment of specific identifiable customer accounts considered at risk or uncollectible, as well as an analysis of current receivables aging and expected future write-offs. The expense associated with the allowance for doubtful accounts is recognized as selling, general, and administrative expense. The Company 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 September 30, 2016 and December 31, 2015:

<b>In thousands</b>	<b>September 30, 2016</b>	<b>December 31, 2015</b>
Gross trade accounts receivable	\$ 22,522	\$ 18,270
Trade allowances	(4,766)	(4,296)
Chargebacks	(240)	(148)
Allowance for doubtful accounts	(12)	
<b>Accounts receivable, net</b>	<b>\$ 17,504</b>	<b>\$ 13,826</b>

**Inventory**

Effective April 2016, the Company adopted ASU No. 2015-11, *Inventory (Topic 330) Simplifying the Measurement of Inventory*, which simplifies the subsequent measurement of inventories by replacing the lower of cost or market test with a lower of cost and net realizable value test and, as such, began to state inventories at the lower of cost or net realizable value. Such adoption had no impact on the carrying value of inventory. 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 net realizable value due to obsolescence, damage, quantities in excess of expected demand, changes in price levels or other causes, the Company will reduce the carrying value of such inventory to net realizable value and recognize the difference as a component of cost of goods sold in the period in which it occurs. The Company capitalizes inventory purchases of saleable product from approved suppliers while inventory purchases from suppliers prior to regulatory approval are included as a component of research and development expense. The Company expenses inventory identified for use as marketing samples when they are packaged. The average cost reflects the actual purchase price of Vascepa active pharmaceutical ingredient, or API.

**Property, Plant and Equipment**

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

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

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

## **Table of Contents**

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

### **Beneficial Conversion Features**

The Company issued Series A preference shares in a private placement transaction executed in two tranches that each contain a conversion feature whereby such shares are convertible into ordinary shares at a fixed rate. The conversion price on the date of issuance was less than the market price of the Company's ordinary shares. It was determined that these discounts represent contingent beneficial conversion features, which were valued based on the difference between the conversion price and the market price of the ordinary shares on the date of issuance, which is the commitment date. These features are analogous to preference dividends and were each recorded as a non-cash return to preferred shareholders through accumulated deficit upon the earliest possible date of conversion, which occurred in the three months ended June 30, 2015 upon effectiveness of the related resale Registration Statement on Form S-3 and in the three months ended September 30, 2015 upon shareholder approval received at the Company's Annual General Meeting of Shareholders. See Note 8 Equity for further discussion.

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

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

### **Research and Development Costs**

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

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

The Company charges selling, general and administrative costs to operations as incurred. Selling, general and administrative costs include costs of salaries, programs and infrastructure necessary for the general conduct of the Company's business, including those incurred as a result of the commercialization of Vascepa in the United States as

well as co-promotion fees payable to Kowa Pharmaceuticals America, Inc.

**Income Taxes**

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

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

---

**Table of Contents**

The Company regularly assesses its ability to realize 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.

In April 2016, the Company adopted ASU No. 2016-09, *Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*, which changes the accounting for certain aspects of share-based payments to employees. One aspect of the standard requires that excess tax benefits and deficiencies that arise upon vesting or exercise of share-based payments be recognized as an income tax benefit and expense in the income statement. Previously, such amounts were recognized as an increase and decrease in additional paid-in capital. This aspect of the standard was adopted prospectively, and accordingly, the benefit from income taxes for the three and nine months ended September 30, 2016, includes \$0.3 million and \$0.4 million, respectively, of excess tax deficiencies arising from share-based payments. Additionally, the new standard requires that historical excess tax benefits that were not previously recognized because the related tax deduction had not reduced current taxes payable should be recognized on a modified retrospective basis as a cumulative-effect adjustment to retained earnings as of the beginning of the annual period of adoption. Consequently, the Company recognized deferred tax assets of approximately \$1.6 million relating to excess tax benefits of stock-based compensation outstanding as of December 31, 2015, with a corresponding cumulative-effect adjustment to accumulated deficit. The new standard also amends the presentation of employee share-based payment-related items in the statement of cash flows by requiring that: (i) excess income tax benefits and deficiencies be classified in cash flows from operating activities, and (ii) cash paid to taxing authorities arising from the withholding of shares from employees be classified as cash flows from financing activities. The Company adopted the aspects of the standard affecting cash flow presentation retrospectively and, accordingly, reclassified \$0.7 million of excess tax provision from cash flows provided by financing activities to cash flows used in operating activities in the condensed consolidated statement of cash flows for the nine months ended September 30, 2015 to conform to the current year presentation. The presentation requirement for cash flows related to taxes paid for withheld shares had no impact to any of the periods presented in the condensed consolidated statement of cash flows since such payments have historically been presented as a financing activity.

The Company's and its subsidiaries' income tax returns are periodically examined by various tax authorities. The Company is currently under audit by the United States Internal Revenue Service (IRS) for the years 2012 to 2013. Although the outcome of tax audits is always uncertain and could result in significant cash tax payments, the Company does not believe the outcome of these audits will have a material adverse effect on the Company's consolidated financial position or results of operations.

**Derivative Instruments**

Derivative financial liabilities are recorded at fair value, with gains and losses arising for changes in fair value recognized in the condensed consolidated 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. Warrants are valued using a Black-Scholes option pricing model. 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 net loss per share purposes, the impact of such gains is reversed and the treasury stock method is used to determine diluted net loss per share.

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



**Table of Contents**

The calculation of net loss and the number of shares used to compute basic and diluted net loss per share for the three and nine months ended September 30, 2016 and 2015 are as follows:

In thousands	Three months ended September 30,		Nine months ended September 30,	
	2016	2015	2016	2015
Net loss	\$ (15,772)	\$ (30,675)	\$ (58,897)	\$ (93,313)
Preferred stock purchase option (see Note 8)				(868)
Preferred stock beneficial conversion features (see Note 8)		(1,646)		(32,987)
Net loss applicable to common shareholders basic	(15,772)	(32,321)	(58,897)	(127,168)
Gain on warrant derivative liability				(119)
Net loss diluted	(15,772)	(32,321)	(58,897)	(127,287)
Net loss per share basic and diluted	(0.08)	(0.18)	(0.31)	(0.71)
Weighted average shares outstanding basic and diluted	209,149	183,245	192,618	179,780

For the three and nine months ended September 30, 2016 and 2015, the following potentially dilutive securities were not included in the computation of net loss per share because the effect would be anti-dilutive:

In thousands	Three months ended September 30,		Nine months ended September 30,	
	2016	2015	2016	2015
Stock options	21,241	17,627	21,241	17,627
Restricted stock and restricted stock units	10,346	11,001	10,346	11,001
Exchangeable senior notes (if converted)	1,714	49,215	1,714	49,215
Preferred stock (if converted)	32,818	32,818	32,818	32,818

**Debt Instruments**

Debt instruments are initially recorded at fair value, with coupon interest and amortization of debt issuance discounts recognized in the condensed consolidated 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 the 2012 Notes and previously the 2014 Notes and 2015 Notes prior to the mandatory exchange qualify for the exception from derivative accounting in accordance with ASC 815-40. The 2012 Notes may be put to the Company by their holders for repurchase in cash. The 2012 Notes are exchangeable under certain circumstances 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 fully amortized over the expected term of the instrument. The conversion features in the 2014 Notes and 2015 Notes could only have been settled in ADSs upon conversion and were therefore accounted for as part of the debt host.

The conversion feature in the 2012 Notes continues to be evaluated on a quarterly basis to determine if it still receives 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. As a result, the 2014 Notes were initially recognized at a discount of \$27.9 million. The 2015 Notes were recognized initially at fair value as part of the issuance of new debt in November 2015. As a result, the 2015 Notes were initially recognized at a discount of \$3.8 million. These discounts were amortized through interest expense through the date of mandatory exchange. See Note 6 Debt for further discussion.

### **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.

---

**Table of Contents**

A significant portion of the Company's sales are to wholesalers in the pharmaceutical industry. The Company monitors the creditworthiness of customers to whom it grants credit terms and has not experienced any credit losses. The Company does not require collateral or any other security to support credit sales. The Company's top three customers accounted for 95% of gross product sales for each of the nine months ending September 30, 2016 and 2015 and represented 95% of the gross accounts receivable balance as of September 30, 2016 and 2015. The Company has not experienced any write-offs of its accounts receivable.

**Concentration of Suppliers**

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

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

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

**Foreign Currency**

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

**Debt Issuance Costs**

Prior to January 2016, debt issuance costs were initially recorded as a deferred cost and amortized to interest expense using the effective interest method over the expected term of the related debt. Effective January 2016, the Company adopted ASU No. 2015-03, *Interest Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs*, and as such began recording debt issuance costs related to a recognized debt liability in the condensed consolidated balance sheet as a direct deduction from the carrying amount of that debt liability and amortized to interest expense using the effective interest method over the expected term of the related debt. As the standard is required to be adopted on a retrospective basis, the Company reclassified \$1.9 million of underwriters' fees and offering costs related to the 2014 Notes and 2015 Notes from other long-term assets to exchangeable senior notes, net of discount, within the condensed consolidated balance sheet as of December 31, 2015. Unamortized debt issuance costs related to the extinguishment of debt are expensed at the time the debt is extinguished and recorded in other expense, net, in the condensed 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).

**Table of Contents**

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

The following tables present information about the Company's assets and liabilities as of September 30, 2016 and December 31, 2015 that are measured at fair value on a recurring basis and indicate the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value:

In thousands	September 30, 2016			
	Total	Level 1	Level 2	Level 3
<b>Asset:</b>				
Cash equivalents money markets	\$ 14,223	\$ 14,223	\$	\$
<b>Liabilities:</b>				
Long-term debt derivative liabilities	\$	\$	\$	\$

In thousands	December 31, 2015			
	Total	Level 1	Level 2	Level 3
<b>Asset:</b>				
Cash equivalents money markets	\$ 14,184	\$ 14,184	\$	\$
<b>Liabilities:</b>				
Long-term debt derivative liabilities	\$ 8,170	\$	\$	\$ 8,170

The carrying amounts of cash, cash equivalents, accounts payable and accrued liabilities approximate fair value because of their short-term nature. The carrying amounts and the estimated fair values of debt instruments as of September 30, 2016 and December 31, 2015 are as follows:

In thousands	September 30, 2016		December 31, 2015	
	Carrying Value	Estimated Fair Value	Carrying Value	Estimated Fair Value
Long-term debt from royalty-bearing instrument	\$ 93,055	\$ 90,800	\$ 91,512	\$ 87,700
2012 Notes	15,107	15,084	15,107	13,637
2014 Notes			94,599	108,034
2015 Notes			27,028	28,448

The estimated fair value of the long-term debt from royalty-bearing instrument pursuant to the December 2012 financing is calculated utilizing the same Level 3 inputs utilized in valuing the related derivative liability (see Long-Term Debt Redemption Features below). The estimated fair value of the 2012 Notes and 2014 Notes is calculated based on Level 1 quoted bond prices, while the estimated fair value of the 2015 Notes is calculated based on Level 2 quoted bond prices for the 2014 Notes. The carrying value of the 2012 Notes as of September 30, 2016 and December 31, 2015 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, which was calculated to be a period of twenty-four months. The carrying value

of the 2014 Notes as of December 31, 2015 includes a debt discount of \$24.1 million, which prior to mandatory exchange was being amortized as non-cash interest expense over the expected term of the 2014 Notes, through January 2019. The carrying value of the 2015 Notes as of December 31, 2015 includes a debt discount of \$4.2 million, which prior to mandatory exchange was being amortized as non-cash interest expense over the expected term of the 2015 Notes, through January 2019. The carrying values and related debt discounts of the 2014 Notes and 2015 Notes as of December 31, 2015 reflect the retroactive reclassification of debt issuance costs per adoption of ASU No. 2015-03 as described in Note 6 Debt. The change in the estimated fair values of these liabilities from December 31, 2015 to September 30, 2016 is largely related to changes in the quoted bond prices and derecognition of the mandatorily exchanged debt.

**Derivative Liabilities**

*Warrant Derivative Liability*

The Company's warrant derivative liability (discussed in Note 5 Warrants and Warrant Derivative Liability) was carried at fair value and was classified as Level 3 in the fair value hierarchy due to the use of significant unobservable inputs. During the nine months ended September 30, 2015, of the 8,087,388 warrants outstanding as of December 31, 2014, 1,844,585 warrants were exercised while the remaining 6,242,803 warrants expired, and the related derivative liability was extinguished. As such, no warrants were outstanding as of September 30, 2016 and December 31, 2015.

---

**Table of Contents***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 Debt) contains a redemption feature whereby, upon a change of control, the Company would be required to repay \$150 million, less any previously repaid amount. The Company determined this redemption feature to be an embedded derivative, which is carried at fair value and is classified as Level 3 in the fair value hierarchy due to the use of significant unobservable inputs. The fair value of the embedded derivative was calculated using a probability-weighted model incorporating management estimates of future revenues and for a potential change in control, and by determining the fair value of the debt with and without the change in control provision included. The difference between the two was determined to be the fair value of the embedded derivative. As of September 30, 2016, the fair value of the derivative was determined to be nil based on current assumptions, and the debt was valued by comparing debt issues of similar companies with (i) remaining terms of between 1.3 and 5.6 years, (ii) coupon rates of between 6.6% and 12.5% and (iii) market yields of between 9.3% and 30.7%. As of December 31, 2015, the fair value of the derivative was determined to be \$5.5 million, and the debt was valued by comparing debt issues of similar companies with (i) remaining terms of between 2.0 and 7.3 years, (ii) coupon rates of between 6.6% and 12.5% and (iii) market yields of between 13.0% and 30.7%. As such, the Company recognized a \$5.5 million gain on change in fair value of derivative liability for the nine months ended September 30, 2016.

The Company's 2014 Notes and 2015 Notes each contained a redemption feature whereby, upon occurrence of a change in control, the Company would have been required to repurchase the notes. The Company determined these redemption features to be embedded derivatives, requiring bifurcation in accordance with ASC 815. The derivatives were carried at fair value and were classified as Level 3 in the fair value hierarchy due to the use of significant unobservable inputs. The fair value of each embedded derivative was calculated using a probability-weighted model incorporating management estimates of the probability of a change in control occurring, and by determining the fair value of the debt with and without the change in control provision included. The difference between the two was determined to be the fair value of the embedded derivative. As of September 30, 2016, the derivatives related to the 2014 Notes and 2015 Notes were each derecognized, as the related debt hosts were exchanged into equity in September 2016. As of December 31, 2015, the fair values of the derivatives related to the 2014 Notes and 2015 Notes were determined to be \$2.1 million and \$0.6 million, respectively, and the debts were valued by using (i) the estimated remaining term of the notes, (ii) a bond yield of 25.6%, (iii) a risk-free interest rate of 2.9% and (iv) volatility of 89.0%. As such, the Company recognized gains on change in fair value of derivative liabilities for the 2014 Notes and 2015 Notes of \$2.1 million and \$0.6 million, respectively, for the nine months ended September 30, 2016.

*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 Equity). 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 for the nine months ended September 30, 2016 and 2015 is as follows:

In thousands	October 2009 Warrants	Long-Term Debt Derivative Liabilities	Preferred Stock Purchase Option	Totals
<b>Balance as of December 31, 2015</b>	\$	\$ 8,170	\$	\$ 8,170
Gain on change in fair value of derivative liabilities		(8,170)		(8,170)
<b>Balance as of September 30, 2016</b>	\$	\$	\$	\$

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



---

**Table of Contents****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 early adopted by the Company or adopted as of the specified effective date.

In January 2016, the Company adopted ASU No. 2015-03, *Interest Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs*, which provides guidance on simplifying the presentation of debt issuance costs on the balance sheet. To simplify presentation of debt issuance costs, the amendments in ASU No. 2015-03 require that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with the treatment of debt discounts. The recognition and measurement guidance for debt issuance costs are not affected by the amendments in this update. In accordance with ASU No. 2015-03, the Company applied the new guidance on a retrospective basis, wherein the condensed consolidated balance sheet of each individual period presented was adjusted to reflect the period-specific effects of applying the new guidance. See Note 6 Debt.

In April 2016, the Company adopted ASU No. 2015-11, *Inventory (Topic 330): Simplifying the Measurement of Inventory*, which simplifies the subsequent measurement of inventories by replacing the lower of cost or market test with a lower of cost or net realizable value test. When evidence exists that the net realizable value of inventory is less than its cost (due to damage, physical deterioration, obsolescence, changes in price levels or other causes), the Company will recognize the difference as a component of cost of goods sold in the period in which it occurs. In accordance with ASU No. 2015-11, the Company applied the new guidance on a prospective basis with no impact on the carrying amount of inventory.

Also in April 2016, the Company adopted ASU No. 2016-09, *Compensation Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*, which changes the accounting for certain aspects of share-based payments to employees. One aspect of the standard requires that excess tax benefits and deficiencies that arise upon vesting or exercise of share-based payments be recognized as an income tax benefit and expense in the income statement. Previously, such amounts were recognized as an increase and decrease in additional paid-in capital. This aspect of the standard was adopted prospectively, and accordingly, the benefit from income taxes for the three and nine months ended September 30, 2016, includes \$0.3 million and \$0.4 million, respectively, of excess tax deficiencies arising from share-based payments. Additionally, the new standard requires that historical excess tax benefits that were not previously recognized because the related tax deduction had not reduced current taxes payable should be recognized on a modified retrospective basis as a cumulative-effect adjustment to retained earnings as of the beginning of the annual period of adoption. Consequently, the Company recognized deferred tax assets of approximately \$1.6 million relating to excess tax benefits on stock-based compensation outstanding as of December 31, 2015, with a corresponding cumulative-effect adjustment to accumulated deficit. The new standard also amends the presentation of employee share-based payment-related items in the statement of cash flows by requiring that: (i) excess income tax benefits and deficiencies be classified in cash flows from operating activities, and (ii) cash paid to taxing authorities arising from the withholding of shares from employees be classified as cash flows from

financing activities. The Company adopted the aspects of the standard affecting cash flow presentation retrospectively and, accordingly, reclassified \$0.7 million of excess tax provision from cash flows provided by financing activities to cash flows used in operating activities in the condensed consolidated statement of cash flows for the nine months ended September 30, 2015 to conform to the current year presentation. The presentation requirement for cash flows related to taxes paid for withheld shares had no impact to any of the periods presented in the condensed consolidated statement of cash flows since such payments have historically been presented as a financing activity.

---

**Table of Contents**

The Company also considered the following recent accounting pronouncements which were not yet adopted as of September 30, 2016:

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

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. 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 has determined that this standard would not have a material impact on its condensed consolidated financial statements based on the assessment of its ability to continue as a going concern as of September 30, 2016.

In January 2016, the FASB issued ASU No. 2016-01, *Financial Instruments Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities*. The new guidance is intended to improve the recognition and measurement of financial instruments by requiring separate presentation of financial assets and financial liabilities by measurement category and form of financial asset (i.e., securities or loans and receivables) within the balance sheet or the accompanying notes to the financial statements, eliminating the requirement for public business entities to disclose the method(s) and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost within the balance sheet, requiring public business entities to use the exit price notion when measuring the fair value of financial instruments for disclosure purposes, requiring equity investments (except those accounted for under the equity method of accounting, or those that result in consolidation of the investee) to be measured at fair value with changes in fair value recognized in net income, and requiring a reporting organization to present separately in other comprehensive income the portion of the total change in the fair value of a liability resulting from a change in the instrument-specific credit risk (also referred to as own credit) when the organization has elected to measure the liability at fair value in accordance with the fair value option for financial instruments, among others. The new guidance is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. The new guidance permits early adoption of the own credit provision. 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 February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*. The new guidance will require lessees to recognize a right-of-use asset and a lease liability for virtually all of their leases (other than leases that meet the definition of a short-term lease). The liability will be equal to the present value of lease payments. The asset will be based on the liability, subject to adjustment, such as for initial direct costs. Under the new guidance, lessor accounting

is largely unchanged but certain targeted improvements were made to align, where necessary, lessor accounting with the lessee accounting model and Topic 606, Revenue from Contracts with Customers. The new lease guidance also simplified the accounting for sale and leaseback transactions primarily because lessees must recognize lease assets and lease liabilities and therefore, will no longer be provided with a source of off-balance sheet financing. The new guidance is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption 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 March 2016, the FASB issued ASU No. 2016-08, *Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net)*, which clarifies that an entity is a principal when it controls the specified good or service before that good or service is transferred to the customer, and is an agent when it does not control the specified good or service before it is transferred to the customer. The new guidance is intended to improve the operability and understandability of the implementation guidance on principal versus agent considerations. In April 2016, the FASB issued ASU No. 2016-10, *Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing*, which clarifies the following two aspects of Topic 606: (a) identifying performance obligations; and (b) the licensing implementation guidance. Further, in May 2016, the FASB issued ASU No. 2016-12, *Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients*, which provides clarifying guidance in certain narrow areas and adds some practical expedients. The amendments do not change the core principles of the guidance in Topic 606 and are effective for the Company's fiscal year beginning January 1, 2018. Early application is permitted only as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period. The Company is currently evaluating the accounting, transition and disclosure requirements of these standards and cannot currently estimate the financial statement impact of adoption.

**Table of Contents**

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*, which is intended to reduce diversity in practice regarding how certain cash receipts and cash payments are presented and classified in the statement of cash flows. Specifically, it addresses the following eight issues: debt prepayment or debt extinguishment costs; settlement of zero-coupon debt instruments; contingent consideration payments made after a business combination; proceeds from the settlement of insurance claims; proceeds from the settlement of corporate-owned life insurance policies, including bank-owned life insurance policies; distributions received from equity method investments; beneficial interests in securitization transactions; and separately identifiable cash flows and application of the predominance principle. The new guidance is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption is permitted. The Company has evaluated the accounting, transition and disclosure requirements of the standard and does not expect it to have a material impact on the Company's condensed consolidated financial statements.

The Company believes that the impact of other recently issued but not yet adopted accounting pronouncements will not have a material impact on the Company's 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 13.8 years. The carrying value as of September 30, 2016 and December 31, 2015 is as follows:

<b>In thousands</b>	<b>September 30, 2016</b>	<b>December 31, 2015</b>
Technology rights	\$ 11,624	\$ 11,624
Accumulated amortization	(2,691)	(2,207)
	\$ 8,933	\$ 9,417

**(4) Inventory**

The Company capitalizes its purchases of saleable inventory of Vascepa from suppliers that have been qualified by the FDA. Inventories as of September 30, 2016 and December 31, 2015 consist of the following:

<b>In thousands</b>	<b>September 30, 2016</b>	<b>December 31, 2015</b>
Raw materials	\$ 8,926	\$ 9,096
Work in process	7,579	1,640
Finished goods	3,268	8,249
Total inventory	\$ 19,773	\$ 18,985

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

On October 16, 2009, the Company completed a \$70.0 million private placement with both existing and new investors resulting in \$62.3 million in net proceeds and an additional \$3.6 million from bridge notes converted in conjunction with the private placement. In consideration for the \$62.3 million in net cash proceeds Amarin issued 66.4 million units, each unit consisting of (i) one ADS (representing one ordinary share) at a purchase price of \$1.00 and (ii) a warrant with a five year term to purchase 0.5 (one half) 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 (one half) 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 were not considered to be indexed to the Company's common stock. Accordingly, the warrants did not qualify for the exception to classify the warrants within equity and were classified as a derivative liability.

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

**Table of Contents**

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. During the nine months ended September 30, 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, the remaining 6,242,803 warrants expired, and the related derivative liability was extinguished. As such, no warrants were outstanding as of September 30, 2016 and December 31, 2015.

**(6) Debt****Long-Term Debt from Royalty-Bearing Instrument December 2012 Financing**

On December 6, 2012, the Company entered into an agreement with BioPharma Secured Debt Fund II Holdings Cayman LP, or BioPharma. Under this agreement, the Company granted to BioPharma a security interest in future receivables associated with the Vascepa patent rights, in exchange for \$100 million received at the closing of the agreement which occurred in December 2012. Under these terms, the Company continues to own all Vascepa intellectual property rights, however, such rights, as described below, could be used by BioPharma as collateral for repayment of the remaining unpaid balance under this agreement if the Company defaults on making required payments. In the agreement, the Company agreed to repay BioPharma up to \$150 million with such repayment based on a portion of revenues and receivables generated from Vascepa.

As of September 30, 2016, the remaining amount to be repaid to BioPharma is \$128.8 million. During the three and nine months ended September 30, 2016, the Company made repayments under the agreement of \$3.3 million and \$8.5 million, respectively, to BioPharma and an additional \$3.2 million is scheduled to be paid in November 2016 for the third quarter of 2016. These payments were calculated based on the threshold limitation, as described below, as opposed to the scheduled quarterly repayments. Additional quarterly repayments, subject to the threshold limitation, are scheduled to be paid.

The maximum quarterly amounts which could be due for payment, except upon a change of control and subject each quarter to the threshold limitation, are as follows: \$15.0 million in the first quarter of 2017 and \$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, 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. Except in the event of the Company's default, there is no compounding of interest and no scheduled cliff payment due under this agreement. Rather, payment will be made, subject to the threshold limitation, until \$150 million in aggregate has been repaid, including payments made previously. The Company can prepay an amount equal to \$150 million less any previously repaid amount.

The Company currently estimates that its Vascepa revenue levels will not be high enough in each quarter to support repayment to BioPharma in accordance with the maximum quarterly amounts in the repayment schedule. For each quarterly period since the inception of the debt, revenues were below the contractual threshold amount such that cash payments were calculated for each period reflecting the optional reduction amount as opposed to the contractual threshold payment due for each quarterly period. In accordance with the agreement with BioPharma, quarterly differences between the calculated optional reduction amounts and the repayment schedule amounts are rescheduled for payment beginning in the second quarter of 2017. Any such deferred repayments will remain subject to continued

application of the quarterly ceiling in amounts due established by the calculated threshold limitation based on quarterly Vascepa revenues. No additional interest expense or liability is incurred as a result of such deferred repayments. These estimates will be reevaluated each reporting period by the Company and adjusted if necessary, prospectively.

The Company determined the redemption feature upon a change of control to be an embedded derivative requiring bifurcation. The fair value of the embedded derivative was calculated by determining the fair value of the debt with the change in control provision included and also without the change in control provision. The difference between the two fair values of the debt was determined to be the fair value of the embedded derivative, and upon closing the Company recorded a derivative liability of \$14.6 million as a reduction to the note payable. The fair value of this derivative liability is remeasured at each reporting period, with changes in fair value recognized in the condensed consolidated 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. Based on current assumptions underlying the valuation, the Company recognized a \$5.5 million gain on change in fair value of derivative liability during the nine months ended September 30, 2016, as compared to a \$0.3 million loss on change in fair value of derivative liability in the prior year period.



---

**Table of Contents**

As of September 30, 2016 and December 31, 2015, the carrying value of the BioPharma debt, net of the unamortized debt discount and issuance costs, was \$93.1 million and \$91.5 million, respectively. During the nine months ended September 30, 2016, the Company recorded cash and non-cash interest expense of \$5.0 million and \$1.5 million, respectively, in connection with the BioPharma debt. During the nine months ended September 30, 2015, the Company recorded cash and non-cash interest expense of \$4.9 million and \$1.4 million, respectively, in connection with the BioPharma debt. The Company will periodically evaluate the remaining term of the agreement and the effective interest rate is 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).

Under the Purchase and Sale Agreement with BioPharma, the Company is restricted from paying dividends on its common shares, unless it has cash and cash equivalents in excess of a specified amount after such payment.

**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 (the 2012 Notes), a portion of which was subsequently exchanged and a portion of which was extinguished (see discussion of May 2014 and November 2015 Exchangeable Senior Notes below), such that \$15.1 million in principal amount remains outstanding as of September 30, 2016. 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 in cash by the Company at the option of the holders on each of January 19, 2017, January 19, 2022, and January 19, 2027, at a price equal to 100% of the principal amount of the 2012 Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the repurchase date. The 2012 Notes are exchangeable under certain circumstances into cash, ADSs, or a combination of cash and ADSs, at the Company's election, with an initial exchange rate of 113.4752 ADSs per \$1,000 principal amount of 2012 Notes (equivalent to an initial exchange price of approximately \$8.8125 per ADS), subject to adjustment in certain circumstances, including adjustment if the Company pays cash dividends. If the Company elected physical settlement, the net remaining outstanding portion of the 2012 Notes would be exchangeable into 1,714,270 ADSs. Based on the closing price of the Company's stock as of September 30, 2016, the principal amount of the 2012 Notes would exceed the value of the shares if converted on that date by \$9.6 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 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 2012 Notes indenture). If the 2012 Notes are not freely tradable, as a result of restrictions pursuant to U.S. securities law or the terms of the 2012 Notes 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.

---

**Table of Contents**

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 both September 30, 2016 and December 31, 2015, the discount created from the allocation of the proceeds to the conversion option was fully amortized and the carrying amount of the conversion option was \$11.5 million. The conversion option will not be subsequently remeasured as long as it continues to meet the criteria for equity classification.

The Company also recorded a debt discount to reflect the value of the 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 both September 30, 2016 and December 31, 2015, the debt discount was fully amortized and the carrying value of the 2012 Notes was \$15.1 million after an exchange and repayment of a portion of the 2012 Notes (see below for further discussion of the May 2014 Notes and November 2015 Notes). The outstanding 2012 Notes may be put to the Company (at the holders' option, upon fundamental change or an event of default), or converted by holders and the holders have the option to put the 2012 Notes back to the Company on each of January 19, 2017, 2022 and 2027 for cash equal to 100% of the principal amount plus accrued and unpaid interest. As a result, the carrying value of the 2012 Notes of \$15.1 million is classified as a current liability as of September 30, 2016. During the nine months ended September 30, 2016 and 2015, the Company recognized contractual coupon interest expense of \$0.4 million and \$0.8 million related to the 2012 Notes, respectively. The Company made the contractual interest payments due on the 2012 Notes during the nine months ended September 30, 2016 and 2015 of \$0.5 million and \$1.1 million, respectively, and had accrued interest of \$0.2 million and \$0.3 million as of September 30, 2016 and December 31, 2015, respectively, which is included in current portion of exchangeable senior notes, net of discount.

**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 3.5% May 2014 Exchangeable Senior Notes due 2032 (the 2014 Notes), 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). In September 2016, Corsicanto mandatorily exchanged \$118.7 million of aggregate principal amount of the 2014 Notes for equity upon satisfaction of specified equity conditions as described below, such that no 2014 Notes remained outstanding as of September 30, 2016.

The 2014 Notes indenture contained a provision that allowed the Company to 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 2014 Notes indenture) equaled or exceeded 110% of the Exchange Price then in effect for at least 20 VWAP Trading Days (as defined in the 2014 Notes indenture) in any 30 VWAP Trading Day period, and upon satisfaction of other 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. In August 2016, Corsicanto gave notice to the holders of the 2014 Notes that the above described conditions had been satisfied and

exercised its option to mandatorily exchange \$118.7 million of aggregate principal amount of the 2014 Notes for equity with settlement in September 2016, such that all of the outstanding 2014 Notes were retired. In the event of physical settlement, the 2014 Notes were initially exchangeable into 45,666,925 ADSs. The initial exchange rate was 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, including, but not limited to, the payment of cash dividends or the Company's exercise of its optional exchange rights. Consistent with the 2014 Notes indenture, the final as-adjusted exchange rate was 402.0746 ADSs per \$1,000 of principal amount, resulting in 47,739,925 ADSs being issued in exchange for the 2014 Notes. Refer to the end of this Note for discussion of the accounting treatment for this transaction.

The 2014 Notes had 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, had the notes not been exchanged early. The 2014 Notes indenture provided holders the option to exchange the 2014 Notes 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. If a fundamental change (as defined in the 2014 Notes indenture) had occurred prior to the 2014 Notes being exchanged, holders may have required 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 have required 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.

---

**Table of Contents**

As a result of the note exchange in 2014 (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 represented 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 initially recognized those costs as deferred assets. Effective January 2016, the Company adopted ASU No. 2015-03, *Interest Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs*, which requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with the treatment of debt discounts. As the standard is required to be adopted on a retrospective basis, the Company reclassified \$1.8 million of underwriter's fees and offering costs related to the 2014 Notes from other long-term assets to exchangeable senior notes, net of discount, within the condensed consolidated balance sheet as of December 31, 2015.

The Company further allocated \$3.5 million of the \$90.8 million fair value of the 2014 Notes to the derivative liability related to the fundamental change redemption feature (as described above). The fair value of this derivative liability was remeasured at each reporting period, with changes in fair value recognized in the condensed consolidated statement of operations. As a result of the mandatory exchange of the debt host, the Company derecognized the related derivative liability and recognized a \$2.1 million gain on change in fair value of derivative liability in the nine months ended September 30, 2016, as compared to a \$0.8 million gain on change in fair value of derivative liability recognized in the prior year period.

Because the conversion option in the 2014 Notes received an exception from derivative accounting and only required gross physical settlement in shares, the embedded option did not require separate accounting and was therefore accounted for as part of the debt host at amortized cost. The debt discount was amortized as interest expense over the estimated life of the 2014 Notes and was recognized in the condensed consolidated statement of operations as interest expense. As of September 30, 2016 and December 31, 2015, the carrying value of the 2014 Notes, net of the unamortized debt discount and issuance costs, was nil and \$94.6 million, respectively. During the nine months ended September 30, 2016, the Company recognized aggregate interest expense of \$7.7 million related to the 2014 Notes, of which \$4.8 million represents non-cash interest and \$2.9 million represents contractual coupon interest. During the nine months ended September 30, 2015, the Company recognized aggregate interest expense of \$7.7 million related to the 2014 Notes, of which \$4.6 million represents non-cash interest and \$3.1 million represents contractual coupon interest. The Company made the contractual interest payments due on the 2014 Notes during the nine months ended September 30, 2016 and 2015 of \$4.2 million in each period, and had accrued interest of nil and \$1.9 million as of September 30, 2016 and December 31, 2015, respectively, which is included in current portion of exchangeable senior notes, net of discount.

**November 2015 Exchangeable Senior Notes**

In November 2015, the Company entered into a privately negotiated subscription agreement with one of its existing investors (the Investor), pursuant to which the Investor agreed to purchase approximately \$31.3 million in aggregate principal amount of new 3.5% November 2015 Exchangeable Senior Notes due 2032 (the 2015 Notes) for approximately \$27.5 million. Approximately \$15.9 million of such proceeds were used to finance the repayment of a portion of the 2012 Notes with the remainder to be used for working capital and general corporate purposes. The 2015 Notes were issued by Amarin Corporation plc and were not guaranteed by any entity, but otherwise had substantially

identical terms to the 2014 Notes, including the provision related to the Company's optional exchange rights.

In August 2016, the Company gave notice to the holders of the 2015 Notes that the Daily VWAP conditions as described above for the 2014 Notes had been satisfied and exercised its option to mandatorily exchange \$31.3 million of aggregate principal amount of the 2015 Notes for equity with settlement in September 2016, such that all of the outstanding 2015 Notes were retired. In the event of physical settlement, the 2015 Notes were initially exchangeable into 12,025,385 ADSs. The initial exchange rate was 384.6154 ADSs per \$1,000 principal amount of 2015 Notes (equivalent to an initial exchange price of approximately \$2.60 per ADS), subject to adjustment in certain circumstances, including, but not limited to, the payment of cash dividends or the Company's exercise of optional exchange rights. Consistent with the terms of the 2015 Notes, the final as-adjusted exchange rate was 402.0746 ADSs per \$1,000 of principal amount, resulting in 12,571,263 ADSs being issued in exchange for the 2015 Notes. Refer to the end of this Note for discussion of the accounting treatment for this transaction.

The 2015 Notes were recorded at fair value of \$27.5 million representing a \$3.8 million discount to par. In addition, the Company recognized \$0.1 million in offering costs and initially recognized those costs as deferred assets. As described for the 2014 Notes above, effective January 2016, the Company adopted ASU No. 2015-03, *Interest Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs*. As the standard is required to be adopted on a retrospective basis, the Company reclassified \$0.1 million of underwriters' fees and offering costs related to the 2015 Notes from other long-term assets to exchangeable senior notes, net of discount, within the condensed consolidated balance sheet as of December 31, 2015.

---

**Table of Contents**

The Company further allocated \$0.5 million of the \$27.5 million fair value of the 2015 Notes to the derivative liability related to the fundamental change redemption feature (as described under the 2014 Notes above). The fair value of this derivative liability was remeasured at each reporting period, with changes in fair value recognized in the condensed consolidated statement of operations. As a result of the mandatory exchange of the debt host, the Company derecognized the related derivative liability and recognized a \$0.6 million gain on change in fair value of derivative liability in the nine months ended September 30, 2016.

Because the conversion option in the 2015 Notes received an exception from derivative accounting and only required gross physical settlement in shares, the embedded option did not require separate accounting and was therefore accounted for as part of the debt host at amortized cost. The debt discount was amortized as interest expense over the estimated life of the 2015 Notes and recognized in the condensed consolidated statement of operations as interest expense. As of September 30, 2016 and December 31, 2015, the carrying value of the 2015 Notes, net of the unamortized debt discount and issuance costs, was nil and \$27.0 million, respectively. During the nine months ended September 30, 2016, the Company recognized aggregate interest expense of \$1.7 million related to the 2015 Notes, of which \$0.9 million represents non-cash interest and \$0.8 million represents contractual coupon interest. The Company made the contractual interest payments due on the 2015 Notes during the nine months ended September 30, 2016 of \$0.7 million, and had accrued interest of nil and \$0.1 million as of September 30, 2016 and December 31, 2015, respectively, which is included in current portion of exchangeable senior notes, net of discount.

Concurrent with the issuance of the 2015 Notes, Corsicanto Limited and the Company entered into separate, privately negotiated purchase agreements with certain holders of the 2012 Notes pursuant to which the Company purchased (the 2012 Notes Purchase ) approximately \$16.2 million in aggregate principal amount of the 2012 Notes for \$15.9 million, which included accrued but unpaid interest on such 2012 Notes. The 2012 Notes Purchase was funded by the issuance of the 2015 Notes. Following the closing of the 2012 Notes Purchase, Corsicanto had approximately \$15.1 million in aggregate principal amount of 2012 Notes outstanding. The 2012 Notes Purchase was accounted for as an extinguishment of debt and the Company recorded a gain of \$1.3 million upon extinguishment during the fourth quarter of 2015, which represents the reacquisition of the conversion option at fair value and a negotiated discount on the purchase of the notes partially offset by legal and transaction advisory costs incurred.

As described in the *May 2014 Exchangeable Senior Notes* and *November 2015 Exchangeable Senior Notes* sections above, the Company mandatorily exchanged, in total, \$150.0 million in aggregate principal amount (\$127.3 million in carrying value, net of unamortized debt discount and issuance costs) of outstanding 2014 Notes and 2015 Notes resulting in the issuance of 60,311,188 ADSs and recognition of \$40.1 million in common stock and \$87.4 million in additional paid-in capital. Included within this \$87.4 million is \$0.8 million of accrued but unpaid interest as of the exchange date deemed satisfied and discharged in full upon delivery of the ADSs consistent with the terms of the notes and ASC 470-20, less \$0.7 million of transaction costs.

**(7) Commitments and Contingencies****Litigation and Other Legal Matters**

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

Item 3. Legal Proceedings of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2015, and Item 1. Legal Proceedings of the Company's Quarterly Reports on Form 10-Q for the quarters ended March 31, 2016 and June 30, 2016 include discussions of the Company's current legal proceedings. There have been no material changes to those disclosures as of the date of this filing other than as set forth below.

In September and October 2016, the Company received paragraph IV certification notices from four companies contending to varying degrees that certain of its patents are invalid, unenforceable and/or will not be infringed by the manufacture, use, sale or offer for sale of a generic form of Vascepa as described in those companies' abbreviated new drug applications, or ANDAs. The Company filed or is in the process of filing patent infringement lawsuits against each of these ANDA applicants. In October 2016, Amarin filed a lawsuit against Roxane Laboratories, Inc. and related entities, or Roxane, in the U.S. District Court for the District of Nevada. The case against Roxane is captioned *Amarin Pharma, Inc. et al. v. Roxane Laboratories, Inc. et al*, Civ. A. No. 2:16-cv-02525 (D. Nev.). In the *Roxane* lawsuit, Amarin is seeking, among other remedies, an order enjoining Roxane from marketing generic versions of Vascepa before the last to expire of the asserted patents in 2030. The Company intends to vigorously enforce its intellectual property rights relating to Vascepa, but cannot predict the outcome of the *Roxane* lawsuit or any subsequently filed lawsuits.

*Milestone and Supply Purchase Obligations*

The Company entered into long-term supply agreements with multiple FDA-approved API suppliers and encapsulators. Certain supply agreements require annual minimum volume commitments by the Company and certain volume shortfalls may require payments for such shortfalls, as detailed below.



---

**Table of Contents**

The Company entered into its initial Vascepa API supply agreement with Nisshin Pharma, Inc. ( Nisshin ) in 2010. In 2011, the Company entered into agreements with two additional suppliers, Chemport, Inc. ( 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 API supply agreement with BASF terminated in February 2014. In July 2014, the Company terminated the supply agreement with Slanmhor and subsequently, in July 2015, entered into a new supply agreement with Finorga SAS ( Novasep ). These agreements included requirements for the suppliers to meet certain product specifications and qualify their materials and facilities with applicable regulatory authorities including the FDA. The Company has incurred certain costs associated with the qualification of product produced by these suppliers as described below. Nisshin, Chemport and Novasep are currently the three manufacturers from which the Company purchases API.

Chemport was approved by the FDA to manufacture API for commercial sale in April 2013 and the Company began purchasing commercial supply from Chemport in 2013. The agreement with Chemport contains a provision requiring the Company to pay Chemport in cash for any shortfall in the minimum purchase obligations. The Company began purchasing commercial supply from Novasep in 2015. API manufactured by Novasep was previously approved by the FDA in July 2014. The 2015 supply agreement with Novasep contains a provision requiring the Company to pay Novasep a cash remedy for any shortfall in the minimum purchase obligations. The Company continues to meet its contractual purchase obligations.

Under the 2004 share repurchase agreement with Laxdale Limited ( Laxdale ) upon receipt of marketing approval in Europe for the first indication for Vascepa (or first indication of any product containing Amarin Neuroscience Limited 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 \$9.7 million as of September 30, 2016). 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 Limited 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 \$6.5 million as of September 30, 2016) for each of the two potential market approvals (i.e. £10 million maximum, or approximately \$13.0 million as of September 30, 2016).

The Company has no provision for any of the obligations above since the amounts are either not probable or able to be estimated as of September 30, 2016.

**(8) Equity****Common Stock**

In September 2016, the Company mandatorily exchanged \$118.7 million and \$31.3 million of aggregate principal amount of the 2014 Notes and 2015 Notes, respectively, resulting in the issuance of 47,739,925 ADSs and 12,571,263 ADSs, respectively, with each ADS representing one ordinary share of the Company (see Note 6 Debt).

In August 2016, the Company completed a public offering of 21,100,000 ADSs, with each ADS representing one ordinary share of the Company. Amarin also granted the underwriters a 30-day option to purchase an additional 3,165,000 ADSs at the same price, which was exercised in full. The underwriters purchased the ADSs from the Company at a price of \$2.679 per ADS after commission, resulting in net proceeds to the Company of approximately \$64.6 million, after deducting estimated offering expenses payable by the Company. The Company currently intends to use the net proceeds from the offering to advance its REDUCE-IT cardiovascular outcomes trial and for general corporate and working capital purposes.

Preferred Stock

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

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

Each ten (10) Series A Preference Shares may be consolidated and redesignated as one (1) ordinary share, par value £0.50 per share, in the capital of the Company, each ordinary share to be represented by 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

---

**Table of Contents**

to the Company, a holder may from time to time increase or decrease the Beneficial Ownership Limitation to any other percentage not in excess of 19.9% specified in such notice; provided that any such increase will not be effective until the sixty-first (61st) day after such notice is delivered to the Company. This consolidation and redesignation may be effected by a holder of Series A Preference Shares following the first to occur of the resale of the ADSs representing the ordinary shares being registered for resale under the Securities Act pursuant to an effective registration statement, following any sale of the ADSs representing the ordinary shares pursuant to Rule 144 under the Securities Act, or if such ADSs representing the ordinary shares are eligible for sale under Rule 144, following the expiration of the one-year holding requirement under Rule 144. Subsequently, at the request of the holders, a portion of the Series A Preference Shares were consolidated and redesignated during the three months ended June 30, 2015, resulting in the issuance of 6,283,333 ADSs such that a maximum of 32,818,464 ordinary shares remain issuable upon future consolidation and redesignation of the remaining Series A Preference Shares as of September 30, 2016, inclusive of the shares issued in July 2015 as discussed below, subject to certain adjustments for dilutive events.

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

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

The restricted American Depositary Shares and Series A Preference Shares were sold in a transaction exempt from the registration requirements under the Securities Act of 1933, as amended (the Securities Act). 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, which was declared effective by the SEC on May 1, 2015. In addition, the Company agreed to use its commercially reasonable best efforts to keep the registration, and any qualification, exemption or compliance under state securities laws which the Company determines to obtain, continuously effective, and to keep the Registration Statement free of any material misstatements or omissions, until the earlier of (a) March 11, 2017 or (b) the date on which all Registrable Securities held by Purchasers may be sold or transferred in compliance with Rule 144 under the Securities Act, without any volume or manner of sale restrictions.

The Series A Preference Shares contain a contingent beneficial conversion feature (BCF) because they contain a conversion feature at a fixed rate that was in-the-money when issued. The BCF was recorded in the three months ended June 30, 2015 as a result of the related Form S-3 Registration Statement being declared effective, which represents the resolution of the contingency to convert the Series A Preference Shares. The BCF was recognized in stockholders' equity 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 was recorded as a non-cash dividend to preferred shareholders through accumulated deficit, and was therefore reflected as an adjustment to net loss applicable to common shareholders for earnings per common share.

purposes in accordance with GAAP for the nine months ended September 30, 2015.

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

---

**Table of Contents**

The Company filed another registration statement with the SEC covering the resale of these restricted American Depositary Shares and the ADSs representing ordinary shares created by the consolidation and redesignation of the Series A Preference Shares (the Sofinnova Registrable Securities ) on July 24, 2015, which was declared effective by the SEC on August 7, 2015. In addition, the Company agreed to use its commercially reasonable best efforts 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) July 10, 2017 or (b) the date on which all Sofinnova Registrable Securities held by Sofinnova may be sold or transferred in compliance with Rule 144 under the Securities Act, without any volume or manner of sale restrictions.

The existence of this preferred stock purchase option was determined to be a derivative liability effective March 5, 2015, the date on which the private placement was initially subscribed. The fair value of this liability was calculated using a Black-Scholes model and was determined to be \$0.9 million at inception and was charged to accumulated deficit as a deemed non-cash dividend to Sofinnova. The liability was then marked to fair value as of March 30, 2015, the date on which the Company executed a subscription agreement with Sofinnova, resulting in a charge of \$0.9 million through 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. Subsequent to approval of the Second Private Placement at the Company's Annual General Meeting of Shareholders in July 2015, the Company recorded the remaining value of the BCF related to this share issuance as a non-cash dividend to preferred shareholders through accumulated deficit. The value of the BCF was determined on the same basis as the first private placement and amounted to \$3.4 million less \$1.8 million previously recorded for the preferred stock purchase option for a net non-cash charge of \$1.6 million in the three months ended September 30, 2015.

**Incentive Equity Awards**

In March 2016, the FASB issued ASU No. 2016-09, *Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*. The Company early adopted this standard during the quarter ended June 30, 2016, without electing to change its existing accounting policy of accounting for forfeitures based on expected vesting. The new standard requires that excess tax benefits and deficiencies that arise upon vesting or exercise of share-based payments be recognized as an income tax benefit and expense in the income statement, and also that historical excess tax benefits that were not previously recognized because the related tax deduction had not reduced current taxes payable should be recognized on a modified retrospective basis as a cumulative-effect adjustment to retained earnings as of the beginning of the annual period of adoption. Further, the new standard amends the presentation of employee share-based payment-related items in the statement of cash flows by requiring that: (i) excess income tax benefits and deficiencies be classified in cash flows from operating activities, and (ii) cash paid to taxing authorities arising from the withholding of shares from employees be classified as cash flows from financing activities. Refer to Note 2 above for additional discussion on the Company's adoption of the new standard.

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 guidance became effective for all entities during the first quarter of fiscal 2016. The Company previously accounted for awards in a manner consistent with the new guidance and as such, adoption of the guidance did not have any impact on the Company's condensed consolidated financial statements.

As of September 30, 2016, there were an aggregate of 21,240,894 stock options and 10,346,162 restricted stock units ( RSUs ) outstanding, representing approximately 6% and 3%, respectively, of outstanding shares (including common

and preferred shares) on a fully diluted basis.

During the nine months ended September 30, 2016 and 2015, the Company issued 94,272 and 18,020 shares, respectively, as a result of the exercise of stock options, resulting in gross and net proceeds of \$0.1 million during the nine months ended September 30, 2016 and \$31 thousand during the nine months ended September 30, 2015.

On July 11, 2016, the Company granted a total of 148,403 RSUs and 208,340 stock options to members of the Company's Board of Directors under the Amarin Corporation plc Stock Incentive Plan (the "2011 Plan"). The RSUs vest in equal installments over a three year period upon the earlier of the anniversary of the grant date or the Company's annual general meeting of shareholders in such anniversary year. The stock options vest in full upon the earlier of the one-year anniversary of the grant date or the Company's annual general meeting of shareholders in such anniversary year. Upon termination of service to the Company or upon a change of control, each Director shall be entitled to a payment equal to the fair market value of one share of Amarin common stock, which is required to be made in shares.

On February 1, 2016, the Company granted a total of 1,607,500 RSUs and 2,442,000 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.

---

**Table of Contents**

On July 6, 2015, the Company granted a total of 1,455,000 RSUs and 5,470,000 stock options to employees under the 2011 Plan. The RSUs granted vest over a four year period. Of the total stock options granted, 3,670,000 stock options vest over a four year period while the remaining 1,800,000 stock options vest upon the achievement of certain performance conditions. During the nine months ended September 30, 2016, the Company issued 272,812 common shares related to the vesting of these RSUs, of which 125,484 shares were retained as treasury shares as settlement of employee tax obligations.

Also on July 6, 2015, the Company granted a total of 413,500 RSUs and 288,657 stock options to members of the Company's Board of Directors under the 2011 Plan. Of the total awards granted, 283,500 RSUs and 121,506 stock options vest in equal installments over a three year period upon the earlier of the one-year anniversary of the grant date or the Company's annual general meeting of shareholders in such anniversary year, while the remaining 130,000 RSUs and 167,151 stock options vest in full upon the earlier of the one-year anniversary of the grant date or the Company's annual general meeting of shareholders in such anniversary year. Upon termination of service to the Company or upon a change of control, each Director shall be entitled to a payment equal to the fair market value of one share of Amarin common stock, which is required to be made in shares.

On January 29, 2015, the Company granted a total of 2,564,251 RSUs and 1,622,500 stock options to employees under the 2011 Plan. The RSUs vest annually over a three year period and the stock options vest 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. The issuance of these performance RSUs was contingent upon shareholder approval to increase the aggregate number of shares authorized for issuance under the 2011 Plan, which was obtained at the Company's Annual General Meeting of Shareholders held on July 6, 2015. During the nine months ended September 30, 2016, the Company issued 818,352 common shares related to the vesting of these RSUs, of which 270,329 shares were retained as treasury shares as settlement of employee tax obligations.

**Warrants**

During the nine months ended September 30, 2015, the Company issued 1,844,585 shares upon the exercise of warrants, resulting in gross and net proceeds of \$2.8 million and \$2.7 million, respectively. There was no warrant activity during the nine months ended September 30, 2016 and no warrants remained outstanding as of September 30, 2016.

**(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 aggregate Vascepa gross margin that increases during the term. The percentage of aggregate Vascepa gross margin earned by Kowa Pharmaceuticals America, Inc. was fifteen percent (15%) in 2015, is nineteen percent (19%) in 2016, and is scheduled to increase to low twenty percent levels in 2017 and 2018, subject to certain adjustments. The co-promotion fee also varies based on sales levels and whether the FDA has approved an ANCHOR indication labeling expansion for Vascepa or has permitted the use of data generated to support obtaining FDA approval of the ANCHOR indication in the promotion of Vascepa, in which case the co-promotion fee would be decreased if specified requirements are met. In certain circumstances, upon the earlier of the expiration or termination of the Agreement in accordance with its terms, Kowa Pharmaceuticals America, Inc. may be eligible for a co-promotion tail fee equal to declining fractions of the co-promotion fee in effect prior to such expiration or termination for periods ranging from one to three years following such expiration or termination.

As of September 30, 2016 and December 31, 2015, the Company had a net payable of \$3.3 million and \$2.5 million, respectively, to Kowa Pharmaceuticals America, Inc. representing co-promotion fees payable to Kowa Pharmaceuticals America, Inc. net of reimbursable amounts incurred for samples and other marketing expenses.



---

**Table of Contents****(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 terms. The Company will retain all Vascepa manufacturing rights. Eddingpharm has agreed to certain restrictions regarding the commercialization of competitive products globally and the Company has agreed to certain restrictions regarding the commercialization of competitive products in the China Territory.

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

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

Upon closing of the DCS Agreement, the Company received a non-refundable \$15.0 million up-front payment, which it will recognize as revenue over the estimated period in which the Company is required to provide initial and on-going regulatory and development support and clinical supply for obtaining regulatory approvals in the China Territory and through the estimated period in which the Company is required to provide commercial supply, which is currently estimated to be a period of approximately 16 years. In March 2016, Eddingpharm submitted its clinical trial application (CTA) with respect to the MARINE indication for Vascepa to the Chinese regulatory authority. Following the CTA submission, the Company received a non-refundable \$1.0 million milestone payment which it will recognize as revenue over the estimated period in which the Company is required to provide on-going development support needed to support the successful approval for a new drug application, which is currently estimated to be a period of approximately four years.

In addition to the non-refundable, up-front and regulatory milestone payments described above, the Company is entitled to receive certain regulatory and sales-based milestone payments of up to an additional \$153.0 million as well

as tiered double-digit percentage royalties on net sales of Vascepa in the China Territory escalating to the high teens. The regulatory milestone events relate to the submission and approval of certain applications to the applicable regulatory authority, such as a clinical trial application, clinical trial exemption, or import drug license application. The sales-based milestone events occur when annual aggregate net sales of Vascepa in the territory equals or exceeds certain specified thresholds. Each such milestone payment shall be payable only once regardless of how many times the sales milestone event is achieved. Each such milestone payment is non-refundable and non-creditable against any other milestone payments. The Company recognizes contingent consideration from activities that is earned upon the achievement of a substantive milestone in the period in which the milestone is achieved.

Licensing and deferred revenues currently consist of revenue attributable to receipt of up-front, non-refundable payments and milestone payments related to the DCS Agreement and other licensing agreements outside the United States. Up-front and milestone payments under such agreements are typically recognized as licensing revenue over the estimated period in which we are required to provide regulatory and development support and clinical and commercial supply pursuant to the agreements. During the nine months ended September 30, 2016 and 2015, the Company recognized \$0.8 million and \$0.5 million of up-front and milestone payments as licensing revenue, respectively, and recorded \$15.4 million as deferred revenue as of September 30, 2016.

**(11) Subsequent Events**

The Company has evaluated subsequent events from September 30, 2016 through the date of the issuance of these condensed consolidated financial statements.

---

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

*This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. These forward-looking statements reflect our plans, estimates and beliefs. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terms such as anticipates, believes, continue, 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, 2015 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. This FDA-approved indication for Vascepa, known as the MARINE indication, is based primarily on the successful results from the MARINE study of Vascepa in this approved patient population. In considering this approval, FDA also reviewed the successful results from our study of Vascepa in patients with high triglyceride levels (TG  $\geq$ 200 mg/dL and  $<$ 500 mg/dL) who are also on statin therapy for elevated low-density lipoprotein cholesterol, or LDL-C, levels which condition we refer to as mixed dyslipidemia or persistently high triglycerides. This study is known as the ANCHOR study. Safety data from both the MARINE and ANCHOR studies are reflected in FDA-approved labeling for Vascepa. In January 2013, we began selling and marketing Vascepa in the United States based on the FDA-approved MARINE indication. In August 2015, we also began marketing Vascepa in the United States for the treatment of the patient population studied in the ANCHOR study based on the federal court declaration described below. In March 2016, we reached agreement with the FDA and U.S. government under which they agreed to be bound by the terms of the August 2015 judicial declaration. Vascepa is available in the United States by prescription only. In May 2016, the FDA determined Vascepa to be eligible for five-year, new chemical entity (NCE) marketing exclusivity thereby providing Vascepa with the benefits of NCE exclusivity afforded by statute from its July 2012 FDA approval.

We sell Vascepa principally to a limited number of major wholesalers, as well as selected regional wholesalers and specialty pharmacy providers, or collectively, our Distributors or our customers, that in turn resell Vascepa to retail pharmacies for subsequent resale to patients and healthcare providers. We market Vascepa in the United States 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 in the United States with Kowa Pharmaceuticals America,

Inc. under which no less than 250 Kowa Pharmaceuticals America, Inc. sales representatives began to devote a substantial portion of their time to promoting Vascepa starting in May 2014.

We have 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, or the China Territory. We also have an agreement to register and commercialize Vascepa in countries within the Middle East and North Africa and are assessing other partnership opportunities for licensing Vascepa in other territories outside of the United States.

Triglycerides are the main constituent of body fat in humans. 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. Many patients with high triglyceride levels also have diabetes and other lipid level abnormalities such as high cholesterol. The patient condition of having more than one lipid level abnormality is referred to as mixed dyslipidemia. According to *The American Heart Association Scientific Statement on Triglycerides and Cardiovascular Disease* (2011), triglycerides provide important information as a marker associated with the risk for heart disease and stroke, especially when

---

**Table of Contents**

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. In 2016, we completed patient enrollment and randomization of 8,175 individual patients into the REDUCE-IT study, slightly exceeding the 8,000 patients targeted for the trial.

The REDUCE-IT study is designed to be completed after reaching 1,612 aggregate cardiovascular events. Based on projected event rates, we estimate the onset of the target aggregate number of cardiovascular events to be reached in or about the fourth quarter of 2017 with study results then expected to be available and published in 2018. In addition, since its inception in 2011, our REDUCE-IT special protocol assessment (SPA) agreement with the FDA has provided for periodic safety reviews and an interim efficacy and safety analysis by the study's independent data monitoring committee (DMC) at approximately 60% of the target aggregate number of primary cardiovascular events. In August 2016, we announced an amendment to our REDUCE-IT SPA agreement with FDA that reaffirmed FDA concurrence on key elements of the study, defined details of the statistical analysis plan for the study, expanded to greater than 30 the pre-specified secondary and tertiary endpoints in the study, and added a second interim efficacy and safety analysis by the DMC at approximately 80% of the target aggregate number of primary cardiovascular events. The periodic safety reviews and interim efficacy and safety analyses are conducted confidentially by the study's DMC. We remain blinded to all data from the study. Since patient enrollment commenced in 2011, more than 23,000 patient years of study experience have been accumulated in the REDUCE-IT study. Following each periodic review of safety data to date, the DMC has communicated to us that we should continue the study as planned.

In March 2016, we announced that the onset of approximately 60% of the target aggregate number of primary cardiovascular events had triggered preparation for the first pre-specified interim analysis of efficacy and safety results, such analysis to include the first review of unblinded efficacy data by the independent DMC. The DMC completed its review of the interim analysis in September 2016 and, consistent with previously stated expectations, recommended that the trial continue as planned without modification. The second planned interim analysis of efficacy results will be triggered by the onset of approximately 80% of the target aggregate number of primary cardiovascular events in the study. Based on historical event rates, we anticipate that the onset of approximately 80% of events will occur in the first half of 2017, with the second pre-specified interim efficacy analysis by the DMC expected in or about the third quarter of 2017. The interim efficacy analysis will be accompanied by an interim safety analysis by the DMC. As is typical, the statistical threshold for defining overwhelming efficacy on the primary endpoint at interim analyses is considerably higher than the threshold for defining statistical significance at the end of the study. In addition, we have requested the DMC to not recommend stopping the study early based only upon achieving statistical significance for the primary endpoint, but to ensure that supportive trends of benefit are also consistently observed in certain secondary endpoints and subpopulations before recommending that the study be stopped early for overwhelming efficacy. It is our expectation that the 80% interim analysis will also result in a recommendation to continue the trial.

In the successful Phase 3 MARINE and ANCHOR clinical trials, Vascepa was studied at a daily dose of 2 grams and 4 grams. We sought approval of Vascepa at the more efficacious 4-gram dose for use in each patient population. These trials demonstrated favorable results in their respective patient populations, particularly with the 4-gram dose of Vascepa, 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).

In April 2015, we received a Complete Response Letter, or CRL, from the FDA in response to our supplemental new drug application, or sNDA, that sought approval of Vascepa for use in patients with mixed dyslipidemia, based on the successful ANCHOR study. The CRL followed an October 2013 rescission by the FDA of a special protocol assessment, or SPA, agreement and three failed attempts by us to appeal that rescission at FDA. The FDA has acknowledged the success of the ANCHOR study, which met all primary and secondary endpoints. However, FDA determined that there were insufficient data to conclude that drug-induced changes in serum triglycerides could be recognized by the FDA as a valid surrogate for reducing cardiovascular risk in the ANCHOR

---

**Table of Contents**

population for the purpose of regulatory approval of a drug targeted at a triglyceride-lowering indication in this population. The FDA has acknowledged that the standard of proof required by the FDA for approval of a new drug indication is higher than that generally used to inform patient treatment guidelines and that used by physicians in clinical practice. 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 and the FDA has encouraged us to complete the REDUCE-IT outcomes 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.

In May 2015, we and a group of independent physicians filed a lawsuit in federal court to permit us to promote to healthcare professionals the use of Vascepa in patients with mixed dyslipidemia so long as the promotion is truthful and non-misleading. This use reflects recognized medical practice but is not covered by current FDA-approved labeling for the drug. Historically, FDA has considered promotion of drug uses not covered by FDA-approved labelling to be illegal off-label promotion, even if such promotion is truthful and non-misleading. In August 2015, we were granted preliminary relief in the form of a declaratory judgment in this lawsuit. The court declaration permitted us to promote to healthcare professionals the FDA-reviewed and agreed effects of Vascepa demonstrated in the ANCHOR clinical trial and presentation of the current state of scientific research related to the potential of Vascepa to reduce the risk of cardiovascular disease including through use of peer-reviewed scientific publications of available data. In August 2015, we began to promote Vascepa to healthcare professionals as permitted by this court declaration and in March 2016, the parties obtained court approval of negotiated settlement terms under which the FDA and the U.S. government agreed to be bound by the court's conclusions from the August 2015 declaration that we may engage in truthful and non-misleading speech promoting the off-label use of Vascepa and that certain statements and disclosures that we proposed to make to healthcare professionals were truthful and non-misleading. While we believe we are now permitted under applicable law to more broadly promote Vascepa, the FDA-approved labeling for Vascepa did not change as a result of this litigation and settlement, and neither government nor other third-party coverage or reimbursement to pay for the off-label use of Vascepa promoted under the court declaration was required.

*Commercialization United States*

We commenced the commercial launch of Vascepa in the United States in January 2013. We commenced sales and shipments of Vascepa at that time to our network of U.S.-based wholesalers. We now market Vascepa in the United States through our sales force of approximately 150 sales professionals, including sales representatives and their managers. Commencing in May 2014, in addition to promotion by our sales representatives, no less than 250 Kowa Pharmaceuticals America, Inc. sales representatives began promoting Vascepa. We also employ various marketing personnel to support our commercialization of Vascepa.

Under our co-promotion agreement with Kowa Pharmaceuticals America, Inc., both parties have agreed to use commercially reasonable efforts to promote, detail and optimize sales of Vascepa in the United States and have agreed to specific performance requirements detailed in the related agreement. The performance requirements include a negotiated minimum number of sales details to be delivered by each party in the first and second position, the use of a negotiated number of minimum sales representatives from each party, including no less than 250 Kowa Pharmaceuticals America, Inc. sales representatives and the achievement of minimum levels of Vascepa revenue in 2015 and beyond. First position refers to when a sales representative's primary purpose in detailing is related to Vascepa, while second position refers to when a sales representative's primary purpose in detailing is to promote another product, but they also devote time in the same sales call to promote Vascepa. 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 margin that increases during the term. The percentage of aggregate Vascepa gross margin earned by Kowa Pharmaceuticals America, Inc. was fifteen percent (15%) in 2015, is nineteen percent (19%) in 2016, and is scheduled to increase to low twenty percent levels in 2017 and 2018, subject to certain adjustments. The term of this co-promotion agreement expires on December 31, 2018, following which Kowa Pharmaceuticals America, Inc. will be entitled to earn tail royalties equal to declining percentages of the co-promotion fee amount earned in the last year prior to such expiration for tail payment periods ranging from one to three years following such expiration.

Based on monthly compilations of data provided by a third party, Symphony Health Solutions, the estimated number of normalized total Vascepa prescriptions for the three months ended September 30, 2016 was approximately 260,000 compared to 230,000, 201,000, and 169,000 in the three months ended June 30, 2016, March 31, 2016, and September 30, 2015, respectively. According to data from another third party, IMS Health, the estimated number of normalized total Vascepa prescriptions for the three months ended September 30, 2016 was approximately 274,000 compared to 249,000, 216,000, and 176,000 in the three months ended June 30, 2016, March 31, 2016, and September 30, 2015, 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). Inventory levels at wholesalers tend to fluctuate based on seasonal factors, prescription trends and other factors. For example, during the quarter ended March 31, 2016, wholesalers decreased inventory levels from year-end 2015. During the three months ended June 30, 2016, the trend was reversed and wholesalers increased inventory levels. During the three months ended September 30, 2016, wholesalers decreased inventory levels slightly from June 30, 2016.



---

**Table of Contents**

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 can be generally indicative of current prescription trends, these data are based on estimates and should not be relied upon as definitive. While we expect to be able to grow Vascepa revenues over time, no guidance should be inferred from the operating metrics described above. We also anticipate that such sales growth will be inconsistent from period to period. We believe that investors should view the above-referenced operating metrics with caution, as data for this limited period may not be representative of a trend consistent with the results presented or otherwise predictive of future results. Seasonal fluctuations in pharmaceutical sales, for example, may affect future prescription trends of Vascepa, as could changes in prescriber sentiment, period-to-period Distributor purchasing habits 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 pharmaceutical products is a complex undertaking, and our ability to effectively and profitably commercialize Vascepa will depend in part on our ability to generate market demand for Vascepa through education, marketing and sales activities, our ability to achieve market acceptance of Vascepa, our ability to generate product revenue and our ability to receive adequate levels of reimbursement from third-party payers. See *Risk Factors Risks Related to the Commercialization and Development of Vascepa*.

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

*Commercialization Outside the United States*

In February 2015, we announced an exclusive agreement with Eddingpharm to develop and commercialize Vascepa capsules in what we refer to as the China Territory, consisting of the territories of Mainland China, Hong Kong, Macau and Taiwan, 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 is responsible for development and commercialization activities in the China Territory and associated expenses. We will provide development assistance and be responsible for supplying the product. Terms of the agreement include up-front and milestone payments to us of up to \$169.0 million, including a non-refundable \$15.0 million up-front payment received at closing, a non-refundable milestone payment of \$1.0 million received upon successful submission of a clinical trial application with respect to the MARINE indication for Vascepa to the Chinese regulatory authority in March 2016, and future development, regulatory and sales-based milestone payments of up to an additional \$153.0 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 terms.

We also have an agreement to register and commercialize Vascepa in countries within the Middle East and North Africa. 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.

In 2016, we completed patient enrollment and randomization of 8,175 individual patients into the REDUCE-IT study, slightly exceeding the 8,000 patients targeted for the trial.

---

**Table of Contents**

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 onset of the target aggregate number of cardiovascular events to be reached in or about the fourth quarter of 2017 with study results then expected to be available in 2018. In addition, since its inception in 2011, our REDUCE-IT special protocol assessment (SPA) agreement with the FDA has provided for periodic safety reviews and an interim efficacy and safety analysis by the independent DMC at approximately 60% of the target aggregate number of primary cardiovascular events. In August 2016, we announced an amendment to our REDUCE-IT SPA agreement with FDA that reaffirmed FDA concurrence on key elements of the study, defined details of the statistical analysis plan for the study, expanded to greater than 30 the pre-specified secondary and tertiary endpoints in the study, and added a second interim efficacy and safety analysis by the DMC at approximately 80% of the target aggregate number of primary cardiovascular events.

In March 2016, we announced that the onset of approximately 60% of the target aggregate number of primary cardiovascular events had triggered preparation for the first pre-specified interim analysis of efficacy and safety results, such analysis to include the first review of unblinded efficacy data by the independent DMC. The DMC completed its review of the interim analysis in September 2016 and, consistent with previously stated expectations, recommended that the trial continue as planned without modification. The second planned interim analysis of efficacy results will be triggered by the onset of approximately 80% of the target aggregate number of primary cardiovascular events in the study. Based on historical event rates, we anticipate that the onset of approximately 80% of events will occur in the first half of 2017, with the second pre-specified interim efficacy analysis by the DMC expected in or about the third quarter of 2017. The interim efficacy analysis will be accompanied by an interim safety analysis by the DMC. As is typical, the statistical threshold for defining overwhelming efficacy on the primary endpoint at interim analyses is considerably higher than the threshold for defining statistical significance at the end of the study. In addition, we have requested the DMC to not recommend stopping the study early based only upon achieving statistical significance for the primary endpoint, but to ensure that supportive trends of benefit are also consistently observed in certain secondary endpoints and subpopulations before recommending that the study be stopped early for overwhelming efficacy. It is our expectation that the 80% interim analysis will also result in a recommendation to continue the trial. By design, it is most common for cardiovascular outcomes studies not to be stopped upon an interim look. We remain blinded to all data from the study. Unless overwhelming efficacy and safety is declared by the DMC at an interim look or the study is halted due to a patient safety concern, Amarin personnel will remain blinded to the efficacy and safety data from the REDUCE-IT study until the study is complete.

Since patient enrollment commenced in 2011, more than 23,000 patient years of study experience have been accumulated in REDUCE-IT. The DMC has reviewed unblinded safety data on a quarterly basis since initiation of the REDUCE-IT study in 2011 and, after each such meeting to date, the DMC has recommended to us that the study be continued as planned.

Our scientific rationale for the REDUCE-IT study is supported by (i) epidemiological data that suggests elevated triglyceride levels correlate with increased cardiovascular disease risk, (ii) genetic data that suggests triglyceride and/or triglyceride-rich lipoproteins (as well as low-density lipoprotein cholesterol (LDL cholesterol), known as bad cholesterol) are independently in the causal pathway for cardiovascular disease and (iii) clinical data that suggest substantial triglyceride reduction in patients with elevated baseline triglyceride levels correlates with reduced cardiovascular risk. Our scientific rationale for the REDUCE-IT study is also supported by research on the putative cardioprotective effects of EPA as presented in scientific literature. It is possible that the effects of EPA may be due not to a single mode of action, such as triglyceride lowering, but rather to multiple mechanisms working together. Studies in the scientific literature explore potentially beneficial effects of EPA on multiple atherosclerosis processes, including endothelial function, oxidative stress, foam cell formation, inflammation/cytokines, plaque formation/progression, platelet aggregation, thrombus formation, and plaque rupture. The REDUCE-IT study is needed to determine the clinical benefit, if any, of EPA therapy in statin-treated patients with elevated triglyceride

levels.

*Commercial Supply*

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

*Financial Position*

We believe that our cash and cash equivalents of \$117.6 million as of September 30, 2016 will be sufficient to fund our projected operations for at least the next twelve months. Depending on the level of cash generated from operations, additional capital may be required to sustain operations, fund debt obligations or expand promotion of Vascepa as contemplated following anticipated successful results of the REDUCE-IT study. We anticipate that quarterly net cash outflows in future periods will be variable.

---

**Table of Contents****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 or our customers, who resell the product to retail pharmacies for purposes of their reselling the product to fill patient prescriptions. We commenced our commercial launch in the United States in January 2013. In accordance with U.S. Generally Accepted Accounting Principles, or 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. In 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.

*Licensing revenue.* Licensing revenue currently consists of revenue attributable to receipt of up-front, non-refundable payments and milestone payments related to license and distribution agreements for Vascepa outside the United States. Up-front and milestone payments under such agreements are typically recognized as licensing revenue over the estimated period in which we are required to provide regulatory and development support and clinical and commercial supply pursuant to the agreements.

*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, quality assurance and insurance. The cost of the API included in cost of goods sold reflects the average cost method of inventory valuation and relief. This average cost reflects the actual purchase price of Vascepa API.

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

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

*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 liabilities related to the change in control provisions associated with the May 2014 and November 2015 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, net.* Interest expense consists of interest incurred under lease obligations, interest incurred under our December 2012 financing arrangement with BioPharma, and interest incurred under our 3.5% exchangeable notes. Interest expense under our BioPharma financing arrangement is calculated based on an estimated repayment schedule. 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 income consists of interest earned on our cash and cash equivalents. Other expense, net, consists primarily of foreign exchange losses and gains.

### **Critical Accounting Policies and Significant Judgments and Estimates**

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

---

**Table of Contents**

*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 healthcare 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. In 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 \$90.6 million and \$54.6 million based on sales to Distributors during the nine months ended September 30, 2016 and 2015, respectively.

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. The gross to net deductions are estimated based on available actual information, historical data, known trends, and levels of inventory in the distribution channel. We rely on resale data provided by our Distributors as well as prescription data provided by Symphony Health Solutions and IMS Health in estimating the level of inventory held in the distribution channel. A hypothetical 5% change in estimated channel inventory would result in a change of less than 1% in net product revenues reported during each of the three and nine months ended September 30, 2016 and 2015.

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

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

*Derivative Financial Liabilities* Derivative financial liabilities are initially recorded at fair value. They are subsequently held at fair value, with gains and losses arising for changes in fair value recognized in the condensed consolidated 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, which include our projections for future estimated revenues, management estimates of the probability of a change in control occurring, and the terms of debt issues of similar companies. Fluctuations in the assumptions used in the valuation model would result in adjustments to the fair value of the derivative liabilities reflected on our condensed consolidated balance sheet and, therefore, our condensed consolidated 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 during the first quarter of 2015), the change in control provision associated with our December 2012 debt financing, the change in control provisions associated with our May 2014 and November 2015 exchangeable senior notes (both derecognized upon exchange of the debt hosts into equity during the third quarter of 2016), and a preferred stock purchase option (subsequently reclassified to permanent equity).



---

**Table of Contents**

*Inventory* We capitalize purchases of saleable inventory of Vascepa from suppliers that have been qualified by the FDA. During the periods presented, we purchased API for Vascepa from three FDA-approved suppliers. If we add a new API supplier, all Vascepa API purchased from such supplier is included as a component of research and development expense until the new API supplier is approved. Upon sNDA approval of each additional supplier, we capitalize subsequent Vascepa API purchases from such supplier as inventory. In April 2016, we adopted ASU No. 2015-11, *Inventory (Topic 330) Simplifying the Measurement of Inventory*, and as such, began to state inventories at the lower of cost or net realizable market value (previously, we stated 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 net realizable value due to obsolescence, damage, quantities in excess of expected demand, changes in price levels or other causes, then we will reduce the carrying value of such inventory to net realizable value and recognize the difference as a component of cost of goods sold in the period in which it occurs. We expense inventory identified for use as marketing samples when they are packaged. The average cost reflects the actual purchase price of Vascepa API. Additionally, the determination of the classification of our inventory requires the use of estimates in order to determine the portion of inventories anticipated to be utilized within twelve months of the balance sheet date.

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

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

We assess our ability to realize deferred tax assets at each reporting period. The realization of deferred tax assets depends on generating future taxable income during the periods in which the tax benefits are deductible or creditable. We have been historically profitable in the United States. When making our assessment about the realization of our U.S. deferred tax assets as of June 30, 2016, we considered all available evidence, placing particular weight on evidence that could be objectively verified. The evidence considered included the (i) historical profitability of our U.S. operations, (ii) sources of future taxable income, giving weight to sources according to the extent to which they can be objectively verified and (iii) the risks to our business related to the commercialization and development of Vascepa. Based on our assessment, we concluded that the U.S. deferred tax assets are more likely than not to be realizable as of September 30, 2016. 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.

In April 2016, we adopted ASU No. 2016-09, *Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*, which changes the accounting for certain aspects of share-based payments to employees. Refer to recent accounting pronouncements below for additional details on the impact of this recently adopted accounting guidance.

**Recent Accounting Pronouncements**

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board, or FASB, and are early adopted by us or adopted as of the specified effective date.

In January 2016, we adopted ASU No. 2015-03, *Interest Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs*, which provides guidance on simplifying the presentation of debt issuance costs on the balance sheet. To simplify presentation of debt issuance costs, the amendments in ASU No. 2015-03 require that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with the treatment of debt discounts. The recognition and measurement guidance for debt issuance costs are not affected by the amendments in this update. In accordance with ASU No. 2015-03, we applied the new guidance on a retrospective basis, wherein the condensed consolidated balance sheet of each individual period presented was adjusted to reflect the period-specific effects of applying the new guidance. See Note 6 Debt.

In April 2016, we adopted ASU No. 2015-11, *Inventory (Topic 330): Simplifying the Measurement of Inventory*, which simplifies the subsequent measurement of inventories by replacing the lower of cost or market test with a lower of cost or net realizable value test. When evidence exists that the net realizable value of inventory is less than its cost (due to damage, physical deterioration, obsolescence, changes in price levels or other causes), we will recognize the difference as a component of cost of goods sold in the period in which it occurs. In accordance with ASU No. 2015-11, we applied the new guidance on a prospective basis with no impact on the carrying amount of inventory.

---

**Table of Contents**

Also in April 2016, we adopted ASU No. 2016-09, *Compensation Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*, which changes the accounting for certain aspects of share-based payments to employees. One aspect of the standard requires that excess tax benefits and deficiencies that arise upon vesting or exercise of share-based payments be recognized as an income tax benefit and expense in the income statement. Previously, such amounts were recognized as an increase and decrease in additional paid-in capital. This aspect of the standard was adopted prospectively, and accordingly, the benefit from income taxes for the three and nine months ended September 30, 2016, includes \$0.3 million and \$0.4 million, respectively, of excess tax deficiencies arising from share-based payments. Additionally, the new standard requires that historical excess tax benefits that were not previously recognized because the related tax deduction had not reduced current taxes payable should be recognized on a modified retrospective basis as a cumulative-effect adjustment to retained earnings as of the beginning of the annual period of adoption. Consequently, we recognized deferred tax assets of approximately \$1.6 million relating to excess tax benefits on stock-based compensation outstanding as of December 31, 2015, with a corresponding cumulative-effect adjustment to accumulated deficit. The new standard also amends the presentation of employee share-based payment-related items in the statement of cash flows by requiring that: (i) excess income tax benefits and deficiencies be classified in cash flows from operating activities, and (ii) cash paid to taxing authorities arising from the withholding of shares from employees be classified as cash flows from financing activities. We adopted the aspects of the standard affecting cash flow presentation retrospectively and, accordingly, reclassified \$0.7 million of excess tax provision from cash flows provided by financing activities to cash flows used in operating activities in the condensed consolidated statement of cash flows for the nine months ended September 30, 2015 to conform to the current year presentation. The presentation requirement for cash flows related to taxes paid for withheld shares had no impact to any of the periods presented in the condensed consolidated statement of cash flows since such payments have historically been presented as a financing activity.

We also considered the following recent accounting pronouncements which were not yet adopted as of September 30, 2016:

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

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. 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 have determined that this standard would not have a material impact on our condensed consolidated financial statements based on the assessment of our ability to continue as a going concern as of September 30, 2016.

In January 2016, the FASB issued ASU No. 2016-01, *Financial Instruments Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities*. The new guidance is intended to improve the recognition and measurement of financial instruments by requiring separate presentation of financial assets and financial liabilities by measurement category and form of financial asset (i.e., securities or loans and receivables) within the balance sheet or the accompanying notes to the financial statements, eliminating the requirement for public business entities to disclose the method(s) and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost within the balance sheet, requiring public business entities to use the exit price notion when measuring the fair value of financial instruments for disclosure purposes, requiring equity investments (except those accounted for under the equity method of accounting, or those that result in consolidation of the investee) to be measured at fair value with changes in fair value recognized in net income, and requiring a reporting organization to present separately in other comprehensive income the portion of the total change in the fair value of a liability resulting from a change in the instrument-specific credit risk (also referred to as own credit ) when the organization has elected to measure the liability at fair value in accordance with the fair value option for financial instruments, among others. The new guidance is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. The new guidance permits early adoption of the own credit provision. We are currently evaluating the accounting, transition and disclosure requirements of the standard and cannot currently estimate the financial statement impact of adoption.

---

**Table of Contents**

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*. The new guidance will require lessees to recognize a right-of-use asset and a lease liability for virtually all of their leases (other than leases that meet the definition of a short-term lease). The liability will be equal to the present value of lease payments. The asset will be based on the liability, subject to adjustment, such as for initial direct costs. Under the new guidance, lessor accounting is largely unchanged but certain targeted improvements were made to align, where necessary, lessor accounting with the lessee accounting model and Topic 606, Revenue from Contracts with Customers. The new lease guidance also simplified the accounting for sale and leaseback transactions primarily because lessees must recognize lease assets and lease liabilities and therefore, will no longer be provided with a source of off-balance sheet financing. The new guidance is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption 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 March 2016, the FASB issued ASU No. 2016-08, *Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net)*, which clarifies that an entity is a principal when it controls the specified good or service before that good or service is transferred to the customer, and is an agent when it does not control the specified good or service before it is transferred to the customer. The new guidance is intended to improve the operability and understandability of the implementation guidance on principal versus agent considerations. In April 2016, the FASB issued ASU No. 2016-10, *Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing*, which clarifies the following two aspects of Topic 606: (a) identifying performance obligations; and (b) the licensing implementation guidance. Further, in May 2016, the FASB issued ASU No. 2016-12, *Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients*, which provides clarifying guidance in certain narrow areas and adds some practical expedients. The amendments do not change the core principles of the guidance in Topic 606 and are effective for our fiscal year beginning January 1, 2018. Early application is permitted only as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period. We are currently evaluating the accounting, transition and disclosure requirements of these standards and cannot currently estimate the financial statement impact of adoption.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*, which is intended to reduce diversity in practice regarding how certain cash receipts and cash payments are presented and classified in the statement of cash flows. Specifically, it addresses the following eight issues: debt prepayment or debt extinguishment costs; settlement of zero-coupon debt instruments; contingent consideration payments made after a business combination; proceeds from the settlement of insurance claims; proceeds from the settlement of corporate-owned life insurance policies, including bank-owned life insurance policies; distributions received from equity method investments; beneficial interests in securitization transactions; and separately identifiable cash flows and application of the predominance principle. The new guidance is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption is permitted. We have evaluated the accounting, transition and disclosure requirements of the standard and do not expect it to have a material impact on our condensed consolidated financial statements.

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

**Results of Operations***Comparison of Three Months Ended September 30, 2016 and September 30, 2015*

*Product Revenue, net.* We recorded net product revenue of \$32.4 million and \$21.3 million during the three months ended September 30, 2016 and 2015, respectively, an increase of \$11.1 million, or 52%. This increase in revenue was driven primarily by an increase in estimated normalized total Vascepa prescriptions offset by a slight decrease in the level of inventories held by our Distributors during the quarter. Based on data provided by Symphony Health Solutions and IMS Health, estimated normalized total Vascepa prescriptions increased by approximately 91,000 and 98,000, respectively, over the three months ended September 30, 2015, representing growth of 54% and 56%, respectively. The level of inventories held by our Distributors as of September 30, 2016 decreased as compared to inventories held at the beginning of the quarter calculated based on estimated days of Vascepa sales on hand. We estimate that product revenues during the quarter ended September 30, 2016 were negatively impacted by approximately \$0.5 million to \$0.8 million due to a net overall decrease in Distributor inventory levels during the quarter as compared to a \$0.5 million to \$0.8 million increase in product revenues due to a net overall increase in Distributor inventory levels in the corresponding period in 2015. The decrease in Distributor inventory levels during the quarter ended September 30, 2016 follows an estimated \$2.9 million to \$3.2 million increase in second quarter 2016 product revenues due to increased Distributor inventory levels during the second quarter of 2016. All of our product revenue in the three months ended September 30, 2016 and 2015 was derived from product sales of Vascepa, net of allowances, discounts, incentives, rebates, chargebacks and returns. Timing of shipments to wholesalers, as used for revenue recognition, and timing of prescriptions as estimated by third-party sources such as Symphony Health Solutions and IMS Health may differ from period to period.

**Table of Contents**

During the quarters ended September 30, 2016 and 2015, 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 during the quarters ended September 30, 2016 and 2015 was up to \$70 per prescription filled. 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 is typical for the pharmaceutical industry, the majority of Vascepa sales are to major commercial wholesalers which then resell Vascepa to retail pharmacies.

*Licensing Revenue.* Licensing revenue during the three months ended September 30, 2016 and 2015 was \$0.3 million and \$0.2 million, respectively, an increase of \$0.1 million. Licensing revenue relates primarily to the amortization of a \$15.0 million up-front payment received in February 2015 and a \$1.0 milestone payment achieved in March 2016, both associated with a Vascepa licensing agreement for the China Territory. The up-front and milestone payments are being recognized over the estimated period in which we are required to provide regulatory and development support and clinical and commercial supply under the agreement. The amount of licensing revenue recorded may be variable from period to period based on changes in estimates of the timing and level of support required.

*Cost of Goods Sold.* Cost of goods sold during the three months ended September 30, 2016 and 2015 was \$8.5 million and \$7.5 million, respectively, an increase of \$1.0 million, or 13%. 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 three months ended September 30, 2016 and 2015 was sourced from three API suppliers. The contracted cost of supply from our initial API supplier was higher than the contracted cost from our other API suppliers. In the future, we anticipate making continued purchases from this initial supplier and to make additional lower unit cost purchases of Vascepa API from other API suppliers, with the amount of such purchases dependent on the rate of our revenue growth. The average cost may be variable from period to period depending upon the timing and quantity of API purchased from each supplier.

Our gross margin on product sales for the three months ended September 30, 2016 and 2015 was 74% and 65%, respectively. This improvement was primarily driven by lower unit cost API purchases.

*Selling, General and Administrative Expense.* Selling, general and administrative expense for the three months ended September 30, 2016 and 2015 was \$26.1 million and \$26.7 million, respectively, a decrease of \$0.7 million, or 2%. Selling, general and administrative expenses for the three months ended September 30, 2016 and 2015 are summarized in the table below:

<b>In thousands</b>	<b>Three Months Ended September 30,</b>	
	<b>2016</b>	<b>2015</b>

Selling, general and administrative expense (1)	\$ 18,657	\$ 21,536
Co-promotion fees (2)	4,558	2,077
Non-cash stock based compensation expense (3)	2,846	3,114
Total selling, general and administrative expense	\$ 26,061	\$ 26,727

- (1) Selling, general and administrative expense, excluding co-promotion fees and non-cash compensation charges for stock compensation and warrants, for the three months ended September 30, 2016 and 2015 was \$18.7 million and \$21.5 million, respectively, a decrease of \$2.9 million, or 13%. The decrease is due primarily to an increase in prior year sales and marketing costs in support of expanded Vascepa promotion following the favorable federal court declaration on August 7, 2015 and related settlement on March 8, 2016 allowing communication of truthful and non-misleading ANCHOR clinical trial and related data to be communicated to healthcare professionals, as well as lower legal costs resulting from the same.
- (2) Co-promotion fees payable to Kowa Pharmaceuticals America, Inc. for the three months ended September 30, 2016 and 2015 were \$4.6 million and \$2.1 million, respectively, an increase of \$2.5 million, or 119%. The increase is due primarily to an increase in gross margin on product sales in the third quarter of 2016 compared to the third quarter of 2015, coupled with an increase in the percentage of aggregate Vascepa gross margin earned by Kowa Pharmaceuticals America, Inc. from 15% in 2015 to 19% in 2016.
- (3) Stock-based compensation expense for the three months ended September 30, 2016 and 2015 was \$2.8 million and \$3.1 million, respectively, a decrease of \$0.3 million, or 9%. The decrease is primarily due to the duration of vesting periods and equity award forfeitures, partially offset by an increase in new stock option and restricted stock awards granted to attract and retain qualified employees.



**Table of Contents**

*Research and Development Expense.* Research and development expense for the three months ended September 30, 2016 and 2015 was \$13.5 million and \$13.1 million, respectively, an increase of \$0.4 million, or 3%. Research and development expenses for the three months ended September 30, 2016 and 2015 are summarized in the table below:

<b>In thousands</b>	<b>Three Months Ended September 30,</b>	
	<b>2016</b>	<b>2015</b>
REDUCE-IT study (1)	\$ 9,919	\$ 9,392
Regulatory filing fees and expenses (2)	479	661
Internal staffing, overhead and other (3)	2,524	2,234
Research and development expense, excluding non-cash expense	12,922	12,287
Non-cash stock-based compensation (4)	568	805
Total research and development expense	\$ 13,490	\$ 13,092

The increase in research and development expenses for the quarter ended September 30, 2016, as compared to the prior year period, is primarily due to quarterly variability in costs related to the REDUCE-IT study.

- (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. In 2016, we completed patient enrollment and randomization of 8,175 individual patients into the REDUCE-IT study, slightly exceeding the 8,000 patients targeted for the trial. The study duration is dependent on the rate of clinical events in the study, which rate may be affected by the epidemiology of the patients enrolled in the study and the length of time that the enrolled patients are followed. We manage the study through a contract research organization (CRO) through which all costs for this outcomes study are incurred with the exception of costs for clinical trial material (CTM) and costs for internal management. Our internal personnel are responsible for managing multiple projects and their costs are not specifically allocated to REDUCE-IT or any other individual project. For the three months ended September 30, 2016 and 2015, we incurred expenses through our CRO in connection with this trial of approximately \$7.5 million in each period. Inclusive of CTM costs, the combined CRO and CTM costs during the three months ended September 30, 2016 and 2015 for REDUCE-IT were approximately \$9.9 million and \$9.4 million, respectively. The increase in expenses in 2016 as compared to 2015 is primarily the result of timing variability for REDUCE-IT costs. We expense costs for CTM when allocated to clinical research. The aggregate cost of this outcomes study will depend on the rate of clinical events in the study. We currently estimate that we will incur \$30 million to \$40 million in annual costs through study completion and the rate at which we incur such costs will vary from quarter to quarter. The study is designed to be completed after reaching 1,612 aggregate cardiovascular events. Based on projected event rates, we estimate the onset of the target aggregate number of cardiovascular events to be reached in or about the fourth quarter of 2017 with study results then expected to be available and published in 2018. We anticipate that our costs for this outcomes study will continue to represent the most significant component of our research

and development expenditures.

- (2) The regulatory filing fees in each of the quarters ended September 30, 2016 and 2015 included annual FDA fees for maintaining manufacturing sites.
- (3) Internal staffing, overhead and other research and development expenses primarily relate to the costs of our personnel employed to manage research, development and regulatory affairs activities and related overhead costs including consulting and other professional fees that are not allocated to specific projects. Also included are costs related to qualifying suppliers and legal costs.
- (4) Non-cash stock-based compensation expense represents the costs associated with equity awards issued to internal staff supporting our research and development and regulatory functions.

*Gain (Loss) on Change in Fair Value of Derivative Liabilities.* Gain (loss) on change in fair value of derivative liabilities for the three months ended September 30, 2016 was a gain of \$3.6 million versus a loss of \$0.2 million in the prior year period. Gain (loss) on change in fair value of derivative liabilities for the three months ended September 30, 2016 and 2015 is comprised of (i) the change in fair value of the derivative liability related to the change in control provision associated with the December 2012 BioPharma financing, and (ii) the change in fair value of the derivative liabilities related to the change in control provisions associated with the May 2014 and November 2015 exchangeable senior notes.

---

**Table of Contents**

Our December 2012 financing agreement with BioPharma contains a redemption feature whereby, upon a change of control, we would be required to repay \$150 million, less any previously repaid amount. The fair value of the derivative liability is recalculated at each reporting period using a probability-weighted model incorporating management estimates for potential change in control, and by determining the fair value of the debt with and without the change in control provision included. The difference between the two fair values of the debt was determined to be the fair value of the embedded derivative. As of June 30, 2016, the fair value of the derivative was determined to be \$2.8 million, and as of September 30, 2016, the fair value of the derivative was determined to be nil based on current assumptions. As such, we recognized a \$2.8 million gain on change in fair value of derivative liability for the three months ended September 30, 2016. As of June 30, 2015, the fair value of the derivative was determined to be \$5.6 million, and as of September 30, 2015, the fair value of the derivative was determined to be \$5.1 million. As such, we recognized a \$0.5 million gain on change in fair value of derivative liability for the three months ended September 30, 2015.

Our 2014 Notes, issued in May 2014, contained a redemption feature whereby, upon occurrence of a change in control, we would have been 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. In September 2016, we exercised our optional exchange rights upon satisfaction of specified equity conditions set forth in the 2014 Notes indenture to mandatorily exchange the 2014 Notes into American Depositary Shares, or ADSs (see Note 6 Debt). As such, the related derivative liability was derecognized and we recognized a \$0.6 million gain on change in fair value of derivative liability for the three months ended September 30, 2016. As of June 30, 2015, the fair value of the derivative was determined to be \$1.1 million, and as of September 30, 2015, the fair value of the derivative was determined to be \$1.8 million. As such, we recognized a \$0.7 million loss on change in fair value of derivative liability for the three months ended September 30, 2015.

Our 2015 Notes, issued in November 2015, contained the same redemption feature as the 2014 Notes and the related derivative liability was calculated utilizing the same methodology. In September 2016, we exercised our optional exchange rights upon satisfaction of specified equity conditions consistent with the terms of the 2015 Notes to mandatorily exchange the 2015 Notes into ADSs (see Note 6 Debt) As such, the related derivative liability was derecognized and we recognized a \$0.2 million gain on change in fair value of derivative liability for the three months ended September 30, 2016. There was no such change in fair value of derivative liability for the three months ended September 30, 2015.

The change in fair value of the derivative liability related to the BioPharma financing agreement is largely related to our projections for future estimated revenues, management estimates of the probability of a change in control occurring, and the terms of debt issues of similar companies. The change in fair value of the derivative liabilities related to the 2014 Notes and 2015 Notes is a result of the exchange of the related debt hosts for the three months ended September 30, 2016 and was largely related to changes in quoted bond prices for the three months ended September 30, 2015. 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 September 30, 2016 and 2015 was \$5.1 million in each period. Net interest expense for the three months ended September 30, 2016 and 2015 is summarized in the table below:

<b>In thousands</b>	<b>Three Months Ended</b>	
	<b>2016</b>	<b>September 30, 2015</b>
<b>Exchangeable senior notes (1):</b>		
Amortization of debt discounts	\$ 1,686	\$ 1,595
Contractual coupon interest	1,182	1,313
<b>Total exchangeable senior notes interest expense</b>	<b>2,868</b>	<b>2,908</b>
<b>Long-term debt from royalty-bearing instrument (2):</b>		
Cash interest	1,675	1,674
Non-cash interest	522	487
<b>Total long-term debt from royalty-bearing instrument interest expense</b>	<b>2,197</b>	<b>2,161</b>
<b>Other interest expense</b>	<b>3</b>	<b>5</b>
<b>Total interest expense</b>	<b>5,068</b>	<b>5,074</b>
<b>Interest income (3)</b>	<b>(17)</b>	<b>(13)</b>
<b>Total interest expense, net</b>	<b>\$ 5,051</b>	<b>\$ 5,061</b>

- (1) Cash and non-cash interest expense related to the exchangeable senior notes for the three months ended September 30, 2016 and 2015 was \$2.9 million in each period.
- (2) Cash and non-cash interest expense related to the BioPharma financing for the three months ended September 30, 2016 and 2015 was \$2.2 million in each period. 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 represents income earned on cash balances.

---

**Table of Contents**

*Other Expense, net.* Other expense, net, for the three months ended September 30, 2016 was \$0.1 million in each period. Other expense, net, primarily consists of gains and losses on foreign exchange transactions.

*Benefit from Income Taxes.* Benefit from income taxes for the three months ended September 30, 2016 and 2015 was \$1.0 million and \$0.5 million, respectively. The current benefit 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. In April 2016, we adopted ASU No. 2016-09, *Compensation Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*, which requires that excess tax benefits and deficiencies that arise upon vesting or exercise of share-based payments be recognized as an income tax benefit and expense in the income statement. Previously, such amounts were recognized as an increase and decrease in additional paid-in capital. This aspect of the standard was adopted prospectively, and accordingly, the benefit from income taxes for the three months ended September 30, 2016, includes \$0.3 million of excess tax deficiencies arising from share-based payments.

*Preferred Stock Beneficial Conversion Features.* In 2015, we issued Series A preference shares in a private placement transaction executed in two tranches that each contain a conversion feature whereby such shares are convertible into ordinary shares at a fixed rate. The conversion price on the date of issuance was less than the market price of our ordinary shares on such date. We determined that these discounts represent contingent beneficial conversion features, which were valued based on the difference between the conversion price and the market price of the ordinary shares on the date of issuance. These features are analogous to preference dividends and were recorded as a non-cash return to preferred shareholders through accumulated deficit, and are therefore reflected as an adjustment to net loss applicable to common shareholders for earnings per common share purposes in accordance with GAAP. During the three months ended September 30, 2015, we recorded an adjustment to net loss applicable to common shareholders of \$1.6 million upon shareholder approval received at the Company's Annual General Meeting of Shareholders. There was no such adjustment to net loss in the three months ended September 30, 2016.

***Comparison of Nine Months Ended September 30, 2016 and September 30, 2015***

*Product Revenue, net.* We recorded net product revenue of \$90.6 million and \$54.6 million during the nine months ended September 30, 2016 and 2015, respectively, an increase of \$36.0 million, or 66%. This increase in revenue was driven primarily by a slight increase in estimated normalized total Vascepa prescriptions as well as an increase in the level of inventories held by our customers during the period. Based on data provided by Symphony Health Solutions and IMS Health, estimated normalized total Vascepa prescriptions increased by approximately 244,000 and 269,000, respectively, over the nine months ended September 30, 2015, representing growth of 55% and 57%, respectively. The level of inventories held by our customers as of September 30, 2016 increased as compared to inventories held as of year-end 2015 calculated based on estimated days of Vascepa sales on hand. We estimate that revenues during the nine months ended September 30, 2016 include approximately \$0.9 million to \$1.2 million in product revenues resulting from a net overall increase in Distributor inventory levels compared to a \$0.5 to \$0.8 million decrease in revenues due to net inventory level changes in the corresponding period in 2015. All of our product revenue in the nine months ended September 30, 2016 and 2015 was derived from product sales of Vascepa, net of allowances, discounts, incentives, rebates, chargebacks and returns. Timing of shipments to wholesalers, as used for revenue recognition, and timing of prescriptions as estimated by third-party sources such as Symphony Health Solutions and IMS Health may differ from period to period.

During the nine months ended September 30, 2016 and 2015, 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

during the nine months ended September 30, 2016 and 2015 was up to \$70 per prescription filled. 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 is typical for the pharmaceutical industry, the majority of Vascepa sales are to major commercial wholesalers which then resell Vascepa to retail pharmacies.

*Licensing Revenue.* Licensing revenue during the nine months ended September 30, 2016 and 2015 was \$0.8 million and \$0.5 million, respectively, an increase of \$0.3 million, or 53%. Licensing revenue relates to the amortization of a \$15.0 million up-front payment received in February 2015 and a \$1.0 million milestone payment achieved in March 2016, both associated with a Vascepa licensing agreement for the China Territory. The up-front and milestone payments are being recognized over the estimated period in which we are required to provide regulatory and development support and clinical and commercial supply under the agreement. The amount of licensing revenue recorded may be variable from period to period based on changes in estimates of the timing and level of support required.

**Table of Contents**

*Cost of Goods Sold.* Cost of goods sold during the nine months ended September 30, 2016 and 2015 was \$24.2 million and \$19.5 million, respectively, an increase of \$4.7 million, or 24%. Cost of goods sold includes the cost of API for Vascepa on which revenue was recognized during the period, as well as the associated costs for encapsulation, packaging, shipment, supply management, insurance and quality assurance. The cost of the API included in cost of goods sold reflects the average cost of API included in inventory. This average cost reflects the actual purchase price of Vascepa API.

The API included in the calculation of the average cost of goods sold during the nine months ended September 30, 2016 and 2015 was sourced from three API suppliers. The contracted cost of supply from our initial API supplier was higher than the contracted cost from our other API suppliers. In the future, we anticipate making continued purchases from this initial supplier and to make additional lower unit cost purchases of Vascepa API from other API suppliers, with the amount of such purchases dependent on the rate of our revenue growth. The average cost may be variable from period to period depending upon the timing and quantity of API purchased from each supplier.

Our gross margin on product sales for the nine months ended September 30, 2016 and 2015 was 73% and 64%, respectively. This improvement was primarily driven by lower unit cost API purchases.

*Selling, General and Administrative Expense.* Selling, general and administrative expense for the nine months ended September 30, 2016 and 2015 was \$80.1 million and \$77.5 million, respectively, an increase of \$2.6 million, or 3%. Selling, general and administrative expenses for the nine months ended September 30, 2016 and 2015 are summarized in the table below:

<b>In thousands</b>	<b>Nine Months Ended</b>	
	<b>September 30,</b>	
	<b>2016</b>	<b>2015</b>
Selling, general and administrative expense (1)	\$ 58,917	\$ 64,547
Co-promotion fees (2)	12,607	5,265
Non-cash stock based compensation expense (3)	8,623	7,719
Non-cash warrant related compensation income		(9)
<b>Total selling, general and administrative expense</b>	<b>\$ 80,147</b>	<b>\$ 77,522</b>

- (1) Selling, general and administrative expense, excluding co-promotion fees and non-cash compensation charges for stock compensation and warrants, for the nine months ended September 30, 2016 and 2015 was \$58.9 million and \$64.5 million, respectively, a decrease of \$5.6 million, or 9%. The decrease is due primarily to lower legal costs following the favorable federal court declaration on August 7, 2015 and related settlement on March 8, 2016 allowing communication of truthful and non-misleading ANCHOR clinical trial and related data to be communicated to healthcare professionals.
- (2) Co-promotion fees payable to Kowa Pharmaceuticals America, Inc. for the nine months ended September 30, 2016 and 2015 were \$12.6 million and \$5.3 million, respectively, an increase of \$7.3 million, or 139%. The increase is due primarily to an increase in gross margin on product sales for the nine months ended September 30, 2016 compared to the same period in 2015, coupled with an increase in the percentage of aggregate Vascepa gross margin earned by Kowa Pharmaceuticals America, Inc. from 15% in 2015 to 19% in 2016.
- (3)

Stock-based compensation expense for the nine months ended September 30, 2016 and 2015 was \$8.6 million and \$7.7 million, respectively, an increase of \$0.9 million, or 12%, primarily due to an increase in new stock option and restricted stock awards granted to attract and retain qualified employees.

*Research and Development Expense.* Research and development expense for the nine months ended September 30, 2016 and 2015 was \$39.8 million and \$37.7 million, respectively, an increase of \$2.1 million, or 6%. Research and development expenses for the nine months ended September 30, 2016 and 2015 are summarized in the table below:

<b>In thousands</b>	<b>Nine Months Ended</b>	
	<b>September 30,</b>	
	<b>2016</b>	<b>2015</b>
REDUCE-IT study (1)	\$ 27,991	\$ 25,952
Regulatory filing fees and expenses (2)	1,776	1,517
Internal staffing, overhead and other (3)	8,278	7,788
Research and development expense, excluding non-cash expense	38,045	35,257
Non-cash stock-based compensation (4)	1,753	2,458
Total research and development expense	\$ 39,798	\$ 37,715



**Table of Contents**

The increase in research and development expenses for the nine months ended September 30, 2016, as compared to the prior year period, is primarily due to quarterly variability in costs related to the REDUCE-IT study.

- (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. In 2016, we completed patient enrollment and randomization of 8,175 individual patients into the REDUCE-IT study, slightly exceeding the 8,000 patients targeted for the trial. The study duration is dependent on the rate of clinical events in the study, which rate may be affected by the epidemiology of the patients enrolled in the study and the length of time that the enrolled patients are followed. We manage the study through a contract research organization (CRO) through which all costs for this outcomes study are incurred with the exception of costs for clinical trial material (CTM) and costs for internal management. Our internal personnel are responsible for managing multiple projects and their costs are not specifically allocated to REDUCE-IT or any other individual project. For the nine months ended September 30, 2016 and 2015, we incurred expenses through our CRO in connection with this trial of approximately \$22.6 million and \$21.3 million, respectively. Inclusive of CTM costs, the combined CRO and CTM costs during the nine months ended September 30, 2016 and 2015 for REDUCE-IT were approximately \$28.0 million and \$26.0 million, respectively. The increase in expenses in 2016 as compared to 2015 is primarily the result of timing variability for REDUCE-IT costs. We expense costs for CTM when allocated to clinical research. The aggregate cost of this outcomes study will depend on the rate of clinical events in the study. We currently estimate that we will incur \$30 million to \$40 million in annual costs through study completion and the rate at which we incur such costs will vary from quarter to quarter. The study is designed to be completed after reaching 1,612 aggregate cardiovascular events. Based on projected event rates, we estimate the onset of the target aggregate number of cardiovascular events to be reached in or about the fourth quarter of 2017 with study results then expected to be available and published in 2018. We anticipate that our costs for this outcomes study will continue to represent the most significant component of our research and development expenditures.
- (2) The regulatory filing fees in each of the nine months ended September 30, 2016 and 2015 included annual FDA fees for maintaining manufacturing sites.
- (3) Internal staffing, overhead and other research and development expenses primarily relate to the costs of our personnel employed to manage research, development and regulatory affairs activities and related overhead costs including consulting and other professional fees that are not allocated to specific projects. Also included are costs related to qualifying suppliers and legal costs.
- (4) Non-cash stock-based compensation expense represents the costs associated with equity awards issued to internal staff supporting our research and development and regulatory functions.

*Gain (Loss) on Change in Fair Value of Derivative Liabilities.* Gain (loss) on change in fair value of derivative liabilities for the nine months ended September 30, 2016 was a gain of \$8.2 million versus a loss of \$0.4 million in the prior year period. Gain (loss) on change in fair value of derivative liabilities for the nine months ended September 30, 2016 and 2015 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 liabilities related to the change in control provisions associated with the May 2014 and November 2015 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 was 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 per warrant and recorded a \$48.3 million warrant derivative liability, representing the fair value of the warrants issued. As these warrants were classified as a derivative liability, they were revalued at each reporting period, with changes in

fair value recognized in the condensed consolidated statement of operations. Of the 8,087,388 warrants outstanding as of December 31, 2014, 1,844,585 warrants were exercised and the remaining 6,242,803 warrants expired on February 27, 2015. As such, no warrants were outstanding as of September 30, 2015 and the derivative liability was extinguished. The fair value of the warrant derivative liability as of December 31, 2014 was \$0.1 million and we recognized a \$0.1 million gain on change in fair value of derivative liability for the nine months ended September 30, 2015. There was no such change in fair value of derivative liability for the nine months ended September 30, 2016.

Our December 2012 financing agreement with BioPharma contains a redemption feature whereby, upon a change of control, we would be required to repay \$150 million, less any previously repaid amount. The fair value of the derivative liability is recalculated at each reporting period using a probability-weighted model incorporating management estimates for potential change in control, and by determining the fair value of the debt with and without the change in control provision included. The difference between the two fair values of the debt was determined to be the fair value of the embedded derivative. As of December 31, 2015, the fair value of the derivative was determined to be \$5.5 million, and as of September 30, 2016, the fair value of the derivative was

---

**Table of Contents**

determined to be nil based on current assumptions. As such, we recognized a \$5.5 million gain on change in fair value of derivative liability for the nine months ended September 30, 2016. As of December 31, 2014, the fair value of the derivative was determined to be \$4.8 million, and as of September 30, 2015, the fair value of the derivative was determined to be \$5.1 million. As such, we recognized a \$0.3 million loss on change in fair value of derivative liability for the nine months ended September 30, 2015.

Our 2014 Notes, issued in May 2014, contained a redemption feature whereby, upon occurrence of a change in control, we would have been 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. In September 2016, we exercised our optional exchange rights upon satisfaction of specified equity conditions set forth in the 2014 Notes indenture to mandatorily exchange the 2014 Notes into ADSs (see Note 6 Debt). As such, the related derivative liability was derecognized and we recognized a \$2.1 million gain on change in fair value of derivative liability for the nine months ended September 30, 2016. As of December 31, 2014, the fair value of the derivative was determined to be \$2.6 million, and as of September 30, 2015, the fair value of the derivative was determined to be \$1.8 million. As such, we recognized a \$0.8 million gain on change in fair value of derivative liability for the nine months ended September 30, 2015.

Our 2015 Notes, issued in November 2015, contained the same redemption feature as the 2014 Notes and the related derivative liability was calculated utilizing the same methodology. In September 2016, we exercised our optional exchange rights upon satisfaction of specified equity conditions consistent with the terms of the 2015 Notes to mandatorily exchange the 2015 Notes into ADSs (see Note 6 Debt). As such, the related derivative liability was derecognized and we recognized a \$0.6 million gain on change in fair value of derivative liability for the nine months ended September 30, 2016. There was no such change in fair value of derivative liability for the nine months ended September 30, 2015.

In connection with the closing of a private placement transaction in early 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. The liability was charged to accumulated deficit as a deemed non-cash dividend and was therefore reflected as an adjustment to net loss applicable to common shareholders for earnings per common share purposes in accordance with GAAP for the nine months ended September 30, 2015. The liability was then marked to fair value through March 30, 2015, the date on which we executed a separate subscription agreement with the investor, resulting in a charge of \$0.9 million through gain (loss) on change in fair value of derivatives in the nine months ended September 30, 2015. The liability of \$1.8 million was then reclassified to permanent equity on March 30, 2015. There was no such change in fair value of derivative liability for the nine months ended September 30, 2016.

The change in fair value of the derivative liability related to the BioPharma financing agreement is largely related to our projections for future estimated revenues, management estimates of the probability of a change in control occurring, and the terms of debt issues of similar companies. The change in fair value of the derivative liabilities related to the 2014 Notes and 2015 Notes is a result of the exchange of the related debt hosts for the nine months ended September 30, 2016 and was largely related to changes in quoted bond prices for the nine months ended September 30, 2015. 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 nine months ended September 30, 2016 and 2015 was \$16.3 million and \$14.8 million, respectively, an increase of \$1.5 million, or 10%. Net interest expense for the nine months ended September 30, 2016 and 2015 is summarized in the table below:

<b>In thousands</b>	<b>Nine Months Ended</b>	
	<b>September 30,</b>	
	<b>2016</b>	<b>2015</b>
Exchangeable senior notes (1):		
Amortization of debt discounts	\$ 5,703	\$ 4,597
Contractual coupon interest	4,072	3,938
Total exchangeable senior notes interest expense	9,775	8,535
Long-term debt from royalty-bearing instrument (2):		
Cash interest current	5,038	4,777
Cash interest deferred		112
Non-cash interest	1,543	1,392
Total long-term debt from royalty-bearing instrument interest expense	6,581	6,281
Other interest expense	12	10
Total interest expense	16,368	14,826
Interest income (3)	(115)	(73)
Total interest expense, net	\$ 16,253	\$ 14,753

**Table of Contents**

- (1) Cash and non-cash interest expense related to the exchangeable senior notes for the nine months ended September 30, 2016 and 2015 was \$9.8 million and \$8.5 million, respectively.
- (2) Cash and non-cash interest expense related to the BioPharma financing for the nine months ended September 30, 2016 and 2015 was \$6.6 million and \$6.3 million, respectively. These amounts reflect the assumption that our Vascepa revenue levels will not be high enough to support repayment to BioPharma in accordance with the repayment schedule without the optional reduction which is allowed to be elected by us if the threshold revenue levels are not achieved. To date, our revenues have been below the contractual threshold amount each quarter such that each payment reflects the calculated optional reduction amount as opposed to the contractual threshold payments for each quarterly period.
- (3) Interest income for the nine months ended September 30, 2016 and 2015 was \$0.1 million in each period. Interest income represents income earned on cash balances.

*Other Expense, net.* Other expense, net, for the nine months ended September 30, 2016 was \$0.4 million versus \$0.1 million in the prior year period. Other expense, net, primarily consists of gains and losses on foreign exchange transactions.

*Benefit from Income Taxes.* Benefit from income taxes for the nine months ended September 30, 2016 and 2015 was \$2.3 million and \$1.5 million, respectively. The current benefit 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. In April 2016, we adopted ASU No. 2016-09, *Compensation Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*, which requires that excess tax benefits and deficiencies that arise upon vesting or exercise of share-based payments be recognized as an income tax benefit and expense in the income statement. Previously, such amounts were recognized as an increase and decrease in additional paid-in capital. This aspect of the standard was adopted prospectively, and accordingly, the benefit from income taxes for the nine months ended September 30, 2016, includes \$0.4 million of excess tax deficiencies arising from share-based payments.

*Preferred Stock Purchase Option.* In connection with the closing of a private placement transaction in early 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. The liability was charged to accumulated deficit as a deemed non-cash dividend and was therefore reflected as an adjustment to net loss applicable to common shareholders for earnings per common share purposes in accordance with GAAP for the nine months ended September 30, 2015. There was no such adjustment to net loss for the nine months ended September 30, 2016.

*Preferred Stock Beneficial Conversion Features.* In 2015, we issued Series A preference shares in a private placement transaction executed in two tranches that each contain a conversion feature whereby such shares are convertible into ordinary shares at a fixed rate (see Note 8). The conversion price on the date of issuance was less than the market price of our ordinary shares on such date. We determined that these discounts represent contingent beneficial conversion features, which were valued based on the difference between the conversion price and the market price of the ordinary shares on the date of issuance. These features are analogous to preference dividends and were recorded as a non-cash return to preferred shareholders through accumulated deficit, and are therefore reflected as an adjustment to net loss applicable to common shareholders for earnings per common share purposes in accordance with GAAP. During the nine months ended September 30, 2015, we recorded an adjustment to net loss applicable to common shareholders of \$31.3 million upon effectiveness of the related resale Registration Statement on Form S-3 and \$1.6 million upon shareholder approval received at the Company's Annual General Meeting of Shareholders. There was no

such adjustment to net loss in the nine months ended September 30, 2016.

### **Liquidity and Capital Resources**

Our sources of liquidity as of September 30, 2016 include cash and cash equivalents of \$117.6 million. On August 16, 2016, we completed a public offering of 24,265,000 American Depositary Shares, or ADSs. The underwriters purchased the ADSs from us at a price of \$2.679 per ADS after commission, resulting in net proceeds to us of approximately \$64.6 million, after deducting estimated offering expenses payable by us. Our projected uses of cash include commercialization of Vascepa, the continued funding of the REDUCE-IT cardiovascular outcomes study, working capital and other general corporate activities. Our cash flows from operating, investing and financing activities, as reflected in the condensed consolidated statements of cash flows, are summarized in the following table:

**Table of Contents**

<b>In millions</b>	<b>Nine Months Ended</b>	
	<b>September 30,</b>	
	<b>2016</b>	<b>2015</b>
Cash (used in) provided by:		
Operating activities	\$ (52.5)	\$ (60.1)
Investing activities		
Financing activities	63.1	59.5
<b>Increase in cash and cash equivalents</b>	<b>\$ 10.6</b>	<b>\$ 0.6</b>

Net cash used in operating activities during the nine months ended September 30, 2016 compared to the nine months ended September 30, 2015 decreased primarily as a result of increased collections resulting from higher revenues and decreased legal costs following the favorable federal court declaration on August 7, 2015 and related settlement on March 8, 2016 allowing communication of truthful and non-misleading ANCHOR clinical trial and related data to be communicated to healthcare professionals, partially offset by receipt in 2015 of \$15.0 million in up-front proceeds from the Eddingpharm license agreement. Increased sales and marketing spend in 2016 in support of expanded Vascepa promotion was more than offset by higher collections from product sales.

On December 6, 2012 we entered into a financing agreement with BioPharma. Under this agreement, we granted to BioPharma a security interest in future receivables and all related rights to Vascepa, in exchange for \$100 million received at the closing of the agreement which closing occurred in December 2012. We have agreed to repay BioPharma up to \$150 million of future revenue and receivables. As of September 30, 2016, the net remaining amount to be repaid to BioPharma is \$128.8 million. To date, our revenues have been below the contractual threshold amount such that each payment made has reflected the calculated optional reduction amount as opposed to the contractual threshold payments for each quarterly period. The maximum amount payable under the contractual threshold for 2016 is \$11.7 million. The quarterly repayments through September 30, 2016 represent 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, through our wholly-owned subsidiary Corsicanto Limited, or Corsicanto, a private limited company incorporated under the laws of Ireland, we completed a private placement of \$150.0 million in aggregate principal amount of 3.5% exchangeable senior notes due 2032, or the 2012 Notes. The proceeds we received from the January 2012 debt offering were approximately \$144.3 million, net of fees and transaction costs. On May 20, 2014, we entered into separate, privately negotiated exchange agreements with certain holders of the 2012 Notes pursuant to which Corsicanto exchanged \$118.7 million in aggregate principal amount of the 2012 Notes for \$118.7 million in aggregate principal amount of new 3.5% May 2014 Exchangeable Senior Notes due 2032, or the 2014 Notes. In November 2015, \$16.2 million of the 2012 Notes was extinguished, following which \$15.1 million in aggregate principal amount of the 2012 Notes remains outstanding with terms unchanged. Also in November 2015, we entered into a privately negotiated subscription agreement with one of our existing investors, or the Investor, pursuant to which the Investor agreed to purchase approximately \$31.3 million in aggregate principal amount of new 3.5% November 2015 Exchangeable Senior Notes due 2032, or the 2015 Notes, for approximately \$27.5 million. In September 2016, we exercised our optional exchange rights upon satisfaction of specified equity conditions set forth

in the 2014 Notes and 2015 Notes to mandatorily exchange the entirety of the 2014 Notes and 2015 Notes into ADSs, such that the only exchangeable senior notes that remain outstanding as of September 30, 2016 are the 2012 Notes (see Note 6 Debt).

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. As a result, the carrying value of the 2012 Notes of \$15.1 million is classified as a current liability as of September 30, 2016. We may in the future seek to negotiate exchange agreements with the remaining holders of the outstanding 2012 Notes or to otherwise refinance this debt obligation on or before all or a portion of the \$15.1 million is put to us.



---

**Table of Contents**

As of September 30, 2016, we had cash and cash equivalents of \$117.6 million, an increase of \$45.1 million from June 30, 2016 and an increase of \$10.6 million from December 31, 2015. The increase during 2016 is primarily due to proceeds from financing activities and accounts receivable collections, less net cash used in operating activities in support of the commercialization of Vascepa and funding of REDUCE-IT. We have incurred annual operating losses since our inception and, as a result, we had an accumulated deficit of \$1.2 billion as of September 30, 2016. We anticipate that our purchases of API will generally be higher in the future, including the fourth quarter of 2016, giving consideration to supplier lead times, economies of larger batch sizes, anticipated revenue growth and preparation for REDUCE-IT study completion. We anticipate that quarterly net cash outflows in future periods will be variable. We believe that our cash and cash equivalents will be sufficient to fund our projected operations for at least the next twelve months. Depending on the level of cash generated from operations, additional capital may be required to sustain operations, fund debt obligations or expand promotion of Vascepa as contemplated based on anticipated successful results of the REDUCE-IT study.

**Contractual Obligations**

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

We have operating lease costs consisting of leases for facilities in Dublin, Ireland and Bedminster, NJ, offset by sublease rental income.

Under the terms of the agreement with BioPharma, we agreed to repay up to \$150 million of future revenue and receivables. As of September 30, 2016, the net remaining amount to be repaid to BioPharma is \$128.8 million. To date, each payment made has reflected the calculated optional reduction amount as opposed to the contractual threshold payments for each quarterly period. The maximum amount payable under the contractual threshold for 2016 is \$11.7 million. The quarterly repayments through September 30, 2016 represent interest only. In accordance with the agreement with BioPharma, quarterly differences between the calculated optional reduction amounts and the repayment schedule amounts are rescheduled for payment beginning in the second quarter of 2017. Any such deferred payments will remain subject to continued application of the quarterly ceiling in amounts due established by the calculated threshold based on quarterly Vascepa revenues. No additional interest expense or liability is incurred as a result of such deferred repayments and no cliff payment of the remaining balance is due except in the event of Company default or Company change of control. The agreement does not expire until \$150 million in aggregate has been repaid. We can prepay an amount equal to \$150 million less any previously repaid amount. We currently estimate that Vascepa revenue levels will not be high enough in each quarter to support repayment to BioPharma in accordance with threshold amounts in the repayment schedule.

We have scheduled interest payments due under the terms of the 2012 Notes, assuming that the 2012 Notes remain outstanding through January 19, 2017.

Concurrent with our supply agreement with Chemport entered into in 2011 for the supply of API materials for Vascepa, we agreed to make a non-controlling minority share equity investment in the supplier of up to \$3.3 million. We invested \$1.7 million under this agreement in July 2011 and the remaining \$1.6 million during 2012. In September

2013, we entered into an equity sale and purchase agreement between this supplier and a third party in which we agreed to sell approximately \$1.3 million of our investment in the supplier to the third party at cost. This transaction closed in the first quarter of 2014. In August 2014, we entered into a second equity sale and purchase agreement between this supplier and another third party in which we agreed to sell approximately \$1.0 million of our remaining investment. This transaction closed in the fourth quarter of 2014. The remaining carrying amount of \$0.2 million as of both September 30, 2016 and December 31, 2015 is included in other long-term assets and is accounted for under the cost method.

Under the 2004 share repurchase agreement with Laxdale Limited, or Laxdale, upon approval of Vascepa by the FDA on July 26, 2012, we were required to make a milestone payment to Laxdale of £7.5 million. We made this payment in 2012 and capitalized this Laxdale milestone payment of \$11.6 million as a component of other long-term assets. This long-term asset is being amortized over the estimated useful life of the intellectual property we acquired from Laxdale and we recognized amortization expense of \$0.5 million in each of the nine months ended September 30, 2016 and 2015. 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 Limited 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 \$9.7 million as of

## **Table of Contents**

September 30, 2016). 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 Limited intellectual property), we must make an aggregate stock or cash payment (at the sole option of each of the sellers) of £5 million (approximately \$6.5 million as of September 30, 2016) for each of the two potential market approvals (i.e. £10 million maximum, or approximately \$13.0 million as of September 30, 2016).

We have recorded a liability of \$0.1 million for uncertain tax positions in other long-term liabilities as of September 30, 2016. We are not able to reasonably estimate in which future periods these amounts will ultimately be settled.

We do not enter into financial instruments for trading or speculative purposes. As of September 30, 2016, we had no outstanding forward exchange contracts.

## **Off-Balance Sheet Arrangements**

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

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

There have been no material changes with respect to the information appearing in PART II, Item 7A *Quantitative and Qualitative Disclosures about Market Risk* of our Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 25, 2016.

### **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, as amended (the *Exchange Act*), is (1) recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our Principal Executive Officer and Principal Financial Officer, to allow timely decisions regarding required disclosure.

As of September 30, 2016, 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 *Exchange Act*). 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 has concluded, based upon the evaluation described above that, as of September 30, 2016, our disclosure controls and procedures were effective at the reasonable assurance level.

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

During the quarter ended September 30, 2016, 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 *Exchange Act*, that have

materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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

In the ordinary course of business, we are from time to time involved in lawsuits, claims, investigations, proceedings, and threats of litigation relating to intellectual property, commercial arrangements and other matters. Item 3. Legal Proceedings of our Annual Report on Form 10-K for the fiscal year ended December 31, 2015 and Item 1. Legal Proceedings of our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2016 and June 30, 2016 include discussions of our current legal proceedings. There have been no material changes to those disclosures as of the date of this filing other than as set forth below.

In September and October 2016, we received paragraph IV certification notices from four companies contending to varying degrees that certain of our patents are invalid, unenforceable and/or will not be infringed by the manufacture, use, sale or offer for sale of a generic form of Vascepa as described in those companies' abbreviated new drug applications, or ANDAs. We filed or are in the process of filing patent infringement lawsuits against each of these ANDA applicants. In October 2016, Amarin filed a lawsuit against Roxane Laboratories, Inc., or Roxane, in the U.S. District Court for the District of Nevada. The case against Roxane is captioned *Amarin Pharma, Inc. et al. v. Roxane Laboratories, Inc. et al*, Civ. A. No. 2:16-cv-02525 (D. Nev.). In the *Roxane* lawsuit, Amarin is seeking, among other remedies, an order enjoining Roxane from marketing generic versions of Vascepa before the last to expire of the asserted patents in 2030. We intend to vigorously enforce our intellectual property rights relating to Vascepa, but we cannot predict the outcome of the *Roxane* lawsuit or any subsequently filed lawsuits.

**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 ability to successfully commercialize Vascepa, our capital resources, 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 February 25, 2016.*

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

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

As a result of our reliance on a single product, Vascepa® (icosapent ethyl) capsules, and our primary focus on the U.S. market in the near-term, much of our near-term results and value as a company depends on our ability to execute our commercial strategy for Vascepa in the United States. If commercialization efforts for Vascepa are not successful, our business will be materially and adversely affected.

Even if we are able to successfully develop Vascepa outside the United States or develop additional products from our research and development efforts, the development time cycle for products typically takes several years. This restricts our ability to respond to adverse business conditions for Vascepa. If we are not successful with development, or if there is not adequate demand for Vascepa or the market for such product develops less rapidly than we anticipate, we may not have the ability to effectively shift our resources to the development of alternative products or do so in a timely manner without suffering material adverse effects on our business. As a result, the lack of alternative markets and products we develop could constrain our ability to generate revenues and achieve profitability.

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

In January 2013, we launched Vascepa based on FDA approval of our MARINE indication, for use as an adjunct to diet to reduce triglyceride levels in adult patients with severe (TG  $\geq$ 500 mg/dL) hypertriglyceridemia. 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. Guidelines for the management of very high triglyceride levels suggest that reducing triglyceride levels is the primary goal in patients to reduce the risk of acute pancreatitis. A secondary goal for this patient population is to reduce cardiovascular risk. The effect of Vascepa on cardiovascular mortality and morbidity, or the risk for pancreatitis, in patients with hypertriglyceridemia has not been determined and our FDA-approved labeling and promotional efforts state these facts.

**Table of Contents**

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

The uncertainties around the ultimate clinical benefit of Vascepa make it more difficult for Vascepa to gain market acceptance by physicians, patients, healthcare payors and others in the medical community. If Vascepa does not achieve an adequate level of acceptance, we may not generate product revenues sufficient to become profitable. The degree of market acceptance of Vascepa for the MARINE indication and in ANCHOR patients and any future approved indications will depend on a number of factors, including:

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

our ability to offer Vascepa for sale at competitive prices;

convenience and ease of administration compared to alternative treatments;

the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;

the scope, effectiveness and strength of product education, marketing and distribution support, including our sales and marketing team;

publicity concerning Vascepa or competing products;

our ability to continually promote Vascepa in the United States outside of FDA-approved labeling and the related perception thereof;

sufficient third-party coverage or reimbursement for on-label use, and for permitted off-label use, the third-party coverage or reimbursement for which was not addressed in the scope of the August 2015 court declaration; and

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

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

In January 2013, we began selling and marketing Vascepa in the United States through our own, newly established sales and marketing teams and through a newly established third-party commercial distribution infrastructure. We hired key personnel in these areas over the last several years and hired and trained a professional sales force in early January 2013. In October 2013, following an FDA advisory committee recommendation against approval for the ANCHOR indication, we implemented a plan to reduce our workforce and our team of sales professionals in half.

In May 2014 we began co-promoting Vascepa in the United States with Kowa Pharmaceuticals America, Inc. under a co-promotion agreement we entered into in March 2014. Under the agreement, no less than 250 Kowa Pharmaceuticals America, Inc. sales representatives devote a substantial portion of their time to promoting Vascepa with our approximately 150 sales professionals, including sales representatives and their managers, based on a plan designed to increase both the number of sales targets reached and the frequency of sales calls on existing sales targets. However, the commercialization of pharmaceutical products is a complex undertaking for a company to manage, and we have very limited experience as a company operating in this area and co-promoting a pharmaceutical product with a partner.

We are also expanding our commercialization activities to markets outside of the United States through partnering arrangements. In February 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, or the China Territory. Under the DCS Agreement, Eddingpharm will be solely responsible for development and commercialization activities in the China Territory and associated expenses. Additionally, Eddingpharm may be required to conduct clinical trials in the China Territory to secure regulatory approval. Significant commercialization of Vascepa in the China Territory is several years away, if at all. 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.



**Table of Contents**

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, which may include conducting clinical trials, 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.

We also have an agreement to register and commercialize Vascepa in countries within the Middle East and North Africa. Development in this region, as in China, is also several years away and subject to similar risks. We continue to assess other partnership opportunities for licensing Vascepa in other territories outside of the United States.

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

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

our inability to adequately train our sales and marketing personnel, in particular as it relates to various healthcare regulatory requirements applicable to the marketing and sale of pharmaceutical products and the court declaration that we believe enables us to expand marketing efforts for Vascepa, and our inability to adequately monitor compliance with these requirements;

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

the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;

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

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

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

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

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

In April 2015, we received a Complete Response Letter, or CRL, from the FDA on our supplemental new drug application ( 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 regulatory communications, the FDA acknowledged that the results of the ANCHOR trial as we presented them to FDA were valid and truthful in that, for example, Vascepa reduced triglyceride levels compared to placebo in patients treated in the ANCHOR study. The clinical rationale for reducing serum triglycerides with Vascepa and modifying other lipid/lipoprotein parameters shown in ANCHOR among statin-treated patients with triglycerides 200-499 mg/dL is to reduce cardiovascular risk. In not approving our ANCHOR sNDA, the FDA concluded that, for regulatory approval purposes, there were insufficient data to support a drug-induced change in serum triglycerides as a surrogate for reducing cardiovascular risk in the ANCHOR population. The FDA did not determine that the drug-induced effects of Vascepa, which go beyond triglyceride-lowering, would not actually reduce cardiovascular risk in this population.

In August 2015, based on a federal court order, we began marketing Vascepa in the United States to healthcare professionals for the treatment of patients in the ANCHOR population through use of a set of qualified statements that reflect the state of research related to this use. In March 2016, we settled the litigation related to this court order under terms by which the FDA and the U.S. government agreed to be bound by the conclusions from the federal court order that we may engage in truthful and non-misleading speech promoting the off-label use of Vascepa and that certain statements and disclosures that we proposed to make to healthcare professionals were truthful and non-misleading. An FDA-approved indication for this patient population has not been granted. Our ability to reach full potential in the commercialization of Vascepa in the United States is dependent upon marketing claims associated with Vascepa that are granted with the approval of an indication statement by the FDA.

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

---

**Table of Contents**

ability to reach profitability. Even if we obtain additional regulatory approvals for Vascepa, the timing or scope of any approvals may prohibit or reduce our ability to commercialize the product successfully. For example, if the approval process for any expanded indication takes too long, we may miss market opportunities and give other companies the ability to develop competing products or establish market dominance. If the FDA does not approve any expanded indication at all, it could have a material impact on our future results of operations and financial condition.

Additionally, the terms of any approvals beyond the approval received from the FDA in July 2012 for the MARINE indication may prove to not have the scope or breadth needed for us to successfully commercialize Vascepa or become profitable.

***\*Our off-label promotion of Vascepa could subject us to additional regulatory scrutiny and present unforeseen risks.***

The Federal Food, Drug, and Cosmetic Act, or FDCA, has been interpreted by the FDA to make it illegal for pharmaceutical companies to promote their products for uses that have not been approved by the FDA. Companies that market drugs for so called off-label uses or indications have been subject to related costly litigation, criminal penalties and civil liability under the False Claims Act.

In May 2015, we and a group of independent physicians filed a lawsuit against the FDA seeking a federal court declaration that would permit us and our agents to promote to healthcare professionals the use of Vascepa in patients with mixed dyslipidemia and promote on the potential of Vascepa to reduce the risk of cardiovascular disease so long as the promotion is truthful and non-misleading. This use of Vascepa at issue reflects recognized medical practice but was not approved by the FDA and is thus not covered by current FDA-approved labeling for the drug. Promotion of a so-called off-label use is considered by the FDA to be illegal under the FDCA. The lawsuit, captioned *Amarin Pharma, Inc., et al. v. Food & Drug Administration, et al.*, 119 F. Supp. 3d 196 (S.D.N.Y. Aug. 7, 2015), was filed in the United States District Court for the Southern District of New York. In the lawsuit, we contended principally that FDA regulations limiting off-label promotion of truthful and non-misleading information are unconstitutional under the freedom of speech clause of the First Amendment to the U.S. Constitution as applied in the case of our proposed promotion of Vascepa. The physicians in the suit regularly treat patients at risk of cardiovascular disease and, as the complaint contended, have First Amendment rights to receive truthful and non-misleading information from Amarin. The suit was based on the principle that better informed physicians make better treatment decisions for their patients. The FDA opposed this lawsuit but did not dispute the veracity of the subject ANCHOR clinical trial data, the safety data from which is already in FDA-approved labeling of Vascepa, or the peer-reviewed research related to Vascepa and the potential for cardiovascular risk reduction.

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

In August 2015, we were granted preliminary relief in this lawsuit through the court's declaratory judgment that confirmed we may engage in truthful and non-misleading speech promoting the off-label use of Vascepa to healthcare professionals, i.e., to treat patients with persistently high triglycerides, and that such speech may not form the basis of a misbranding action under the FDCA. In August 2015, we began to promote Vascepa to healthcare professionals as permitted by this court declaration. The FDA did not appeal the court's ruling. In March 2016, we settled this litigation under terms by which the FDA and the U.S. government agreed to be bound by the conclusions from the federal court

order that we may engage in truthful and non-misleading speech promoting the off-label use of Vascepa and that certain statements and disclosures that we proposed to make to healthcare professionals were truthful and non-misleading.

While we believe we are now permitted under applicable law to more broadly promote Vascepa, the FDA-approved labeling for Vascepa did not change as a result of this litigation and settlement, and neither government nor other third-party coverage or reimbursement to pay for the off-label use of Vascepa promoted under the court declaration was required. 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.

Even though we have the benefit of a final settlement in this litigation, our promotion is still subject to a high, perhaps abnormally high, degree of scrutiny to ensure that our promotion remains within the scope covered by the settlement. For example, under the settlement, we remain responsible for ensuring our speech is truthful and non-misleading. Federal and state governments may also seek to find other means to prevent our promotion of unapproved truthful and non-misleading information about Vascepa. If our promotional activities or other operations are found to be in violation of any law or governmental regulation through existing or new interpretations, we may be subject to prolonged litigation, penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

---

**Table of Contents**

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

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

Our competitors both in the United States and Europe include large, well-established pharmaceutical companies, specialty pharmaceutical sales and marketing companies, and specialized cardiovascular treatment companies. GlaxoSmithKline plc, which currently sells 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 sells Tricor<sup>®</sup> and Trilipix<sup>®</sup> for the treatment of severe hypertriglyceridemia and Niaspan<sup>®</sup>, which is primarily used to raise HDL-C but is also used to lower triglycerides. Generic versions of Tricor, Trilipix, and Niaspan are also now available in the United States. In addition, in May 2014, Epanova<sup>®</sup> (omega-3-carboxylic acids) capsules, a free fatty acid form of omega-3 (comprised of 55% EPA and 20% DHA), was approved by the FDA for patients with severe hypertriglyceridemia. Epanova was developed by Omthera Pharmaceuticals, Inc., and is now owned by AstraZeneca Pharmaceuticals LP (AstraZeneca). Also, in April 2014, Omtryg, another omega-3-acid fatty acid composition developed by Trygg Pharma AS, received FDA approval for severe hypertriglyceridemia. Neither Epanova nor Omtryg have been commercially launched, but could launch at any time. Each of these competitors, other than potentially Trygg, has greater resources than we do, including financial, product development, marketing, personnel and other resources.

Currently, six manufacturers have launched generic versions of Lovaza. 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, respectively, 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, Apotex launched a generic version of Lovaza in January 2015. Prasco Labs launched a generic version of Lovaza in March 2015 and AvKARE, Inc., or AvKARE, launched its version in May 2015. AvKARE supplies government agencies and does not participate in the commercial marketplace. Amneal Pharmaceuticals launched a generic version of Lovaza in January 2016.

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, or Acasti, a subsidiary of Neptune Technologies & Bioresources Inc., announced in December 2015 that it intends to pursue a regulatory pathway under section 505(b)(2) of the FDCA for its omega-3 prescription drug candidate, CaPre<sup>®</sup>, derived from krill oil for the treatment of hypertriglyceridemia. In September 2016, Acasti announced positive results from its pivotal bioavailability bridging study comparing CaPre to Lovaza, establishing a scientific bridge between the two that is expected to support the feasibility of a 505(b)(2) regulatory pathway. Acasti intends to complete long-term toxicity studies in the next 6-9 months and follow these with a Phase 3 clinical program to assess the safety and efficacy of CaPre in patients with very high (≥500 mg/dL) triglycerides. We believe Sancilio & Company, or Sancilio, is also

developing potential treatments for hypertriglyceridemia based on omega-3 fatty acids. To our knowledge, Sancilio is pursuing a regulatory pathway under section 505(b)(2) of the FDCA for its product and submitted an Investigational New Drug Application, or IND, in July 2015. Sancilio completed two pivotal pharmacokinetic studies, and we expect the company to initiate a pivotal clinical endpoint study as the next step in development. 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 IND with the FDA to conduct a human study in the treatment of severe hypertriglyceridemia. Akcea Therapeutics/Ionis Pharmaceuticals (formerly Isis Pharmaceuticals) announced favorable Phase 2 results of volanesorsen (formerly 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. Phase 3 trials are currently ongoing studying volanesorsen in patients with severe hypertriglyceridemia, familial chylomicronemia syndrome (FCS), and familial partial lipodystrophy (FPL) with data expected in 2017 and 2018. Madrigal Pharmaceuticals has completed Phase 1 clinical testing of MGL-3196 for the treatment of high triglycerides and various lipid parameters in patients. We expect Madrigal to begin Phase 2 trials in homozygous familial hypercholesterolemia (HoFH) and heterozygous familial hypercholesterolemia (HeFH) in 2016. Finally, Gemfire Therapeutics has initiated a Phase 2 trial to evaluate the safety and efficacy of gemcabene, an oral, once-daily pill, in the treatment of patients with homozygous familial hypercholesterolemia (HoFH) on stable lipid-lowering therapy. The novel mechanism of action of gemcabene may support multiple indications including a potential severe triglyceride reduction.

---

**Table of Contents**

*\*Vascepa's recently granted five-year, new chemical entity, or NCE, regulatory exclusivity from the FDA, based on its July 2012 FDA approval, could be challenged by companies seeking to make generic versions of Vascepa or via a citizens petition.*

The timelines and conditions under the abbreviated new drug application, or 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. FDA marketing exclusivity is separate from, and in addition to, patent protection, trade secrets and manufacturing barriers to entry which also help protect Vascepa against generic competition.

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 five-year NCE marketing exclusivity to Vascepa and granted three-year marketing exclusivity. Under applicable regulations, such three-year exclusivity would have extended through July 25, 2015 and would have been supplemented by a 30-month stay triggered by patent litigation that would have extended into September 2016, unless such patent litigation was resolved against us sooner.

NCE marketing exclusivity 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.

In contrast, a three-year period of exclusivity under the Hatch-Waxman Amendments is generally granted for a drug product that contains an active moiety that has been previously approved, such as 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. Accordingly, we expect to receive three-year exclusivity in connection with any future regulatory approvals of Vascepa, such as an approval sought based on positive REDUCE-IT outcomes study results. 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 patents at any time, subject to any prior four-year period pending from a grant of five-year exclusivity. This three-year form of exclusivity may also not prevent the FDA from approving an NDA that relies only on its own data to support the change or innovation.

On February 27, 2014, we sued the FDA in the U.S. District Court for the District of Columbia to challenge the agency's denial of 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. On May 28, 2015, the court granted our motion for summary judgment. The decision vacated the FDA's denial of our claim for such exclusivity and remanded to the FDA for proceedings

consistent with the decision. On July 22, 2015, Watson Laboratories Inc., the purported first Vascepa ANDA filer, sought to intervene and appeal the court's decision. We and FDA opposed this intervention effort. The applicable courts denied Watson the relief sought and appeal periods have expired.

On May 31, 2016, in a reversal that FDA and we view as consistent with the court's May 28, 2015 summary judgment motion, FDA determined that Vascepa is eligible for five-year, NCE marketing exclusivity. This determination provides Vascepa with the benefits of NCE exclusivity afforded by statute. NCE exclusivity for Vascepa runs from its date of FDA approval on July 26, 2012 and extends until July 26, 2017. The statutory 30-month stay triggered by patent litigation following generic application submissions permitted on July 26, 2016 would continue until January 26, 2020, seven-and-a-half years from FDA approval, unless such patent litigation was resolved against us sooner.

It is possible that FDA's NCE determination could be challenged by interested parties. If challenged, we plan to vigorously support FDA's determination. Any such challenge could have a negative impact on our company and create uncertainty around the continued benefits associated with a five-year exclusivity status.



---

**Table of Contents*****\*Generic company competitors are seeking FDA approval of generic versions of Vascepa and we are now engaged in related patent litigation.***

The FDCA, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, as amended, or the Hatch-Waxman Amendments, permits the FDA to approve 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.

In the first half of 2014, we received six Paragraph IV notices notifying us of accepted ANDAs to Vascepa under the Hatch-Waxman Amendments. These ANDAs were submitted and accepted by FDA under the regulatory scheme adopted under the Hatch-Waxman Amendments based on the FDA's determination that we were entitled to three, and not five-year exclusivity. As a result from the first half of 2014 until June 2015, we were engaged in costly litigation with the ANDA applicants to protect our patent rights.

Based on the May 28, 2015, District of Columbia court order granting our motion for summary judgment in the NCE litigation, on June 26, 2015, the parties to the related Vascepa patent litigation that followed acceptance by FDA of ANDAs to Vascepa based on a three-year regulatory exclusivity determination, agreed to a full stay of proceeding in that patent litigation.

Following the May 28, 2015 District of Columbia court order setting aside FDA's denial of NCE exclusivity for Vascepa, FDA notified the ANDA filers that FDA had changed the status of their ANDAs to submitted, but no longer accepted, and notified ANDA filers that FDA had ceased review of the pending ANDAs. In rescinding acceptance of the ANDAs, the statutory basis for the patent litigation (accepted ANDAs) no longer existed. Thus, on July 24, 2015, we moved to dismiss the pending patent infringement lawsuits against each of the Vascepa ANDA applicants in the U.S. District Court for the District of New Jersey.

On January 22, 2016, the U.S. District Court for the District of New Jersey granted our motion to dismiss all patent infringement litigation related to the 2014 acceptance by the FDA of ANDAs to Vascepa. An appeal of the court's dismissal was filed by one ANDA filer and, after FDA's May 2016 grant of Vascepa NCE exclusivity, that appeal was withdrawn by the ANDA filer. This dismissal and terminated appeal ended this patent litigation related to Vascepa.

In September and October 2016, we received paragraph IV certification notices from four companies contending to varying degrees that certain of our patents are invalid, unenforceable and/or will not be infringed by the manufacture, use, sale or offer for sale of a generic form of Vascepa as described in those companies' ANDAs. These certifications were expected given the eligibility for submission of ANDAs under the NCE regulatory structure, after the expiration of four years from the July 2012 approval of Vascepa.

We filed and are now in the process of filing of patent infringement lawsuits against each of these ANDA applicants. In October 2016, Amarin filed a lawsuit against Roxane Laboratories, Inc. and related parties in the U.S. District Court for the District of Nevada. The case against Roxane is captioned *Amarin Pharma, Inc. et al. v. Roxane Laboratories, Inc. et al*, Civ. A. No. 2:16-cv-02525 (D. Nev.). In the *Roxane* lawsuit, we are seeking, among other remedies, an order enjoining Roxane from marketing generic versions of Vascepa before the last to expire of the asserted patents in 2030. We intend to vigorously enforce our intellectual property rights relating to Vascepa, but we cannot predict the outcome of the *Roxane* lawsuit or any subsequently filed lawsuits.

---

**Table of Contents**

If an ANDA filer is ultimately successful in patent litigation against us, it meets the requirements for a generic version of Vascepa to the satisfaction of the FDA under its ANDA (after the applicable regulatory exclusivity period and the litigation-related 30-month stay period ends), 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.

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

Our only current product, Vascepa, is a prescription-only omega-3 fatty acid. Mixtures of omega-3 fatty acids are naturally occurring substances contained in various foods, including fatty fish. Omega-3 fatty acids are also marketed by others as non-prescription dietary supplements. We cannot be sure physicians will view the pharmaceutical grade purity and tested safety of Vascepa as having a superior therapeutic profile to naturally occurring omega-3 fatty acids and dietary supplements. In addition, the FDA has not enforced what we view as illegal drug claims made by certain omega-3 fatty acid 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. As a result of our First Amendment litigation and settlement, we may now make this claim to healthcare professionals subject to certain qualifications. These factors enable dietary supplements to effectively compete with Vascepa. In addition, to the extent the net price of Vascepa after insurance and offered discounts is significantly higher than the prices of commercially available omega-3 fatty acids marketed by other companies as dietary supplements (through that lack of coverage by insurers or otherwise), physicians and pharmacists may recommend these commercial alternatives instead of writing or filling prescriptions for Vascepa or patients may elect on their own to take commercially available omega-3 fatty acids. Either of these outcomes may adversely impact our results of operations by limiting how we price our product and limiting the revenue we receive from the sale of Vascepa due to reduced market acceptance.

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

In March 2014, we entered into a co-promotion agreement with Kowa Pharmaceuticals America, Inc. to co-promote Vascepa in the United States under which no less than 250 Kowa Pharmaceuticals America, Inc. sales representatives devote a substantial portion of their time to promoting Vascepa with our approximately 150 sales professionals, including sales representatives and their managers. Co-promotion under the agreement commenced in May 2014 based on a plan designed to substantially increase both the number of sales targets reached and the frequency of sales calls on existing sales targets. While our agreement provides for minimum performance criteria, we have little control over Kowa Pharmaceuticals America, Inc., and it may fail to devote the necessary resources and attention to promote Vascepa effectively. If that were to occur, depending on Vascepa revenues, we may have to curtail the continued development of Vascepa for approval for additional indications or increase our planned expenditures and undertake additional development or commercialization activities at our own expense. Or, we may seek to terminate the agreement and search for another commercialization partner. If we elect to increase our expenditures to fund development or commercialization activities on our own, depending on Vascepa's revenues, we may need to obtain additional capital, which may not be available to us on acceptable terms, or at all, or which may not be possible due to

our other financing arrangements. If we do not generate sufficient funds from the sale of Vascepa or, to the extent needed to supplement funds generated from product revenue, cannot raise sufficient funds, we may not be able to devote resources sufficient to market and sell Vascepa on our own in a manner required to realize the full market potential of Vascepa.

***The commercial value to us of current and sought marketing rights may be smaller than we anticipate.***

There can be no assurance as to the adequacy for commercial success of the scope and breadth of the marketing rights we currently have or, if approved, an indication based on a successful outcome of the REDUCE-IT study. Even if we obtain marketing approval for additional indications, the FDA may impose restrictions on the product's conditions for use, distribution or marketing and in some cases may impose ongoing requirements for post-market surveillance, post-approval studies or clinical trials. Also, the number of actual patients with conditions within the scope of our marketing efforts may be smaller than we anticipate. If any such marketing right or approved indication is narrower than we anticipate, the market potential for our product would suffer.

---

**Table of Contents**

***\*Our special protocol assessment, or 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 a 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 not a guarantee of approval. 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. The FDA reserves the right of final determinations for approval based on its review of the entire data presented in a marketing application.

In October 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 a SPA agreement, our ANCHOR SPA agreement was rescinded and there is no assurance that the FDA will not rescind our REDUCE-IT SPA agreement.

In August 2016, we announced an amendment to our REDUCE-IT SPA agreement with FDA that reaffirmed FDA concurrence on key elements of the study, defined details of the statistical analysis plan for the study, expanded to greater than 30 the pre-specified secondary and tertiary endpoints in the study, and added a second interim efficacy and safety analysis by the independent data monitoring committee (DMC) at approximately 80% of the target aggregate number of primary cardiovascular events. In this amended REDUCE-IT SPA agreement, FDA agreed that, based on the information submitted to the agency, the critical elements of the revised REDUCE-IT protocol and analysis plans adequately address the objectives necessary to support a regulatory submission. However, secondary and/or tertiary endpoints, their ordering in the statistical hierarchy, their clinical significance, or whether any would yield results appropriate for labeling are considered review issues and are not intended to be a binding component of the REDUCE-IT SPA agreement. Further, matters such as endpoint adjudication procedures (including potential endpoint ascertainment, adjudication process, and detailed definitions) were specified by FDA as issues to be reviewed by the agency as part of a drug approval application. Consistent with the May 2016 FDA SPA draft guidance, FDA stated that the SPA agreement does not necessarily indicate the agency's agreement with every detail of a protocol; instead, such an agreement indicates FDA's concurrence with the elements critical to ensuring that the trial conducted under the protocol would have the potential to form the primary basis of an efficacy claim in a marketing application. In September 2016, we announced that the DMC completed its review of the first pre-specified interim efficacy analysis and, consistent with previously stated expectations, recommended that the trial continue as planned without modification.

The inability to obtain marketing approval in the ANCHOR or REDUCE-IT indications has prevented, and would continue to prevent us, from growing revenue more significantly, and it has had, and could continue to have, a material adverse effect on our operations and financial condition, including our ability to reach profitability.

***The commercial value to us of sales of Vascepa outside the United States, such as under the DCS Agreement with Eddingpharm, may be smaller than we anticipate.***

There can be no assurance as to the adequacy for commercial success of Vascepa outside the United States. For example, 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 territories outside the United States, the number of actual patients with the condition included in such approved indication may be smaller than we anticipate. If any such approved indication is narrower than we anticipate, the market potential in these countries for our product would suffer.

***Our products and marketing efforts are subject to extensive post-approval government regulation.***

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

With respect to sales and marketing activities including direct-to-healthcare provider and direct-to-consumer advertising and promotional activities involving the internet, advertising and promotional materials must comply with FDA rules in addition to other applicable federal and local laws in the United States and in other countries. The result of our First Amendment litigation and settlement may cause the government to scrutinize our promotional efforts or otherwise monitor our business more closely. Industry-sponsored scientific and educational activities also must comply with FDA and other requirements. In the United States, the distribution of product samples to physicians must comply with the requirements of the U.S. Prescription Drug Marketing Act.

---

**Table of Contents**

Manufacturing facilities remain subject to FDA inspection and must continue to adhere to the FDA's pharmaceutical 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, given we received communication from the FDA that it considers this matter to be closed, 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 and in other territories outside the United States. Given our inexperience with marketing and commercializing products outside the United States, we will need to rely on third parties, such as Eddingpharm in China, to assist us in dealing with any such issues.

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

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products. In particular, in general, the U.S. government's position has been that a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. Even though we received FDA marketing approval for Vascepa for the MARINE indication and we believe the First Amendment court ruling and litigation settlement affords us a degree of protection for other promotional efforts, physicians may still prescribe Vascepa to their patients for use in the treatment of conditions that are not included as part of the indication statement in our FDA-approved Vascepa label or our settlement. If we are found to have promoted Vascepa outside the terms of the litigation settlement or in violation of what federal or state government may determine to be acceptable, we may

become subject to significant government fines and other related liability, such as under the False Claims Act or other theories of liability. Government may also seek to hold us responsible for the non-compliance of our co-promotion partner, Kowa Pharmaceuticals America, Inc., or our ex-U.S. commercialization partner, Eddingpharm. For example, the Federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

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

Even though we have a final settlement in our litigation related to promotion beyond FDA-approved labeling, our promotion would still be subject to a high, perhaps abnormally high, degree of scrutiny to ensure that our promotion remains within the permitted scope. Likewise, federal or state government may seek to find other means to prevent our promotion of truthful and non-misleading information.



---

**Table of Contents**

***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 agreements 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, which commenced in 2011 and completed patient enrollment and randomization of 8,175 individual patients in 2016, 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, even though they reduced triglyceride levels and showed other favorable effects on parameters relevant to cardiovascular health in studied patients. 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 outcomes study of 1 gram per day of an omega-3 acid ethyl ester composition. In that study, the composition failed to show a benefit in reducing the rate of death from cardiovascular causes or hospitalization for cardiovascular causes when administered to patients with cardiovascular risk factors under different study conditions than in the REDUCE-IT study. Vascepa is comprised of highly-pure ethyl-EPA, and has been approved by the FDA for use in adult patients with severe hypertriglyceridemia at a dose of 4 grams per day and is being studied in REDUCE-IT at 4 grams per day.

The only other outcomes study involving the use of a highly-pure formulation of ethyl-EPA, called the Japan EPA Lipid Intervention Study (JELIS), suggested that use of a highly-pure formulation of ethyl-EPA in Japan, when used in conjunction with statins, reduced cardiovascular events by 19% compared to the use of statins alone. However, there are several limitations to the JELIS study. First, the patient population was exclusively Japanese, the majority of the participants were women, and at baseline patients had a much higher LDL, limiting its generalizability to the intended target population. Also, a low dose of statins was used. It is unknown whether the positive treatment effects would have persisted if these patients had been optimally treated with statins using contemporary LDL targets in the United States. In addition, JELIS was an open-label trial, which could influence patient and physician behavior and reporting of symptoms, decisions regarding hospitalization, and referral of events for adjudication. This may be particularly relevant since hospitalization for unstable angina was a primary contributor of the overall positive result, and is considered a softer endpoint than fatal cardiovascular events.

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

---

**Table of Contents**

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 labeled approval of Vascepa or even call into question the currently understood efficacy and safety profile of Vascepa.

***\*The prospective 80% interim efficacy and safety analysis of the REDUCE-IT cardiovascular outcomes trial may not be completed in the contemplated timeframe 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 independent monitoring committee may, at its discretion, also recommend that the study be stopped for safety or related concerns.***

In September 2016, we announced that the DMC completed its review of the first pre-specified interim efficacy analysis upon reaching approximately 60% of the target aggregate number of cardiovascular events in accordance with the SPA agreement for our REDUCE-IT cardiovascular outcomes trial and, consistent with previously stated expectations, recommended that the trial continue as planned without modification. The second planned interim analysis of efficacy results will be triggered by the onset of approximately 80% of the target aggregate number of primary cardiovascular events in the study. Based on historical event rates, we anticipate that the onset of approximately 80% of events will occur in the first half of 2017, with the second pre-specified interim efficacy and safety analysis by the DMC expected in or about the third quarter of 2017. The interim efficacy analysis will be accompanied by an interim safety analysis by the DMC. It may actually take longer than anticipated for 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 or about the fourth quarter of 2017. We do not expect the study to be stopped due to overwhelming efficacy at the next interim look. We have requested the DMC to not recommend stopping the study early based only upon achieving statistical significance for the primary endpoint, but to ensure that supportive trends of benefit are also consistently observed in certain secondary endpoints and subpopulations before recommending that the study be stopped early for overwhelming efficacy. 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 due to low likelihood of obtaining a favorable result at completion. Despite no formal futility analysis or boundary being pre-specified in the protocol, it is within the purview of the DMC to weigh all available information and recommend study stoppage or continuation.

Moreover, it is the DMC that will make the formal recommendation as to whether to stop the study early or to continue as planned. We are blinded to the interim analysis results and are 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 recommend continuing 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 it believes 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 reviews 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 and elsewhere. In the United States, the FDA generally requires preclinical 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;

**Table of Contents**

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 trials or preclinical studies;

the emergence of unforeseen safety issues in clinical trials 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 preclinical studies 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 healthcare 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 healthcare services to contain or reduce healthcare 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 healthcare 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 changed the way healthcare is financed by both governmental and private insurers. Among other cost-containment measures, PPACA established:

An annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic products;

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.

---

## **Table of Contents**

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

The continuing efforts of government and other third-party payors to further contain or reduce the costs of healthcare through various means may limit our commercial opportunity. It will be time consuming and expensive for us to go through the process of seeking coverage and reimbursement from Medicare and private payors. Our products may not be considered cost effective, and government and third-party private health insurance coverage and reimbursement may not be available to patients for any of our future products or sufficient to allow us to sell our products on a competitive and profitable basis. Our results of operations could be adversely affected by PPACA and by other healthcare 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 product 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 the commercial market 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 rely 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 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 an NDA supplement for Chemport, Inc. and BASF (formerly Equateq Limited) as additional Vascepa API suppliers. 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, as it remains an NDA-approved supplier. In 2014, we obtained sNDA approval for a fourth supplier of API, which includes the manufacturing facility of Finorga SAS (Novasep). We currently purchase and use commercial supply from Novasep, Chemport, and Nisshin. Each of the API manufacturers obtains supply of the key raw material to manufacture API from other third-party sources of supply.



---

**Table of Contents**

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, Novasep, 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 mitigate the risk of reliance on any single supplier.

Expanding manufacturing capacity and qualifying such capacity is difficult and subject to numerous regulations and other operational challenges. The resources of our suppliers vary and are limited; costs associated with projected expansion and qualification can be significant. For example, Chemport, which was approved as one of our API suppliers in April 2013, is a privately-held company and their commitment to Vascepa supply has required them to seek additional resources. There can be no assurance that the expansion plans of any of our suppliers will be successful. Our aggregate capacity to produce API is dependent upon the qualification of our API suppliers. Each of our API suppliers has outlined plans for potential further capacity expansion. If no additional API supplier is approved by the FDA as part of an sNDA, 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 applicable regulatory requirements, we may not be able to supply sufficient quantities of Vascepa to meet anticipated demand. We cannot guarantee 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 Plöerme SAS. 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 guarantee 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, packaging and distribution 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, packaging and distribution 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 pharmaceutical 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

---

**Table of Contents**

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 voluntary recalls of product, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business. If we are not able to manufacture Vascepa to required specifications through our current and potential API suppliers, we may be delayed in successfully supplying the product to meet anticipated demand and our anticipated future revenues and financial results may be materially adversely affected.

Changes in the manufacturing process or procedure, including a change in the location where the product is manufactured or a change of a third-party manufacturer, may require prior FDA review and approval of the manufacturing process and procedures in accordance with the FDA's cGMPs. Any new facility may be subject to a pre-approval inspection by the FDA and would again require us to demonstrate product comparability to the FDA. There are comparable foreign requirements. This review may be costly and time consuming and could delay or prevent the launch of a product.

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

The FDA and similar foreign regulatory bodies may also implement new requirements, or change their interpretation and enforcement of existing 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 requirements, 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 and others to commercialize Vascepa in certain regions outside of the United States, and if such third parties fail to successfully fulfill their obligations, or are ineffective in their commercialization of Vascepa, or if our collaborations are 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, which may require conducting clinical trials in the China Territory to secure regulatory approval, as well as 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.

We also have an agreement to register and commercialize Vascepa in countries within the Middle East and North Africa. Development in this region, as in China, is subject to similar third party risk.

**Table of Contents**

**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.

We have prosecuted, and are currently prosecuting, multiple patent applications to protect the intellectual property developed during the Vascepa development program. As of the date of this report, we had 49 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. Such 49 allowed and issued applications include the following:

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,

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

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

2 additional patents related to the use of a pharmaceutical composition comprised of free fatty acids to treat the MARINE patient population with a term that expires in 2030,

1 additional patent related to a pharmaceutical composition comprised of free fatty acids and uses thereof to treat both the MARINE and ANCHOR patient populations with a term that expires in 2030,

1 additional patent related to a formulation of EPA/DHA and uses thereof with a term that expires in 2030,

1 additional patent related to the use of Vascepa to treat obesity with a term that expires in 2030, and

1 additional patent covering a pharmaceutical composition comprised of EPA and a hydroxyl compound with a term that expires in 2034.

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. For example, we may choose to not assert all issued patents in patent litigation and patents or claims within patents may be determined to be invalid.

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

---

**Table of Contents**

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. For example, one of our patents was revoked in an opposition proceeding in Europe due to a determination of improper claim amendments under a provision of law not applicable in the United States. 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 our 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.

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 these additional MARINE and ANCHOR patents or any of our pending patent applications intended to cover an indication based on future results from the REDUCE-IT clinical trial will be granted or, if they grant, that they will prevent competitors from competing with Vascepa.

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



---

**Table of Contents**

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

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

**Risks Related to our Business**

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

In January 2016, we issued financial and business guidance, including expected fiscal year 2016 total net revenue, which is based on estimates and the judgment of management. In August 2016, we updated this guidance based on new information. Because of the inherent nature of estimates, there could be significant differences between our estimates and the actual amount of product demand. If, for any reason, we are unable to realize our currently projected 2016 revenue, we may not realize our publicly announced financial guidance. If we fail to realize or if we change or update any element of our publicly disclosed financial guidance or other expectations about our business, our stock price could decline in value.

*\*We and certain of our current and former executive officers were named as defendants in a class action lawsuit that could result in substantial costs and divert management's attention.*

The market price of our American Depositary Shares, or 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 were named as defendants in a class action lawsuit that generally alleged 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 sought unspecified damages, interest, attorneys' fees, and other costs.

We engaged in a vigorous defense of this lawsuit. On June 29, 2015, the court granted our first motion to dismiss the class action litigation without prejudice. The court held that the plaintiffs failed to state a claim upon which relief could be granted and plaintiffs were given 30 days to refile an amended complaint.

On July 29, 2015, the plaintiffs filed an amended complaint and we again moved to dismiss. On April 26, 2016, the court granted a second motion to dismiss, again without prejudice, with leave for plaintiffs to file an amended complaint. On May 24, 2016, plaintiffs notified the court they would not file another amended complaint and on September 21, 2016, filed a brief in support of their appeal of the most recent dismissal to the Third Circuit Court of Appeals. We plan a vigorous defense to this appeal.

We are unable to predict the ultimate outcome of this matter at this time. 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.

## **Table of Contents**

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

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

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

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

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

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

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

### ***\*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. Our and our subsidiaries' income tax returns are periodically examined by various tax authorities. We are currently under audit by the United States Internal Revenue Service (IRS) for the years 2012 to

2013. Although the outcome of tax audits is always uncertain and could result in significant cash tax payments, we do not believe the outcome of these audits will have a material adverse effect on our consolidated financial position or results of operations. The ultimate resolution may result in a payment that is materially different from our current estimate of the tax liabilities. 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

---

**Table of Contents**

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. The failure to recruit key scientific, technical and management personnel would be detrimental to our ability to implement our business plan.

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

A significant portion of our sales are to wholesalers in the pharmaceutical industry. Our top three customers accounted for 95% of gross product sales for each of the nine months ended September 30, 2016 and 2015 and represented 95% of the gross accounts receivable balance as of September 30, 2016 and 2015. 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 yet reached profitability. For the fiscal years ended December 31, 2015, 2014, and 2013, we reported losses of approximately \$149.1 million, \$56.4 million, and \$166.2 million, respectively, and we had an accumulated deficit as of December 31, 2015 of \$1.1 billion. For the nine months ended September 30, 2016 and 2015, we reported losses of approximately \$58.9 million and \$127.2 million, respectively and we had an accumulated deficit as of September 30, 2016 of \$1.2 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 commercial launch of Vascepa in 2013 in the United States, our historical financial results do not form an accurate basis upon which investors should base their assessment of our business and prospects. In addition, we expect that our costs will increase substantially as we continue to commercialize Vascepa in the MARINE indication and with ANCHOR data and seek to obtain additional regulatory approval of Vascepa from continuation of the REDUCE-IT cardiovascular outcomes study. Accordingly, our historical financial results reflect a substantially different business from that currently being conducted and from that expected in the future. In addition, we have a limited history of obtaining regulatory approval for, and no demonstrated ability to successfully commercialize, a product candidate. Consequently, any predictions about our future performance may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.

---

**Table of Contents**

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

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

the level of demand for Vascepa, including due to changes in prescriber sentiment or period-to-period Distributor purchasing habits;

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 and other territories outside the United States, including obtaining necessary regulatory approvals and establishing marketing channels;

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

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

outcomes of litigation and other legal proceedings, including our pending FDA determination on regulatory exclusivity, 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 \$117.6 million as of September 30, 2016 will be sufficient to fund our projected operations for at least the next twelve months. Depending on the level of cash generated from operations, additional capital may be required to sustain operations, fund debt obligations or expand promotion of Vascepa as contemplated following anticipated successful results of the

REDUCE-IT study. We anticipate that quarterly net cash outflows in future periods will be variable.

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:

the timing, amount and consistency of revenue generated from the commercial sale of Vascepa;

the costs associated with commercializing Vascepa in the United States and for additional indications in the United States and in jurisdictions in which we receive regulatory approval, if any, including the cost of sales and marketing capabilities with our new co-promotion partner, Kowa Pharmaceuticals America, Inc., and the cost and timing of securing commercial supply of Vascepa and the timing of entering into any new strategic collaboration with others relating to the commercialization of Vascepa, if at all, and the terms of any such collaboration;

the continued cost associated with our REDUCE-IT cardiovascular outcomes study;

continued costs associated with litigation and other legal proceedings;

the time and costs involved in obtaining additional regulatory approvals for Vascepa;

the extent to which we continue to develop internally, acquire or in-license new products, technologies or businesses; and

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

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



## **Table of Contents**

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

While we may seek additional funding through public or private financings, we may not be able to obtain financing on acceptable terms, or at all. There can be no assurance that we will be able to access equity or credit markets in order to finance our current operations or expand development programs for Vascepa, or that there will not be a further deterioration in financial markets and confidence in economies. We may also have to scale back or further restructure our operations. If we are unable to obtain additional funding on a timely basis, we may be required to curtail or terminate some or all of our research or development programs or our commercialization strategies.

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

To the extent we are permitted under our Purchase and Sale Agreement with BioPharma 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.

In January 2012, we issued \$150 million in aggregate principal amount of 3.5% exchangeable senior notes due 2032, or the 2012 Notes, \$16.2 million of which was subsequently repaid. In May 2014, we entered into separate, privately negotiated exchange agreements with certain holders of the 2012 Notes pursuant to which Corsicanto exchanged \$118.7 million in aggregate principal amount of the existing 2012 Notes for \$118.7 million in aggregate principal amount of new 3.5% May 2014 Exchangeable Senior Notes due 2032, or the 2014 Notes, such that \$15.1 million of 2012 Notes remains outstanding. In November 2015, we issued \$31.3 million in aggregate principal amount of 3.5% exchangeable senior notes due 2032, or the 2015 Notes. In September 2016, we mandatorily exchanged the entirety of the 2014 Notes and 2015 Notes into 60,311,188 ADSs in accordance with their respective terms such that, currently, only the 2012 Notes remain outstanding. In the event of physical settlement, the remaining 2012 Notes would be exchangeable into a total of 1,714,270 ADSs.

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 November 1, 2016 we had 269,952,889 common shares outstanding including 268,067,924 shares held as ADSs and 1,884,965 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.

## Table of Contents

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

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

litigation and regulatory developments in the United States affecting our Vascepa promotional rights, and regulatory developments in the European Union or other countries;

actual or potential medical results relating to our products or our competitors' products;

interim failures or setbacks in product development;

innovation by us or our competitors;

currency exchange rate fluctuations; and

period-to-period variations in our results of operations.

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

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

Pursuant to the securities subscription agreements that we entered into with the investors in the private placement, we agreed to file with the SEC a registration statement to register the resale of the Series A Preference Shares represented by American Depositary Shares issued in the private placement and the ordinary shares issuable upon the consolidation and consolidation and redesignation of such Series A Preference Shares. Upon such registration and subsequent consolidation and redesignation, these securities will become generally available for immediate resale in

the public market. The market price of our ordinary shares could fall as a result of an increase in the number of shares available for sale in the public market.

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

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

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

---

**Table of Contents**

In addition, under the securities subscription agreement dated as of March 5, 2015, we are required to offer to certain investors party to that agreement an opportunity to participate in future equity and debt financings we may conduct from time to time, and to not publicly disclose the identity of the investors party to that agreement, subject to certain exceptions for disclosures required in securities filings and under applicable law. If we fail to comply with these obligations we could become liable to these investors for damages, including specified liquidated damages. For example, following certain public statements made by us on a quarterly conference call concerning the 2015 private placement, we agreed to specified liquidated damages in the event we are found to have violated the confidentiality provisions of the subscription agreement in the future.

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

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

***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 is 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, 2014 or 2015. Our status as a PFIC is subject to change in 2016 and future years.

If we are a PFIC, U.S. holders of notes, ordinary shares or ADSs would be subject to adverse U.S. federal income tax consequences, such as ineligibility for any preferred tax rates on capital gains or on actual or deemed dividends,

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

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

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

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

---

**Table of Contents**

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, the 2012 Notes, consists of \$15.1 million in aggregate principal amount of 3.5% exchangeable senior notes due 2032, with a provision for such notes to be put to us by the holders for repayment in cash on each of January 19, 2017, January 19, 2022 and January 19, 2027.

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

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



---

**Table of Contents**

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 2012 Notes, if triggered, may adversely affect our financial condition and operating results.***

The outstanding 2012 Notes may be redeemed by us on or after January 19, 2017 and may be put back to us by the holders on each of January 19, 2017, 2022 and 2027 for cash equal to 100% of the principal amount of \$15.1 million plus any accrued and unpaid interest. The 2012 Notes are exchangeable under certain circumstances into cash, ADSs, or a combination of cash and ADSs, at our election. Accordingly, the 2012 Notes represent a potential short-term claim on our liquid assets.

In the event the conditional exchange feature of the 2012 Notes is triggered, holders of the 2012 Notes will be entitled to exchange the 2012 Notes at any time during specified periods at their option. If one or more holders elect to exchange their 2012 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 2012 Notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the 2012 Notes as a current rather than long-term liability, which would result in a material reduction of our net working capital. Further, we may seek to refinance the outstanding 2012 Notes under terms that may result in the issuance of additional debt, convertible debt and/or equity securities, the terms of which may not be viewed as favorable to us.

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

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

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

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

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

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

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

Under English law and our Articles of Association, certain matters require the approval of 75% of the shareholders who vote (in person or by proxy) on the relevant resolution (or on a poll shareholders representing 75% of the ordinary shares voting (in person or by proxy)), including amendments to the Articles of Association. This may make it more difficult for us to complete corporate transactions deemed advisable by our board of directors. Under U.S. law, generally only majority shareholder approval is required to amend the certificate of incorporation or to approve other significant transactions.

---

**Table of Contents**

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 2. Unregistered Sales of Equity Securities and Use of Proceeds

### *Issuer Purchases of Equity Securities*

Shares purchased in the third quarter of 2016 are as follows:

<i>Period</i>	<b>Total Number of Shares Purchased <sup>(1)</sup></b>	<b>Average Price Paid per Share</b>
July 1 31, 2016		\$
August 1 31, 2016		
September 1 30, 2016	48,079	3.19
Total	48,079	\$ 3.19

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

**Table of Contents****Item 6. Exhibits**

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

<b>Exhibit Number</b>	<b>Description</b>
10.1	Underwriting Agreement, dated as of August 11, 2016, among Amarin Corporation plc, Jefferies LLC and Citigroup Global Markets Inc., as representatives of the underwriters named therein (incorporated herein by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed August 12, 2016, File No. 000-21392)
31.1	Certification of President and Chief Executive Officer (Principal Executive Officer) pursuant to Section 302 of Sarbanes-Oxley Act of 2002
31.2	Certification of Senior Vice President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer) pursuant to Section 302 of Sarbanes-Oxley Act of 2002
32.1	Certification of President and Chief Executive Officer (Principal Executive Officer) and Senior Vice President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer) pursuant to Section 906 of Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

Table of Contents

**SIGNATURE**

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

AMARIN CORPORATION PLC

By: /s/ John F. Thero

John F. Thero

President and Chief Executive Officer

(Principal Executive Officer)

(On behalf of the Registrant)

Date: November 3, 2016