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

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**FORM 10-Q**

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

For the quarterly period ended September 30, 2018

OR

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

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

Commission File No. 000-21392

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**Amarin Corporation plc**

(Exact Name of Registrant as Specified in its Charter)

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

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

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files). YES  NO

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

Large accelerated filer	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

307,461,189 common shares were outstanding as of October 30, 2018, including 303,882,906 shares held as American Depositary Shares (ADSs), each representing one Ordinary Share, 50 pence par value per share and 358,685 Ordinary Shares. In addition, 28,931,746 ordinary share equivalents were issuable in exchange for outstanding preferred shares as of October 30, 2018, for a total of 336,392,935 ordinary shares and ordinary share equivalents outstanding as of October 30, 2018.

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

	September 30, 2018	December 31, 2017
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 81,892	\$ 73,637
Restricted cash	600	600
Accounts receivable, net	47,648	45,318
Other receivables	25,654	—
Inventory, net	43,673	30,260
Prepaid and other current assets	2,935	3,455
Total current assets	<u>202,402</u>	<u>153,270</u>
Property, plant and equipment, net	69	28
Other long-term assets	174	174
Intangible asset, net	7,642	8,126
<b>TOTAL ASSETS</b>	<u>\$ 210,287</u>	<u>\$ 161,598</u>
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
Current Liabilities:		
Accounts payable	\$ 26,174	\$ 25,155
Accrued expenses and other current liabilities	93,899	58,902
Current portion of exchangeable senior notes, net of discount	219	481
Current portion of long-term debt from royalty-bearing instrument	30,130	22,348
Deferred revenue, current	1,220	1,644
Total current liabilities	<u>151,642</u>	<u>108,530</u>
Long-Term Liabilities:		
Exchangeable senior notes, net of discount	29,159	28,992
Long-term debt from royalty-bearing instrument	53,924	70,834
Deferred revenue, long-term	19,736	17,192
Other long-term liabilities	8,652	1,150
Total liabilities	<u>263,113</u>	<u>226,698</u>
Commitments and contingencies (Note 6)		
Stockholders' Deficit:		
Series A Convertible Preferred Stock, £0.05 par, unlimited authorized; 289,317,460 shares issued and outstanding as of September 30, 2018 (equivalent to 28,931,746 ordinary shares upon future consolidation and redesignation at a 10:1 ratio); 328,184,640 shares issued and outstanding as of December 31, 2017 (equivalent to 32,818,464 ordinary shares upon future consolidation and redesignation at a 10:1 ratio)	21,850	24,364
Common stock, £0.50 par, unlimited authorized; 307,309,316 issued, 304,089,718 outstanding as of September 30, 2018; 272,719,044 issued, 271,022,011 outstanding as of December 31, 2017	232,646	208,768
Additional paid-in capital	1,057,408	977,866
Treasury stock; 3,219,598 shares as of September 30, 2018; 1,697,033 shares as of December 31, 2017	(9,867)	(4,229)
Accumulated deficit	(1,354,863)	(1,271,869)
Total stockholders' deficit	<u>(52,826)</u>	<u>(65,100)</u>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT</b>	<u>\$ 210,287</u>	<u>\$ 161,598</u>

See notes to condensed consolidated financial statements.

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

	<u>Three months ended September 30,</u>		<u>Nine months ended September 30,</u>	
	<u>2018</u>	<u>2017</u>	<u>2018</u>	<u>2017</u>
Product revenue, net	\$ 54,973	\$ 47,051	\$ 151,286	\$ 126,343
Licensing revenue	350	309	598	895
Total revenue, net	<u>55,323</u>	<u>47,360</u>	<u>151,884</u>	<u>127,238</u>
Less: Cost of goods sold	<u>13,541</u>	<u>11,921</u>	<u>37,035</u>	<u>31,520</u>
Gross margin	<u>41,782</u>	<u>35,439</u>	<u>114,849</u>	<u>95,718</u>
Operating expenses:				
Selling, general and administrative	49,960	33,194	147,310	98,910
Research and development	14,072	10,694	43,993	35,211
Total operating expenses	<u>64,032</u>	<u>43,888</u>	<u>191,303</u>	<u>134,121</u>
Operating loss	(22,250)	(8,449)	(76,454)	(38,403)
Interest expense, net	(2,163)	(2,401)	(6,188)	(7,097)
Other (expense) income, net	(58)	25	(134)	100
Loss from operations before taxes	(24,471)	(10,825)	(82,776)	(45,400)
(Provision for) benefit from income taxes	—	—	—	—
Net loss	<u>\$ (24,471)</u>	<u>\$ (10,825)</u>	<u>\$ (82,776)</u>	<u>\$ (45,400)</u>
Loss per share:				
Basic	\$ (0.08)	\$ (0.04)	\$ (0.28)	\$ (0.17)
Diluted	\$ (0.08)	\$ (0.04)	\$ (0.28)	\$ (0.17)
Weighted average shares:				
Basic	295,595	270,803	291,526	270,566
Diluted	295,595	270,803	291,526	270,566

See notes to condensed consolidated financial statements.

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

	Preferred Shares	Common Shares	Treasury Shares	Preferred Stock	Common Stock	Additional Paid-in Capital	Treasury Stock	Accumulated Deficit	Total
<b>December 31, 2017</b>	<b>328,184,640</b>	<b>272,719,044</b>	<b>(1,697,033)</b>	<b>\$ 24,364</b>	<b>\$ 208,768</b>	<b>\$ 977,866</b>	<b>\$ (4,229)</b>	<b>\$ (1,271,869)</b>	<b>\$ (65,100)</b>
Cumulative-effect adjustment	—	—	—	—	—	—	—	(218)	(218)
<b>January 1, 2018</b>	<b>328,184,640</b>	<b>272,719,044</b>	<b>(1,697,033)</b>	<b>\$ 24,364</b>	<b>\$ 208,768</b>	<b>\$ 977,866</b>	<b>\$ (4,229)</b>	<b>\$ (1,272,087)</b>	<b>\$ (65,318)</b>
Issuance of common stock, net of transaction costs	—	20,616,438	—	—	14,635	55,372	—	—	70,007
Issuance of common stock under employee stock purchase plan	—	127,872	—	—	85	338	—	—	423
Conversion of Series A Convertible Preferred Stock, net	(38,867,180)	3,886,718	—	(2,514)	2,514	(39)	—	—	(39)
Exercise of stock options	—	5,439,239	—	—	3,589	12,905	—	—	16,494
Vesting of restricted stock units	—	4,520,005	(1,522,565)	—	3,055	(3,055)	(5,638)	—	(5,638)
Stock-based compensation	—	—	—	—	—	14,021	—	—	14,021
Loss for the period	—	—	—	—	—	—	—	(82,776)	(82,776)
<b>September 30, 2018</b>	<b><u>289,317,460</u></b>	<b><u>307,309,316</u></b>	<b><u>(3,219,598)</u></b>	<b><u>\$ 21,850</u></b>	<b><u>\$ 232,646</u></b>	<b><u>\$ 1,057,408</u></b>	<b><u>\$ (9,867)</u></b>	<b><u>\$ (1,354,863)</u></b>	<b><u>\$ (52,826)</u></b>

See notes to condensed consolidated financial statements.

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

	<u>Nine months ended September 30,</u>	
	<u>2018</u>	<u>2017</u>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (82,776)	\$ (45,400)
Adjustments to reconcile loss to net cash used in operating activities:		
Depreciation and amortization	12	51
Stock-based compensation	14,032	10,471
Amortization of debt discount and debt issuance costs	1,687	1,736
Amortization of intangible asset	484	485
Changes in assets and liabilities:		
Accounts receivable, net	(2,330)	(14,625)
Other receivables	(25,654)	—
Inventory, net	(13,413)	(8,043)
Prepaid and other current assets	520	5,298
Other long-term assets	—	567
Accrued interest payable	(371)	(6,959)
Deferred revenue	1,902	1,604
Accounts payable and other current liabilities	36,005	23,670
Other long-term liabilities	7,502	448
Net cash used in operating activities	<u>(62,400)</u>	<u>(30,697)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchases of equipment	(53)	(12)
Net cash used in investing activities	<u>(53)</u>	<u>(12)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from issuance of exchangeable debt	—	30,000
Payment of debt issuance costs	—	(1,207)
Payment of transaction costs for conversion of preferred stock	(39)	—
Proceeds from issuance of common stock, net of transaction costs	70,007	—
Proceeds from issuance of common stock under employee stock purchase plan	423	—
Proceeds from exercise of stock options, net of transaction costs	16,494	451
Repurchase of exchangeable senior notes	—	(15,107)
Payment on long-term debt from royalty-bearing instrument	(10,539)	—
Taxes paid related to stock-based awards	(5,638)	(2,593)
Net cash provided by financing activities	<u>70,708</u>	<u>11,544</u>
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS AND RESTRICTED CASH	8,255	(19,165)
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH, BEGINNING OF PERIOD	74,237	98,851
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH, END OF PERIOD	<u>\$ 82,492</u>	<u>\$ 79,686</u>
Supplemental disclosure of cash flow information:		
Cash paid during the year for:		
Interest	\$ 16,030	\$ 12,536
Income taxes	<u>\$ 825</u>	<u>\$ 1,186</u>

See notes to condensed consolidated financial statements.

**AMARIN CORPORATION PLC**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

For purposes of this Quarterly Report on Form 10-Q, 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 pharmaceutical 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 1-gram size Vascepa capsules in the United States, and in October 2016, introduced a smaller 0.5-gram capsule size. 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 is also developing Vascepa for FDA approval of potential additional indications for use. In particular, the Company conducted 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, was designed to evaluate the efficacy of Vascepa in reducing major cardiovascular events in a high-risk patient population on statin therapy. The REDUCE-IT study topline results were made public in September 2018, and broader reporting of results is planned at the 2018 Scientific Sessions of the American Heart Association (AHA) on November 10, 2018 in Chicago, Illinois.

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 direct sales force, which, in connection with positive REDUCE-IT results, is currently being increased from approximately 170 sales professionals, including sales representatives and their managers, to a planned total of over 400 sales professionals, and through a co-promotion agreement with Kowa Pharmaceuticals America, Inc. Under this co-promotion agreement, which commenced in May 2014 and extends until the end of 2018, Kowa Pharmaceuticals America, Inc. co-promotes Vascepa in conjunction with its promotion of its primary product, a branded statin for patients with high cholesterol. The Company operates in one business segment.

**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, 2017, or the 2017 Form 10-K, filed with the SEC. The balance sheet amounts at December 31, 2017 in this report were derived from the Company’s audited 2017 consolidated financial statements included in the 2017 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, 2018 and 2017 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 year balances related to beginning and ending cash and cash

equivalents and restricted cash in the condensed consolidated statements of cash flows have been conformed to the current year presentation.

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

As of September 30, 2018, the Company had current assets of \$202.4 million, including cash and cash equivalents of \$81.9 million, accounts receivable, net, of \$47.6 million and other receivables of \$25.7 million. The Company's condensed consolidated balance sheets also include long-term debt from royalty-bearing instrument and exchangeable senior notes. In January 2017, the Company issued \$30.0 million in aggregate principal amount of January 2017 3.5% exchangeable senior notes due 2047, or the 2017 Notes. The terms of the 2017 Notes are such that they may be redeemed by the Company for cash on or after January 19, 2021 and may be put back to the Company by the holders on January 19, 2022 for cash equal to 100% of the principal amount plus any accrued and unpaid interest. The 2017 Notes are exchangeable into American Depositary Shares ("ADSs") at the option of holders at any time after issuance and prior to maturity and are exchangeable into ADSs at the option of the Company upon satisfaction of certain equity conditions. Accordingly, the exchangeable senior notes do not represent a short-term claim on the liquid assets of the Company as of September 30, 2018. On October 19, 2018, the Company announced that it exercised its option to mandatorily exchange the entirety of the 2017 Notes into ADSs. When completed on November 2, 2018, the mandatory exchange will result in extinguishment of the debt and issuance of an aggregate amount of 7,716,048 ADSs, subject to certain adjustments as provided in the 2017 Notes, such that the Company will have no outstanding debt or related interest obligations.

The Company believes its cash and cash equivalents will be sufficient to fund its projected operations through planned expansion of its sales force and the anticipated submission in early 2019 of a supplemental new drug application (sNDA) with the FDA based on REDUCE-IT study results. Depending on the level of cash generated from operations, and in light of the recently announced successful results of the REDUCE-IT study, additional capital may be required to support planned expansion of Vascepa promotion and potential Vascepa promotion beyond which the Company is currently executing. If additional capital is required and the Company is unable to obtain additional capital, the Company may be forced to delay, limit or eliminate certain promotional activities. 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, evaluating the need for valuation allowances for deferred tax assets, and assessing the Company's ability to continue as a going concern. 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

Effective January 1, 2018, the Company adopted Accounting Standards Codification, or ASC, Topic 606, *Revenue from Contracts with Customers*, using the modified retrospective transition method. Under this method, the Company revised its opening retained earnings balance with a cumulative-effect adjustment as of January 1, 2018. This standard applies to all contracts with customers except for contracts that are within the scope of other standards, such as leases, insurance, and financial instruments. Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. For a complete discussion of accounting for net product revenue and licensing revenue, see Note 9—Revenue Recognition.

### 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 significant credit losses.

The following table summarizes the impact of accounts receivable reserves on the gross trade accounts receivable balances as of September 30, 2018 and December 31, 2017:

<i>In thousands</i>	September 30, 2018	December 31, 2017
Gross trade accounts receivable	\$ 62,727	\$ 57,802
Trade allowances	(14,624)	(12,035)
Chargebacks	(455)	(449)
Accounts receivable, net	<u>\$ 47,648</u>	<u>\$ 45,318</u>

### Other Receivables

Other receivables consist of amounts due from parties other than customers, such as amounts due from financial institutions resulting from the timing of stock option exercises which amounts were received shortly after period end and amounts due from licensing partners resulting from the achievement of milestones related to the Company's licensing agreements.

### Inventory

The Company states inventories at the lower of cost or net realizable value. Cost is determined based on actual cost using the average cost method. Net realizable value is the estimated selling price in the ordinary course of business, less reasonably predictable costs of

completion, disposal, and transportation. 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 or 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.

**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 6—Commitments and Contingencies for further information regarding other obligations related to the acquisition of Laxdale Limited.

**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, as well as license fees related to the Company's strategic collaboration with Mochida Pharmaceutical Co., Ltd.

**Selling, General and Administrative Costs**

The Company charges selling, general and administrative costs to operations as incurred. Selling, general and administrative costs include salaries and benefits, stock-based compensation expense, and costs of 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**

On December 22, 2017, the U.S. enacted the Tax Cuts and Jobs Act (the “Act”) which instituted fundamental changes to the taxation of multinational corporations. The Act includes changes to the taxation of foreign earnings by implementing a dividend exemption system, expansion of the current anti-deferral rules, a minimum tax on low-taxed foreign earnings and new measures to deter base erosion. The Act also includes a permanent reduction in the corporate tax rate to 21%, repeal of the corporate alternative minimum tax, expensing of capital investment, and limitation of the deduction of interest expense. Furthermore, as part of the transition to the new tax system, a one-time transition tax is imposed on a U.S. shareholder's historical undistributed earnings of foreign affiliates. The Company is applying the guidance in SAB 118 when accounting for the enactment-date effects of the Act. As of December 31, 2017, the Company had recorded provisional amounts to account for the impact of tax effects of the Act related to the change in corporate tax rate from 34% to 21% and the changes to executive compensation deductibility. As of September 30, 2018, the Company has not completed its accounting for all of the tax effects of the Act. The Company will continue to make and refine its calculations as additional analysis is completed. The Company's estimates may also be affected as it gains a more thorough understanding of the tax law. The Company will disclose the impact to the provisional amounts in the reporting period in which the accounting analysis is completed, which will not exceed one year from the date of enactment. Any changes are not expected to have an impact to the tax provision or condensed consolidated financial statements.

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. Deferred tax assets and liabilities are classified as non-current in the condensed consolidated balance sheets.

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

The Company regularly assesses its ability to realize deferred tax assets. Changes in historical earnings performance, future earnings projections, and changes in tax laws and tax rates, 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.

Excess tax benefits and deficiencies that arise upon vesting or exercise of share-based payments are recognized as an income tax benefit and expense, respectively, in the condensed consolidated statement of operations. Excess income tax benefits and deficiencies are classified as cash flows from operating activities and cash paid to taxing authorities arising from the withholding of shares from employees are classified as cash flows from financing activities.

The Company's and its subsidiaries' income tax returns are periodically examined by various tax authorities. The Company is currently undergoing federal and state audits, including audit by the United States Internal Revenue Service (IRS) for the years 2013 to 2014. 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 its consolidated financial position or results of operations.

### **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 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 are deemed anti-dilutive such that basic net loss per share and diluted net loss per share are equal.

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

The calculation of net loss and the number of shares used to compute basic and diluted net loss per share for the three and nine months ended September 30, 2018 and 2017 are as follows:

<i>In thousands</i>	<u>Three months ended September 30,</u>		<u>Nine months ended September 30,</u>	
	<u>2018</u>	<u>2017</u>	<u>2018</u>	<u>2017</u>
Net loss—basic and diluted	\$ (24,471)	\$ (10,825)	\$ (82,776)	\$ (45,400)
Weighted average shares outstanding—basic and diluted	295,595	270,803	291,526	270,566
Net loss per share—basic and diluted	\$ (0.08)	\$ (0.04)	\$ (0.28)	\$ (0.17)

For the three and nine months ended September 30, 2018 and 2017, the following potentially dilutive securities were not included in the computation of net loss per share because the effect would be anti-dilutive:

<i>In thousands</i>	<u>Three months ended September 30,</u>		<u>Nine months ended September 30,</u>	
	<u>2018</u>	<u>2017</u>	<u>2018</u>	<u>2017</u>
Stock options	21,037	23,631	21,037	23,631
Restricted stock and restricted stock units	9,634	11,887	9,634	11,887
Exchangeable senior notes (if converted)	7,716	7,716	7,716	7,716
Preferred stock (if converted)	28,932	32,818	28,932	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. The Company records debt issuance costs related to a recognized debt liability in the condensed consolidated balance sheets 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. Unamortized debt issuance costs related to the extinguishment of debt are expensed at the time the debt is extinguished and recorded in other (expense) income, net, in the condensed consolidated statements of operations. If the Company issues shares to discharge the liability, the debt obligation is derecognized and common stock and additional paid-in capital are recognized upon the issuance of those shares.

The 2017 Notes can only be settled in ADSs upon conversion. The terms of the 2017 Notes also allow for repurchase in cash by the Company at the option of the holders as well as redemption by the Company for cash at specified times. The conversion feature in the 2017 Notes qualifies for the exception from derivative accounting in accordance with ASC 815-40 and is therefore accounted for as part of the debt host. The conversion feature in the 2017 Notes will continue 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 2017 Notes were recognized at par of \$30.0 million. The Company also recognized a \$1.2 million discount related to placement agent fees and offering expenses. This discount is being amortized through interest expense over the expected term of the 2017 Notes, through the first optional put date in January 2022.

See Note 5—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.

The Company estimates the level of forfeitures expected to occur based on its historical data and records compensation cost only for those awards that are ultimately expected to vest.

### **Concentration of Credit Risk**

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

A significant portion of the Company's sales are to wholesalers in the pharmaceutical industry. The Company monitors the creditworthiness of customers to whom it grants credit terms and has not experienced any credit losses. The Company does not require

collateral or any other security to support credit sales. Three customers individually accounted for 10% or more of the Company's gross product sales. Customers A, B, and C accounted for 26%, 31%, and 31%, respectively, of gross product sales for the nine months ended September 30, 2018, and represented 37%, 33%, and 17%, respectively, of the gross accounts receivable balance as of September 30, 2018. Customers A, B, and C accounted for 28%, 27%, and 35%, respectively, of gross product sales for the nine months ended September 30, 2017 and represented 36%, 27%, and 24%, respectively, of the gross accounts receivable balance as of September 30, 2017. The Company has not experienced any significant 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.

The Company cannot provide assurance that its efforts to procure uninterrupted supply of Vascepa to meet market demand will continue to be successful or that it will be able to renew current supply agreements on favorable terms or at all. Significant alteration to or termination of the Company's current supply chain or its failure to enter into new and similar agreements in a timely fashion, 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 independent FDA-approved commercial API manufacturers and three independent 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 remain qualified to manufacture the product to its specifications or that these and any future suppliers will have the manufacturing capacity to meet anticipated demand for Vascepa.

#### **Foreign Currency**

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

#### **Fair Value of Financial Instruments**

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

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

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

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

The following tables present information about the Company's assets and liabilities as of September 30, 2018 and December 31, 2017 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:

<i>In thousands</i>	September 30, 2018			
	Total	Level 1	Level 2	Level 3
<b>Asset:</b>				
Cash equivalents—money markets	\$ 9,834	\$ 9,834	\$ —	\$ —

<i>In thousands</i>	December 31, 2017			
	Total	Level 1	Level 2	Level 3
<b>Asset:</b>				
Cash equivalents—money markets	\$ 9,317	\$ 9,317	\$ —	\$ —

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, 2018 and December 31, 2017 are as follows:

<i>In thousands</i>	September 30, 2018		December 31, 2017	
	Carrying Value	Estimated Fair Value	Carrying Value	Estimated Fair Value
Current portion of long-term debt from royalty-bearing instrument, net of accrued interest	\$ 29,460		\$ 21,569	
Long-term debt from royalty-bearing instrument	53,924		70,834	
Total long-term debt from royalty-bearing instrument	\$ 83,384	\$ 83,200	\$ 92,403	\$ 88,000
2017 Notes	29,159	103,583	28,992	38,200

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 Derivative Liabilities below). The estimated fair value of the 2017 Notes is calculated based on Level 1 quoted bond prices or, in the absence of quoted bond prices, is calculated using a Level 3 binomial model. The carrying value of the 2017 Notes as of September 30, 2018 and December 31, 2017 includes a debt discount of \$0.8 million and \$1.0 million, respectively, which is being amortized as non-cash interest expense over the expected term of the 2017 Notes, through the first optional put date in January 2022.

#### Derivative Liabilities

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.

#### Long-Term Debt Redemption Feature

The Company's December 2012 royalty-bearing instrument financing arrangement (discussed in Note 5—Debt) contains a redemption feature whereby, upon a change of control, the Company would be required to repay \$150.0 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. 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. As of September 30, 2018, the fair value of the derivative was determined to be nil, and the debt was valued by comparing debt issues of similar companies with (i) remaining terms of between 1.5 and 4.3 years, (ii) coupon rates of between 5.4% and 10.8% and (iii) market yields of between 7.0% and 12.0%. As of December 31, 2017, the fair value of the derivative was determined to be nil based on underlying assumptions, and the debt was valued by comparing debt issues of similar companies with (i) remaining terms of between 2.3 and 4.3 years, (ii) coupon rates of between 5.8% and 10.8% and (iii) market yields of between 10.2% and 18.4%. As such, the Company recognized no gain or loss on change in fair value of derivative liability for the nine months ended September 30, 2018. The Company also recognized no gain or loss on change in fair value of derivative liability for the nine months ended September 30, 2017.

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.

#### 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 May 2014, the FASB issued Accounting Standards Update ("ASU"), No. 2014-09, which amends the guidance for accounting for revenue from contracts with customers. This ASU supersedes the revenue recognition requirements in Accounting Standards Codification ("ASC") Topic 605, *Revenue Recognition*, and creates a new Topic 606, *Revenue from Contracts with Customers*. In 2015 and 2016, the FASB issued additional ASUs related to Topic 606 that delayed the effective date of the guidance and clarified various aspects of the new revenue guidance, including principal versus agent considerations, identifying performance obligations, and licensing, and they include other improvements and practical expedients. The Company adopted this standard effective January 1, 2018 using the modified retrospective transition method.

The Company, as a result of adopting Topic 606 on January 1, 2018, has adjusted its opening retained earnings and deferred revenue balances by \$0.2 million. The adjustment relates solely to the Company's licensing revenues and the timing over which certain non-refundable upfront and milestone payments received from Eddingpharm (Asia) Macao Commercial Offshore Limited and HLS Therapeutics Inc. are recognized under Topic 606. No practical expedients associated with the adoption of Topic 606 were applied.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation—Stock Compensation: Scope of Modification Accounting*. The amendments in ASU No. 2017-09 provide guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. The Company adopted this standard effective January 1, 2018 and, in accordance with the ASU, will apply it prospectively. The Company does not expect it to have a material impact on the Company's condensed consolidated financial statements.

In January 2017, the FASB issued ASU No. 2017-01, *Clarifying the Definition of a Business*. The standard clarifies the definition of a business when evaluating whether transactions should be accounted for as acquisitions or disposals of assets or businesses. Under the provisions of this new standard, it is expected that more transactions will be accounted for as asset acquisitions rather than business acquisitions. The Company adopted this standard effective January 1, 2018 and, in accordance with the ASU, will apply it prospectively. The Company does not expect it to have a material impact on the Company's condensed consolidated financial statements.

In October 2016, the FASB issued ASU No. 2016-16, *Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other Than Inventory*, which requires the recognition of income tax consequences of an intra-entity transfer of an asset, other than inventory, when the transfer occurs. The Company adopted this standard effective January 1, 2018, which had no impact on the Company's condensed consolidated financial statements.

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 related to eight specific issues are presented and classified in the statement of cash flows. In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash*, which requires that the statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. The Company adopted this standard effective January 1, 2018 and, in accordance with the ASUs, applied them using a retrospective transition method to each period presented. Adoption of these ASUs did not have a material impact on the Company's condensed consolidated financial statements.

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. In February 2018, the FASB issued ASU No. 2018-03, *Technical Corrections and Improvements to Financial Instruments—Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities*, which is intended to clarify certain aspects of the guidance issued in ASU 2016-01. The Company adopted these standards effective January 1, 2018, which had no impact on the Company’s condensed consolidated financial statements.

The Company also considered the following recent accounting pronouncements which were not yet adopted as of September 30, 2018:

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*, which eliminates, adds and modifies certain disclosure requirements for fair value measurements, including eliminating the requirement to disclose the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, and requiring disclosure of the range and weighted average used to develop significant unobservable inputs for Level 3 fair value measurements. The new guidance is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption, either of the entire standard or only the provisions that eliminate or modify requirements, is permitted. The Company has evaluated the disclosure requirements of this standard and does not expect it to have a material impact on the Company’s consolidated financial statements.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*, which is intended to simplify the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. 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 has evaluated the accounting, transition and disclosure requirements of this standard and does not expect it to have a material impact on the Company’s consolidated financial statements.

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.

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 Asset

Intangible asset consists of the historical acquisition cost of certain technology rights for Vascepa and has an estimated weighted-average remaining useful life of 11.8 years. The carrying value as of September 30, 2018 and December 31, 2017 is as follows:

<i>In thousands</i>	<b>September 30, 2018</b>	<b>December 31, 2017</b>
Technology rights	\$ 11,624	\$ 11,624
Accumulated amortization	(3,982)	(3,498)
Intangible asset, net	<u>\$ 7,642</u>	<u>\$ 8,126</u>



#### (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, 2018 and December 31, 2017 consist of the following:

<i>In thousands</i>	September 30, 2018	December 31, 2017
Raw materials	\$ 8,709	\$ 7,044
Work in process	11,597	10,844
Finished goods	23,655	12,372
Inventory	43,961	30,260
Inventory reserve	(288)	—
Inventory, net	<u>\$ 43,673</u>	<u>\$ 30,260</u>

#### (5) Debt

##### *Long-Term Debt from Royalty-Bearing Instrument—December 2012 Financing*

On December 6, 2012, the Company entered into a Purchase and Sale 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 \$100.0 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 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 \$150.0 million with such repayment based on a portion of net revenues and receivables generated from Vascepa. On December 20, 2017, BioPharma assigned all rights under this agreement to CPPIB Credit Europe S.à r.l., or CPPIB.

As of September 30, 2018, the remaining amount to be repaid to CPPIB is \$94.1 million. During the three and nine months ended September 30, 2018, the Company made repayments under the agreement of \$5.3 million and \$15.0 million, respectively, to CPPIB and an additional \$5.5 million is scheduled to be paid in November 2018 for the third quarter of 2018. 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. All such payments reduce the remainder of the \$150.0 million in aggregate payments to CPPIB.

These quarterly payments are subject to a quarterly threshold amount whereby, if a calculated threshold, based on quarterly Vascepa net 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 net revenue levels. Except upon a change of control in Amarin, the agreement does not expire until \$150.0 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 \$150.0 million in aggregate has been repaid, including payments made previously. The Company can prepay an amount equal to \$150.0 million less any previously repaid amount.

For each quarterly period since the inception of the debt, net 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, quarterly differences between the calculated optional reduction amounts and the repayment schedule amounts were 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 net revenues. No additional interest expense or liability is incurred as a result of such deferred repayments. These estimates are 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 no gain or loss on change in fair value of derivative liability during the nine months ended September 30, 2018 and 2017.

As of September 30, 2018 and December 31, 2017, the carrying value of the royalty-bearing instrument, net of the unamortized debt discount and issuance costs, was \$83.4 million and \$92.4 million, respectively. During the nine months ended September 30, 2018, the Company recorded cash and non-cash interest expense of \$4.3 million and \$1.5 million, respectively, in connection with the royalty-bearing instrument. During the nine months ended September 30, 2017, the Company recorded \$4.8 million and \$1.6 million of cash and non-cash interest expense, respectively, in connection with the royalty-bearing instrument. 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, the Company granted BioPharma, which it subsequently assigned to CPPIB, 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 CPPIB 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 agreement, 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, May 2014, and November 2015 Exchangeable Senior Notes

In 2012, 2014 and 2015, the Company and its subsidiaries entered into a series of transactions pertaining to exchangeable notes. In January 2017, holders of the 3.5% exchangeable senior notes due 2032 (the "2012 Notes") exercised their option to put approximately \$15.0 million in aggregate principal amount of 2012 Notes to the Company for cash and, in March 2017, the Company redeemed the entirety of the remaining \$0.1 million in aggregate principal amount of 2012 Notes, such that no 2012 Notes remained outstanding as of September 30, 2017. The carrying value of the related conversion option will remain in equity hereafter as a result of the repayment in full of the related debt instrument. As of September 30, 2018 and December 31, 2017, all debt issued in these transactions was exchanged or redeemed such that none remained outstanding.

#### January 2017 Exchangeable Senior Notes

On January 20, 2017, the Company and Corsicanto II DAC ("Corsicanto II"), a designated activity company formed under the laws of Ireland and a wholly owned subsidiary of the Company, entered into separate, privately negotiated purchase agreements with certain investors pursuant to which Corsicanto II issued and sold \$30.0 million in aggregate principal amount of 3.5% exchangeable senior notes due 2047 (the "2017 Notes") at an issue price of 100%. The net proceeds from the offering were \$28.8 million after deducting placement agent fees and offering expenses payable by the Company. The offering of the 2017 Notes closed on January 25, 2017. Corsicanto II has no assets, operations, revenues or cash flows other than those related to the issuance, administration and repayment of the 2017 Notes. On October 19, 2018, the Company announced that it exercised its option to mandatorily exchange the entirety of the 2017 Notes into ADSs upon satisfaction of the specified equity conditions as described below. When completed on November 2, 2018, the mandatory exchange will result in extinguishment of the debt and issuance of an aggregate amount of 7,716,048 ADSs, subject to certain adjustments as provided in the 2017 Notes, such that the Company will have no outstanding debt or related interest obligations.

The 2017 Notes were issued pursuant to an Indenture (the "Indenture") entered into by the Company, Corsicanto II and Wilmington Trust, National Association, as trustee (the "Trustee"). The 2017 Notes are the senior unsecured obligations of Corsicanto II and are guaranteed by the Company. The 2017 Notes bear interest at a rate of 3.5% per annum from, and including, January 25, 2017, payable semi-annually in arrears on January 15 and July 15 of each year, beginning on July 15, 2017 and ending upon the 2017 Notes' maturity date of January 15, 2047, unless earlier repurchased, redeemed or exchanged.

At any time after the issuance of the 2017 Notes and prior to the close of business on the second business day immediately preceding January 15, 2047, holders may exchange their 2017 Notes for ADSs at their option and at the exchange rate described below. If prior to January 19, 2021, a make-whole fundamental change (as defined in the Indenture) occurs and a holder elects to exchange its 2017 Notes in connection with such make-whole fundamental change, such holder may be entitled to an increase in the exchange rate as described in the Indenture.

The initial exchange rate is 257.2016 ADSs per \$1,000 principal amount of the 2017 Notes (equivalent to an initial exchange price of approximately \$3.89 per ADS (the "Exchange Price")), subject to adjustment in certain circumstances. The initial exchange price for the 2017 Notes represents a premium of approximately 35% over the last reported sale price of \$2.88 per share of the Company's ADSs on The NASDAQ Global Market on January 19, 2017. Upon exchange, the 2017 Notes are to be settled in ADSs. The exchange rate is subject to adjustment from time to time upon the occurrence of certain events, including, but not limited to, the payment of cash dividends. In the event of physical settlement, the 2017 Notes would be exchangeable into a total of 7,716,048 ADSs, subject to certain adjustments as provided in the Indenture. Based on the closing price of the Company's stock as of September 30, 2018, the value of the shares if converted on that date would exceed the principal amount of the 2017 Notes by \$95.5 million.

Prior to January 19, 2021, Corsicanto II may not redeem the 2017 Notes at its option other than in connection with certain changes in the tax law of a relevant taxing jurisdiction that results in additional amounts (as defined in the Indenture) becoming due with respect to payments and/or deliveries on the 2017 Notes. On or after January 19, 2021, Corsicanto II may redeem for cash all or a portion of the 2017 Notes at a redemption price of 100% of the aggregate principal amount of the 2017 Notes to be redeemed, plus accrued and unpaid interest to, but not including, the redemption date. If a Fundamental Change (as defined in the Indenture) occurs, holders may require Corsicanto II to repurchase all or part of their 2017 Notes for cash at a Fundamental Change repurchase price equal to 100% of the aggregate principal amount of the 2017 Notes to be repurchased, plus accrued and unpaid interest to, but not including, the Fundamental Change repurchase date. In addition, holders of the 2017 Notes may require Corsicanto II to repurchase all or any portion of the 2017 Notes on January 19, 2022 for cash at a price equal to 100% of the aggregate principal amount of the 2017 Notes to be repurchased, plus accrued and unpaid interest to, but not including, the repurchase date.

Corsicanto II may elect at its option to cause all or any portion of the 2017 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, 2047 if the Daily VWAP (as defined in the Indenture) equals or exceeds 130% of the Exchange Price then in effect (which quotient equals approximately \$5.05 on the date hereof) for at least 20 VWAP Trading Days (as defined in the Indenture) in any 30 consecutive VWAP Trading Day period. Corsicanto II may only exercise its optional exchange rights upon satisfaction of specified equity conditions, including that the ADSs issuable upon exchange of the 2017 Notes be eligible for resale without registration by non-affiliates and listed on The NASDAQ Global Market, its related exchanges or the New York Stock Exchange. If Corsicanto II elects to exercise its optional exchange rights on or prior to January 19, 2021, each holder whose 2017 Notes are exchanged may upon exchange receive a specified number of additional ADSs as set forth in the Indenture.

The Indenture contains customary terms and covenants and events of default. If an event of default (other than certain events of bankruptcy, insolvency or reorganization involving Corsicanto II) occurs and is continuing, the Trustee by notice to Corsicanto II, or the holders of at least 25% in principal amount of the outstanding 2017 Notes by notice to Corsicanto II and the Trustee, may declare 100% of the principal of and accrued and unpaid interest, if any, on all of the 2017 Notes to be due and payable. Upon such a declaration of acceleration, such principal and accrued and unpaid interest, if any, will be due and payable immediately. Upon the occurrence of certain events of bankruptcy, insolvency or reorganization involving Corsicanto II, 100% of the principal of and accrued and unpaid interest, if any, on all of the 2017 Notes will become due and payable automatically. Notwithstanding the foregoing, the Indenture will provide that, to the extent Corsicanto II elects and for up to 360 days, the sole remedy for an event of default relating to certain failures by Corsicanto II or the Company, as the case may be, to comply with certain reporting covenants in the Indenture consists exclusively of the right to receive additional interest on the 2017 Notes.

Corsicanto II agreed to use commercially reasonable efforts to procure the listing of the 2017 Notes on the Global Exchange Market operated under the supervision of the Irish Stock Exchange (or on another recognized stock exchange for the purposes of Section 64 of the Taxes Consolidation Act 1997 of Ireland and within the meaning of Section 1005 ITA 2007 of the United Kingdom) prior to July 15, 2017, which was the first interest payment date for the 2017 Notes.

The 2017 Notes were recorded at par of \$30.0 million. In addition, the Company recorded a discount of \$1.2 million in placement agent fees and offering expenses. Such costs are presented as a direct deduction from the debt liability on the condensed consolidated balance sheets. This discount is being amortized as interest expense over the estimated life of the 2017 Notes, through the first optional put date in January 2022. As of September 30, 2018 and December 31, 2017, the carrying value of the 2017 Notes, net of unamortized discount, was \$29.2 million and \$29.0 million, respectively.

Because the conversion option in the 2017 Notes receives an exception from derivative accounting and only requires gross physical settlement in shares, the embedded option does not require separate accounting and is therefore accounted for as part of the debt host

at amortized cost. In addition, the Company determined that the fundamental change redemption feature is clearly and closely related to the debt host in accordance with ASC 815-15 and therefore does not require bifurcation.

During the nine months ended September 30, 2018, the Company recognized interest expense of \$1.0 million related to the 2017 Notes, of which \$0.2 million represents non-cash interest and \$0.8 million represents contractual coupon interest. During the nine months ended September 30, 2017, the Company recognized interest expense of \$0.9 million related to the 2017 Notes, of which \$0.1 million represents non-cash interest and \$0.7 million represents contractual coupon interest. As of both September 30, 2018 and December 31, 2017, the Company had accrued interest of \$0.2 million related to the 2017 Notes, which is presented as current portion of exchangeable senior notes, net of discount, on the condensed consolidated balance sheets. The Company made the contractual interest payments due on the 2017 Notes during the nine months ended September 30, 2018 and 2017 of \$1.1 million and \$0.5 million, respectively.

## **(6) Commitments and Contingencies**

### Litigation

In the ordinary course of business, the Company is from time to time involved in lawsuits, claims, investigations, proceedings, and threats of litigation relating to 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, 2017 and “Item 1. Legal Proceedings” of the Company’s Quarterly Report on Form 10-Q for the quarters ended March 31, 2018 and June 30, 2018 include discussions of the Company’s current legal proceedings. There have been no material changes to the matters described in those disclosures as of the date of this filing.

### 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.

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 June 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. As of September 30, 2018, the Company has no royalty, milestone or minimum purchase commitments with Nisshin. In the ordinary course, pursuant to the results of the REDUCE-IT study, the Company is increasing its orders for API from these manufacturers while taking steps to help qualify at least one additional potential API manufacturer.

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 certain 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 \$9.8 million as of September 30, 2018). 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, 2018) for each of the two potential market approvals (i.e. £10 million maximum, or approximately \$13.0 million as of September 30, 2018).

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, 2018.

(7) **Equity**

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 American Depositary Shares (“ADSs”), provided that consolidation will be prohibited if, as a result, the holder of such Series A Preference Shares and its affiliates would beneficially own more than 4.99% of the total number of Amarin ordinary shares or ADSs outstanding following such redesignation (the “Beneficial Ownership Limitation”). By written notice to the Company, a holder may from time to time increase or decrease the Beneficial Ownership Limitation to any other percentage not in excess of 19.9% specified in such notice; provided that any such increase will not be effective until the sixty-first (61st) day after such notice is delivered to the Company. This consolidation and redesignation may be effected by a holder of Series A Preference Shares following the first to occur of the resale of the ADSs representing the ordinary shares being registered for resale under the Securities Act pursuant to an effective registration statement, following any sale of the ADSs representing the ordinary shares pursuant to Rule 144 under the Securities Act, or if such ADSs representing the ordinary shares are eligible for sale under Rule 144, following the expiration of the one-year holding requirement under Rule 144. During the year ended December 31, 2015, at the request of the holders, a portion of the Series A Preference Shares were consolidated and redesignated, resulting in the issuance of 6,283,333 ADSs.

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’ deficit and was measured by allocating a portion of the proceeds equal to the intrinsic value of that feature to additional paid-in capital. The effective purchase price of the ordinary shares into which the preferred shares are convertible was \$1.50, which was used to compute the intrinsic value. The intrinsic value was calculated as the difference between the effective purchase price of the ordinary shares and the market value (\$2.39 per share) on the date the preferred shares were issued, multiplied by the number of shares into which the preferred shares are convertible. The BCF resulting from the issuance of the Series A Preference Shares was determined to be \$31.3 million. The BCF 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 year ended December 31, 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, each representing one Series A Preference Share, which could 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. At the time of the transaction, Dr. James Healy was a member of the Company's Board and a managing general partner of Sofinnova Management VII, L.L.C., which is the general partner of Sofinnova. Dr. James Healy resigned as Director of the Company's Board effective December 20, 2016.

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 year ended December 31, 2015.

During the three months ended September 30, 2018, the Company issued 3,886,718 ADSs upon consolidation and redesignation of Series A Preference Shares at the request of the holder, such that a maximum of 28,931,746 ordinary shares remain issuable upon future consolidation and redesignation of the remaining Series A Preference Shares as of September 30, 2018, subject to certain adjustments for dilutive events.

#### Common Stock

On February 1, 2018, the Company completed a public offering of 19,178,082 ADSs, with each ADS representing one ordinary share of the Company. The Company also granted the underwriters a 30-day option to purchase an additional 2,876,712 ADSs, which was partially exercised on March 5, 2018 for issuance of 1,438,356 ADSs. The underwriters purchased the ADSs from the Company at a price of \$3.41 per ADS after commission, resulting in net proceeds to the Company of approximately \$70.0 million, after deducting estimated offering expenses payable by the Company. The stated uses of net proceeds in connection with this offering were as follows: to expand medical education and market awareness initiatives, including, in advance of REDUCE-IT results being known, pilot testing of new promotional initiatives for potential broader application following REDUCE-IT results, to increase its inventory balances for incremental inventory build prior to REDUCE-IT results and for general corporate and working capital purposes.

#### Incentive Equity Awards

As of September 30, 2018, there were an aggregate of 21,036,913 stock options and 9,634,188 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, 2018 and 2017, the Company issued 5,439,239 and 259,195 shares, respectively, as a result of the exercise of stock options, resulting in gross and net proceeds of \$16.5 million during the nine months ended September 30, 2018 and \$0.5 million during the nine months ended September 30, 2017. The Company recorded a receivable of \$23.2 million in other receivables on the condensed consolidated balance sheet as of September 30, 2018 representing the cost of shares plus taxes withheld due from financial institutions resulting from the timing of stock option exercises in late September 2018, which amounts were collected in early October 2018.

In September 2018, in connection with positive REDUCE-IT results, the Company issued 2,499,750 shares upon vesting of performance-based RSUs granted in 2015, of which 764,819 shares were retained as treasury shares as settlement of employee tax obligations.

On May 14, 2018, the Company granted a total of 190,034 RSUs and 286,536 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 per award vested or granted, respectively, which is required to be made in shares.

On February 1, 2018, the Company granted a total of 1,305,575 RSUs and 2,205,075 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.

On May 15, 2017, the Company granted a total of 91,504 RSUs and 131,575 stock options to members of the Company's Board of Directors under the 2011 Plan. The RSUs vest in equal installments over a three-year period 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 per award vested or granted, respectively, which is required to be made in shares.

On May 15, 2017, October 2, 2017, and March 12, 2018, the Company granted a total of 2,310,000 RSUs, 220,000 RSUs, and 970,000 RSUs, respectively, to employees under the 2011 Plan that vest over three years commencing after REDUCE-IT results upon the achievement of certain regulatory and sales performance conditions associated with the REDUCE-IT clinical trial and subsequent revenue growth.

On February 1, 2017, the Company granted a total of 1,575,000 RSUs and 2,642,500 stock options to employees under the 2011 Plan. The RSUs vest annually over a three-year period and the stock options vest over a four-year period. During the nine months ended September 30, 2018, the Company issued 506,679 common shares related to the vesting of these RSUs, of which 183,828 shares were retained as treasury shares as settlement of employee tax obligations.

#### **(8) 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 until the end of 2018. The Agreement was amended on July 25, 2017 to reflect evolving promotional needs, including refinement of target lists.

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. Kowa Pharmaceuticals America, Inc. has agreed 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 varies during the term. The percentage of aggregate Vascepa gross margin earned by Kowa Pharmaceuticals America, Inc. was, as amended, approximately eighteen percent (18%) in 2017, partially offset by certain other refinements. During 2018, which is the last year of the Agreement, as amended, the Company is incurring expense for both the annual co-promotion fee, which in 2018 is calculated as eighteen-and-a-half percent (18.5%) of Vascepa gross margin, plus accrual for co-promotion tail payments which are calculated as a percentage of the 2018 co-promotion fee. Assuming Kowa Pharmaceuticals America, Inc. fulfills its obligations in accordance with the terms of the Agreement, as amended, after expiration of the Agreement, Kowa Pharmaceuticals America, Inc. is eligible to receive up to three years of co-promotion tail payments equal to declining percentages of the co-promotion fee amount earned in the final year of the Agreement with the sum of the three years of co-promotion tail payments totaling less than the co-promotion fee amount earned in the final year of the agreement.

This co-promotion tail payment obligation is being accrued by the Company in 2018. As of September 30, 2018 and December 31, 2017, the Company accrued \$10.8 million and nil, respectively, related to such co-promotion tail payments.

As of September 30, 2018 and December 31, 2017, the Company had a net payable of \$18.0 million and \$8.3 million, respectively, to Kowa Pharmaceuticals America, Inc. representing co-promotion fees, net of reimbursable amounts incurred for samples and other marketing expenses, and accrual for co-promotion tail payments payable to Kowa Pharmaceuticals America, Inc.

## **(9) Revenue Recognition**

The Company sells Vascepa principally to a limited number of major wholesalers, as well as selected regional wholesalers and specialty pharmacy providers in the United States, 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 addition to distribution agreements with Distributors, the Company enters into arrangements with health care providers and payors that provide for government-mandated and/or privately-negotiated rebates, chargebacks and discounts with respect to the purchase of the Company's product.

Revenues from product sales are recognized when the Distributor obtains control of the Company's product, which occurs at a point in time, typically upon delivery to the Distributor. Payments from Distributors are generally received 30-60 days from date of sale. 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. The Company calculates gross product revenues generally based on the wholesale acquisition cost that the Company charges its Distributors for Vascepa.

### *Reserves for Variable Consideration*

Revenues from product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established and which result from (a) trade allowances, such as invoice discounts for prompt pay and distributor fees, (b) estimated government and private payor rebates and chargebacks and discounts, such as Medicaid reimbursements, (c) reserves for expected product returns and (d) estimated costs of incentives that are offered within contracts between the Company and its Distributors, health care providers, payors and other indirect customers relating to the Company's sales of its product. These reserves are based on the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if the amount is payable to the Distributor) or as a current liability (if the amount is payable to a party other than a Distributor). Where appropriate, these estimates take into consideration a range of possible outcomes which are probability-weighted for relevant factors such as the Company's historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. Overall, these reserves reflect the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the contract. The amount of variable consideration which is included in the transaction price may be constrained, and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from the Company's estimates, the Company adjusts these estimates, which would affect net product revenue and earnings in the period such variances become known.

*Trade Allowances:* The Company generally provides invoice discounts on Vascepa sales to its Distributors for prompt payment and 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 prompt payment while the fees for distribution services are based on contractual rates agreed with the respective Distributors. Based on historical data, 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, Medicare, 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 these reserves based upon a range of possible outcomes that are probability-weighted for the estimated payor mix. These reserves are recorded in the same period the revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability, which is included in accrued expenses and other current liabilities on the condensed consolidated balance sheets. For Medicare, the Company also estimates the number of patients in the prescription drug coverage gap for whom the Company will owe an additional liability under the Medicare Part D program. 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. The Company's liability for these rebates consists of invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet been received, estimates of claims for the current quarter, and estimated future claims that will be made for product that has been recognized as revenue, but remains in the distribution channel inventories at the end of each reporting period.

*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 1-gram and 0.5-gram size capsules is currently four years and three years, respectively, after being 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. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses and other current liabilities on the condensed consolidated balance sheets.

*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. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses and other current liabilities on the condensed consolidated balance sheets. 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, 2018 and 2017:

<i>In thousands</i>	Trade Allowances	Rebates, Chargebacks and Discounts	Product Returns	Other Incentives	Total
<b>Balance as of December 31, 2017</b>	<b>\$ 12,035</b>	<b>\$ 32,064</b>	<b>\$ 1,887</b>	<b>\$ 2,107</b>	<b>\$ 48,093</b>
Provision related to current period sales	30,814	128,905	812	14,636	175,167
Provision related to prior period sales	(660)	(836)	—	(69)	(1,565)
Credits/payments made for current period sales	(15,908)	(76,015)	—	(15,038)	(106,961)
Credits/payments made for prior period sales	(11,657)	(29,594)	(69)	(2,297)	(43,617)
<b>Balance as of September 30, 2018</b>	<b>\$ 14,624</b>	<b>\$ 54,524</b>	<b>\$ 2,630</b>	<b>\$ (661)</b>	<b>\$ 71,117</b>

<i>In thousands</i>	Trade Allowances	Rebates, Chargebacks and Discounts	Product Returns	Other Incentives	Total
<b>Balance as of December 31, 2016</b>	<b>\$ 3,743</b>	<b>\$ 20,915</b>	<b>\$ 859</b>	<b>\$ 1,681</b>	<b>\$ 27,198</b>
Provision related to current period sales	24,780	87,499	1,496	10,796	124,571
Provision related to prior period sales	(297)	(841)	—	(82)	(1,220)
Credits/payments made for current period sales	(11,061)	(62,014)	(391)	(8,834)	(82,300)
Credits/payments made for prior period sales	(3,107)	(16,722)	(24)	(1,770)	(21,623)
<b>Balance as of September 30, 2017</b>	<b>\$ 14,058</b>	<b>\$ 28,837</b>	<b>\$ 1,940</b>	<b>\$ 1,791</b>	<b>\$ 46,626</b>

#### *Licensing Revenue*

The Company enters into licensing agreements which are within the scope of Topic 606, *Revenue from Contracts with Customers*, under which it licenses certain rights to Vascepa for uses that are currently commercialized and under development by the Company. The terms of these arrangements typically include payment to the Company of one or more of the following: non-

refundable, up-front license fees; development, regulatory and commercial milestone payments; payments for manufacturing supply services the Company provides through its contract manufacturers; and royalties on net sales of licensed products. Each of these payments results in licensing revenues.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under each of its agreements, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation.

In determining performance obligations, management evaluates whether the license is distinct from the other performance obligations with the collaborative partner based on the consideration of the relevant facts and circumstances for each arrangement. Factors considered in the determination of 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.

*Licenses of intellectual property:* If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

*Milestone Payments:* At the inception of each arrangement that includes development, regulatory and commercial milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The Company evaluates factors such as the scientific, clinical, regulatory, commercial and other risks that must be overcome to achieve the respective milestone as well as the level of effort and investment required. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such development, regulatory and commercial milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect licensing revenues and earnings in the period of adjustment.

The Company receives payments from its customers based on billing schedules established in each contract. Up-front payments and fees are recorded as deferred revenue upon receipt or when due, and may require deferral of revenue recognition to a future period until the Company performs its obligations under these arrangements. Amounts are recorded as accounts receivable when the Company's right to consideration is unconditional. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the customer and the transfer of the promised goods or services to the customer will be one year or less.

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

### *In-licenses*

#### *Mochida Pharmaceutical Co., Ltd.*

In June 2018, the Company entered into a collaboration with Mochida Pharmaceutical Co., Ltd. ("Mochida") related to the development and commercialization of drug products and indications based on the active pharmaceutical ingredient in Vascepa, the omega-3 acid, EPA (eicosapentaenoic acid). Among other terms in the agreement, the Company obtained an exclusive license to certain Mochida intellectual property to advance the Company's interests in the United States and certain other territories and the parties will collaborate to research and develop new products and indications based on EPA for the Company's commercialization in the United States and certain other territories. The potential new product and indication opportunities contemplated under this agreement are currently in early stages of development.

Upon closing of the collaboration agreement, the Company made a non-refundable, non-creditable upfront payment of approximately \$2.7 million, which was recorded in research and development expense in the condensed consolidated statement of operations for the nine months ended September 30, 2018. In addition, the agreement provides for the Company to pay milestone payments upon the

achievement of certain product development milestones and royalties on net sales of future products arising from the collaboration, if any.

#### Out-licenses

##### Eddingpharm (Asia) Macao Commercial Offshore Limited

In February 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, or 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 REDUCE-IT clinical trials of Vascepa.

Under the DCS Agreement, Eddingpharm is solely responsible for development and commercialization activities in the China Territory and associated expenses. The Company provides development assistance and is responsible for supplying finished and later bulk drug product at defined prices under negotiated terms. The Company retains all Vascepa manufacturing rights. Eddingpharm agreed to certain restrictions regarding the commercialization of competitive products globally and the Company 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 are paid by Eddingpharm to the extent such costs are incurred in connection with the negotiated development plan or otherwise incurred by Eddingpharm. Eddingpharm is 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, supply, 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. 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. In March 2017, the CTA was approved by the Chinese regulatory authority, and in December 2017, Eddingpharm commenced a pivotal clinical trial aimed to support the regulatory approval of the first indication of Vascepa in a patient population with severe hypertriglyceridemia in Mainland China.

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 amounts to be received upon achievement of the regulatory milestone events relate to the submission and approval for three indications, and range from \$2.0 million to \$15.0 million for a total of \$33.0 million. The sales-based milestone events occur when annual aggregate net sales of Vascepa in the territory equals or exceeds certain specified thresholds, and range from \$5.0 million to \$50.0 million for a total of \$120.0 million. 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 assessed this arrangement in accordance with Topic 606 and concluded that the contract counterparty, Eddingpharm, is a customer. The Company identified the following performance obligations at the inception of the DCS Agreement: (1) the exclusive license to develop and commercialize Vascepa in the China Territory for uses that are currently commercialized and under development by the Company, (2) the obligation to participate in various steering committees, (3) ongoing development and

regulatory assistance, and (4) manufacture and supply of commercial product. Based on the analysis performed, the Company concluded that the identified performance obligations are not distinct and therefore a combined performance obligation.

The transaction price includes the \$15.0 million up-front consideration received and the \$1.0 million milestone payment received related to the successful submission of the CTA for the MARINE indication. None of the other clinical or regulatory milestones have been included in the transaction price, as all milestone amounts were fully constrained. As part of its evaluation of the constraint, the Company considered numerous factors, including that receipt of the milestones is outside the control of the Company and contingent upon success in future clinical trials and the licensee's efforts. Any consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur as they were determined to relate predominantly to the license granted to Eddingpharm and therefore have also been excluded from the transaction price. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

During the nine months ended September 30, 2018 and 2017, the Company recognized \$0.1 million and \$0.9 million, respectively, as licensing revenue related to the up-front and milestone payments received in connection with the Eddingpharm agreement. Through September 30, 2018 and December 31, 2017, the Company has recognized \$2.8 million and \$3.1 million, respectively, as licensing revenue under the DCS Agreement concurrent with the support provided by Amarin to Eddingpharm in achieving the combined performance obligation, which in the Company's judgment is the best measure of progress towards satisfying the performance obligation. The remaining transaction price of \$13.2 million and \$12.9 million is recorded in deferred revenue as of September 30, 2018 and December 31, 2017, respectively, on the condensed consolidated balance sheets and will be recognized as revenue over the remaining period of 16 years.

#### Biologix FZCo

In March 2016, the Company entered into an agreement with Biologix FZCo ("Biologix"), a company incorporated under the laws of the United Arab Emirates, to register and commercialize Vascepa in several Middle Eastern and North African countries. Under the terms of the distribution agreement, the Company granted to Biologix a non-exclusive license to use its trademarks in connection with the importation, distribution, promotion, marketing and sale of Vascepa in the Middle East and North Africa territory. Upon closing of the agreement, the Company received a non-refundable up-front payment, which will be recognized as revenue over 10 years commencing upon first marketing approval of Vascepa in the territory. The Company is entitled to receive all payments based on total product sales and pays Biologix a service fee in exchange for its services, whereby the service fee represents a percentage of gross selling price which is subject to a minimum floor price.

In March 2018 and July 2018, the Company received approval for Vascepa as a prescription medication for use in Lebanon and United Arab Emirates, respectively, as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia.

#### HLS Therapeutics, Inc.

In September 2017, the Company entered into an agreement with HLS Therapeutics Inc. ("HLS"), a company incorporated under the laws of Canada, to register, commercialize and distribute Vascepa in Canada. Under the agreement, HLS will be responsible for regulatory and commercialization activities and associated costs. The Company is responsible for providing assistance towards local filings, supplying finished product under negotiated supply terms, maintaining intellectual property, and continuing the development and funding of REDUCE-IT-related activities.

Upon closing of the agreement, the Company received one-half of a non-refundable \$5.0 million up-front payment, and received the remaining half on the six-month anniversary of the closing. Following achievement of the REDUCE-IT trial primary endpoint, which was announced in September 2018, the Company is entitled to receive a non-refundable \$2.5 million milestone payment which is recorded in other receivables on the condensed consolidated balance sheet as of September 30, 2018. In addition to the non-refundable, up-front and regulatory milestone payments just described, the Company is entitled to receive certain regulatory and sales-based milestone payments of up to an additional \$57.5 million, as well as tiered double-digit royalties on net sales of Vascepa in Canada.

The Company assessed this arrangement in accordance with Topic 606 and concluded that the contract counterparty, HLS, is a customer. The Company identified the following performance obligations at the inception of the contract: (1) license to HLS to develop, register, and commercialize Vascepa in Canada, (2) support general development and regulatory activities, (3) participate in various steering committees, and (4) manufacture and provide finished form of product. Based on the analysis performed, the Company concluded that the identified performance obligations in the agreement are not distinct and therefore a combined performance obligation.

The transaction price includes the \$5.0 million up-front consideration and the \$2.5 million milestone related to the achievement of the REDUCE-IT trial primary endpoint. None of the other regulatory milestones have been included in the transaction price, as all of the remaining regulatory milestone amounts were fully constrained. As part of its evaluation of the constraint, the Company considered numerous factors, including that receipt of the milestones is outside the control of the Company and contingent upon the licensee's efforts. Any consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur as they were determined to relate predominantly to the license granted to HLS and therefore have also been excluded from the transaction price. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

During the nine months ended September 30, 2018 and 2017, the Company recognized \$0.5 million and less than \$0.1, respectively, as licensing revenue related to up-front and milestone payments received in connection with the HLS agreement. Through September 30, 2018 and December 31, 2017, the Company has recognized \$0.7 million and \$0.1 million, respectively, as licensing revenue under the agreement concurrent with the support provided by Amarin to HLS in achieving the performance obligation, which in the Company's judgment is the best measure of progress towards satisfying the combined performance obligation. The remaining transaction price of \$6.8 million and \$4.9 million is recorded in deferred revenue as of September 30, 2018 and December 31, 2017, respectively, on the condensed consolidated balance sheets and will be recognized as revenue over the remaining period of 12 years.

The following table presents changes in the balances of the Company's contract assets and liabilities during the nine months ended September 30, 2018:

<i>In thousands</i>	<u>Balance at Beginning of Period</u>	<u>Additions</u>	<u>Deductions</u>	<u>Balance at End of Period</u>
<b>Nine months ended September 30, 2018:</b>				
Contract assets	\$ —	\$ —	\$ —	\$ —
<b>Contract liabilities:</b>				
Deferred revenue	\$ 19,054	\$ 2,500	\$ (598)	\$ 20,956

During the nine months ended September 30, 2018, the Company recognized the following revenues as a result of changes in the contract asset and contract liability balances in the respective periods:

<i>In thousands</i>	<u>Nine Months Ended September 30,</u>	
<b>Revenue recognized in the period from:</b>	<u>2018</u>	
Amounts included in contract liability at the beginning of the period	\$	405
Performance obligations satisfied in previous periods	\$	193

#### (11) Subsequent Events

The Company has evaluated subsequent events from September 30, 2018 through the date of the issuance of these condensed consolidated financial statements.

On October 19, 2018, the Company announced that it exercised its option to mandatorily exchange the entirety of the 2017 Notes into ADSs. Refer to *January 2017 Exchangeable Senior Notes* in Note 5—Debt for further discussion.

## 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, 2017 and below under Part II, Item 1A, "Risk Factors".*

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

### Overview

We are a pharmaceutical 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 began communicating promotional information beyond the MARINE indication to healthcare professionals in the United States 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.

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 direct sales force. In March 2014, we entered into a co-promotion agreement in the United States with Kowa Pharmaceuticals America, Inc. under which Kowa Pharmaceuticals America, Inc. began to co-promote Vascepa in conjunction with its promotion of its primary product, a branded statin for patients with high cholesterol, which commenced in May 2014 and extends until the end of 2018. Prior to REDUCE-IT results topline announcement in September 2018, our direct sales force consisted of approximately 170 sales professionals, including sales representatives and their managers. We are currently increasing the size of our sales force to a planned total of over 400 sales professionals in the United States in connection with positive REDUCE-IT results and expanding our promotion of Vascepa.

In February 2015, we entered into 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. In March 2016, we entered into an agreement with Biologix FZCo, or Biologix, to register and commercialize Vascepa in countries within the Middle East and North Africa. In September 2017, we entered into an agreement with HLS Therapeutics Inc., or HLS, to register, commercialize and distribute Vascepa in Canada.

In June 2018, we entered into a collaboration with Mochida Pharmaceutical Co., Ltd., or Mochida, related to development and potential subsequent commercialization of drug products and indications based on the active pharmaceutical ingredient in Vascepa, the omega-3 acid, EPA (eicosapentaenoic acid). The potential new product and indication opportunities contemplated under this agreement are currently in early stages of development.

We continue to assess other collaboration opportunities to maximize the value of the Vascepa franchise globally.

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 greater than one in four adults in the United States, or more than 50 million people, have elevated triglyceride levels. This data is based upon the most recent review of patient demographics, including the impact of patients on statin therapy, as published in the *Journal of Clinical Lipidology* in April 2018. 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 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 recently announced topline results of the 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. The REDUCE-IT study, since its inception in 2011, was conducted based on a special protocol assessment, or SPA, agreement with the FDA. In REDUCE-IT, cardiovascular event rates for patients on stable statin therapy plus 4 grams per day of Vascepa were 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, exceeding the 8,000 patients targeted for the trial. Since patient enrollment commenced in 2011, over 35,000 patient years of study experience were accumulated in the REDUCE-IT study. The REDUCE-IT study topline results were made public in September 2018, and broader reporting of results is planned at the 2018 Scientific Sessions of the American Heart Association (AHA) on November 10, 2018 in Chicago, Illinois. Based on the final positive results of REDUCE-IT, we plan to seek additional indicated uses for Vascepa in the United States and to continue to develop Vascepa commercially in major markets around the world.

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 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 encouraged us to complete the REDUCE-IT outcomes study. Based on our communications with the FDA, we expect that the FDA’s review and analysis of our final positive results from the REDUCE-IT outcomes study will be required for FDA-approved label expansion for Vascepa. We anticipate submitting an sNDA to the FDA in early 2019 based on the positive results of the REDUCE-IT study.

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 labeling 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 permits us to promote to healthcare professionals the FDA-reviewed and agreed effects of Vascepa demonstrated in the ANCHOR clinical trial and presentation of the current state of scientific research related to the potential of Vascepa to reduce the risk of cardiovascular disease including through use of peer-reviewed scientific publications of available data.

In August 2015, we began to communicate promotional information beyond the MARINE indication to healthcare professionals in the United States 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. In September 2018, in connection with the public release of topline REDUCE-IT results, we commenced communications to healthcare professionals which were intended to ensure we meet our continuing obligation to update healthcare professionals regarding off-label use of Vascepa to ensure that our communications remain truthful and non-misleading, which we believe is consistent with the federal court approved settlement under *Amarin Pharma, Inc. et al. v. United States Food and Drug Administration et al.*, 119 F.Supp.3d 196, 236 (S.D.N.Y. 2015). 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 1-gram size Vascepa capsules 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. Prior to REDUCE-IT results topline announcement in September 2018, our direct sales force consisted of approximately 170 sales professionals, including sales representatives and their managers. We are currently increasing the size of our sales force to a planned total of over 400 sales professionals in connection with positive REDUCE-IT results and expanding our promotion of Vascepa. Commencing in May 2014, in addition to Vascepa promotion by our sales representatives, Kowa Pharmaceuticals America, Inc. began co-promoting Vascepa in conjunction with its promotion of its primary product, a branded statin for patients with high cholesterol. We also employ various medical affairs and marketing personnel to support our commercialization of Vascepa.

In October 2016, in addition to the original 1-gram capsule size for Vascepa, we introduced a smaller 0.5-gram capsule size, the first and only 0.5-gram prescription omega-3 alternative available on the market, for the subset of patients who prefer a smaller capsule. The FDA-approved dosing for Vascepa continues to be 4 grams per day, and, as expected, the majority of new and existing patients taking Vascepa continue to be prescribed the 1-gram size Vascepa capsule.

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, 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 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 varies during the term. The percentage of aggregate Vascepa gross margin earned by Kowa Pharmaceuticals America, Inc. was, as amended, approximately eighteen percent (18%) in 2017, partially offset by certain other refinements. During 2018, which is the last year of the agreement, as amended, we are incurring expense for both the annual co-promotion fee, which in 2018 is calculated as eighteen-and-a-half percent (18.5%) of Vascepa gross margin, plus accrual for co-promotion tail payments which are calculated as a percentage of the 2018 co-promotion fee. Assuming Kowa Pharmaceuticals America, Inc. fulfills its obligations in accordance with the terms of the agreement, as amended, after expiration of the agreement, Kowa Pharmaceuticals America, Inc. is eligible to receive up to three years of co-promotion tail payments equal to declining percentages of the co-promotion fee amount earned in the final year of the agreement with the sum of the three years of co-promotion tail payments totaling less than the co-promotion fee amount earned in the final year of the agreement.

Based on monthly compilations of data provided by a third party, Symphony Health, the estimated number of normalized total Vascepa prescriptions for the three months ended September 30, 2018 was approximately 458,000 compared to 430,000, 391,000 and 384,000 in the three months ended June 30, 2018, March 31, 2018 and September 30, 2017, respectively. According to data from another third party, IQVIA, the estimated number of normalized total Vascepa prescriptions for the three months ended September 30, 2018 was approximately 457,000 compared to 430,000, 392,000 and 374,000 in the three months ended June 30, 2018, March 31, 2018 and September 30, 2017, respectively. Normalized total prescriptions represent the estimated total number of Vascepa prescriptions dispensed to patients, calculated on a normalized basis (i.e., one month's supply, or total capsules dispensed multiplied by the number of grams per capsule divided by 120 grams). Inventory levels at wholesalers tend to fluctuate based on seasonal factors, prescription trends and other factors.



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, quarterly changes in Distributor purchases, 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 promotional information beyond MARINE clinical trial data to targeted healthcare professionals. Such qualified communications are being made pursuant to the August 2015 federal district court declaration and related March 2016 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. In September 2018, in connection with the public release of topline REDUCE-IT results, we commenced communications to healthcare professionals which were intended to ensure we meet our continuing obligation to update healthcare professionals regarding off-label use of Vascepa to ensure that our communications remain truthful and non-misleading, which we believe is consistent with the federal court approved settlement under *Amarin Pharma, Inc. et al. v. United States Food and Drug Administration et al.*, 119 F.Supp.3d 196, 236 (S.D.N.Y. 2015).

### *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 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 and a non-refundable milestone payment of \$1.0 million received upon successful submission of a clinical trial application, or CTA, with respect to the MARINE indication for Vascepa to the Chinese regulatory authority in March 2016. In March 2017, the CTA was approved by the Chinese regulatory authority and, in December 2017, Eddingpharm commenced a pivotal clinical trial aimed to support the regulatory approval of the first indication of Vascepa in a patient population with severe hypertriglyceridemia in Mainland China. We are also entitled to receive future regulatory and sales-based milestone payments of up to an additional \$153.0 million. 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 amounts to be received upon achievement of the regulatory milestone events relate to the submission and approval for three indications, and range from \$2.0 million to \$15.0 million for a total of \$33.0 million. The sales-based milestone events occur when annual aggregate net sales of Vascepa in the territory equals or exceeds certain specified thresholds, and range from \$5.0 million to \$50.0 million for a total of \$120.0 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.

In March 2016, we entered into an agreement with Biologix FZCo, or Biologix, to register and commercialize Vascepa in several Middle Eastern and North African countries. Under the terms of the distribution agreement, we granted to Biologix a non-exclusive license to use our trademarks in connection with the importation, distribution, promotion, marketing and sale of Vascepa in the Middle East and North Africa territory. Upon closing of the agreement, we received a non-refundable up-front payment, which will be recognized as revenue over 10 years commencing upon first marketing approval of Vascepa in the territory. We receive all payments based on total product sales and pay Biologix a service fee in exchange for its services, whereby the service fee represents a percentage of gross selling price which is subject to a minimum floor price. In March 2018 and July 2018, we received approval for Vascepa as a prescription medication for use in Lebanon and United Arab Emirates, respectively, as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia.

In September 2017, we entered into an agreement with HLS to register, commercialize and distribute Vascepa in Canada. Under the agreement, HLS will be responsible for regulatory and commercialization activities and associated costs. We will be responsible for providing assistance towards local filings, supplying finished product under negotiated supply terms, maintaining intellectual property, and continuing the development and funding of REDUCE-IT-related activities. Terms of the agreement include up-front and milestone payments to us of up to \$65.0 million. These payments include a non-refundable \$5.0 million up-front payment received in two equal installments, the first of which was received at closing with the second received upon the six-month anniversary of the closing, as well as a non-refundable milestone payment of \$2.5 million received upon achievement of the REDUCE-IT trial primary endpoint. In addition to the non-refundable, up-front payment, we are entitled to receive certain regulatory and sales-based milestone payments of up to an additional \$57.5 million, the timing and achievability of which cannot be determined at least until discussions with Canadian regulatory authorities have commenced, as well as tiered double-digit royalties on net sales of Vascepa in Canada.

We continue to assess other partnership opportunities for licensing Vascepa to partners 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. REDUCE-IT was not designed to demonstrate that lowering triglycerides alone in the study population is sufficient to lower the rate of major adverse cardiovascular events compared to placebo. Rather, it was designed to test the hypothesis that the clinical effects of Vascepa, including, but not limited to, its impact on triglyceride lowering, are effective in lowering the rate of major adverse cardiovascular events compared to placebo in patients who despite statin therapy have risk factors for cardiovascular disease, including elevated triglyceride levels. Based on the final positive results of REDUCE-IT, we plan to 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, exceeding the 8,000 patients targeted for the trial.

The REDUCE-IT study topline study results were made public in September 2018, and broader reporting of results is planned at the 2018 Scientific Sessions of the American Heart Association (AHA) on November 10, 2018 in Chicago, Illinois.

The REDUCE-IT study, since its inception in 2011, was conducted based on a SPA agreement with the FDA. Since patient enrollment commenced in 2011, over 35,000 patient years of study experience were accumulated in the REDUCE-IT study. Our scientific rationale for the REDUCE-IT study was 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 was 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 was needed to determine the clinical benefit of Vascepa therapy in statin-treated patients with controlled levels of LDL cholesterol, elevated triglyceride levels and other cardiovascular risk factors.

In June 2018, we entered into a multi-faceted collaboration with Mochida related to the development and commercialization of drug products and indications based on the active pharmaceutical ingredient in Vascepa, the omega-3 acid, EPA. Among other terms in the agreement, we obtained an exclusive license to certain Mochida intellectual property to advance our interests in the United States and certain other territories and the parties will collaborate to research and develop new products and indications based on EPA for our commercialization in the United States and certain other territories. The potential new product and indication opportunities contemplated under this agreement are currently in early stages of development. Upon closing of the collaboration agreement, we are required to make a non-refundable, non-creditable upfront payment of approximately \$2.7 million. In addition, the agreement provides for milestone payments from us upon the achievement of certain product development milestones and royalties on net sales of future products arising from the collaboration, if any. We expect that expenditures related to research and development activities for product candidates under the collaboration agreement will be immaterial in 2018 and less than \$5.0 million in 2019.

#### *Commercial and Clinical Supply*

We manage our supply chain internally but rely on contract manufacturers in each step of our commercial and clinical product supply, namely, active pharmaceutical ingredient, or API, manufacturing, encapsulation, packaging and supply-related logistics. Our approach to product supply seeks to mitigate risk of supply interruption and maintain an environment of cost competition and supply chain diversification. API for Vascepa is manufactured by three independent FDA-approved suppliers: Nisshin Pharma, Inc., or Nisshin, Finorga SAS, or Novasep, and Chemport, Inc., or Chemport. We encapsulate Vascepa through three independent FDA-approved commercial API encapsulators: Patheon, Inc. (formerly Banner Pharmacaps, now part of Thermo Fisher Scientific), Catalent Pharma Solutions, and Capsugel Plöemmel SAS, (now a Lonza company), or Capsugel. 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 \$81.9 million as of September 30, 2018 will be sufficient to fund our projected operations through planned expansion of our sales force and the anticipated submission in early 2019 of a supplemental new drug application (sNDA) with the FDA based on REDUCE-IT study results. Depending on the level of cash generated from operations, and in light of the recently announced successful results of the REDUCE-IT study, additional capital may be required to support planned expansion of Vascepa promotion and potential Vascepa promotion beyond which we are currently executing. If additional capital is required and we are unable to obtain additional capital, we may be forced to delay, limit or eliminate certain promotional activities. We anticipate that quarterly net cash outflows in future periods will be variable.

## Financial Operations Overview

*Product Revenue, net.* All of our product revenue is derived from product sales of 1-gram and 0.5-gram size capsules 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 of 1-gram size Vascepa capsules in the United States in January 2013, and introduced a smaller 0.5-gram capsule size in October 2016. Revenues from product sales are recognized when the Distributor obtains control of our product, which occurs at a point in time, typically upon delivery to the Distributor.

*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. We recognize revenue from licensing arrangements as we fulfill the performance obligations under each of 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, insurance, and other indirect manufacturing, logistics and product support costs. 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, costs of product supply received from suppliers when such receipt by us is prior to regulatory approval of the supplier, as well as license fees related to our strategic collaboration with Mochida Pharmaceutical Co., Ltd. We expense research and development costs as incurred.

*Interest and Other (Expense) Income, Net.* Interest expense consists of interest incurred under lease obligations, interest incurred under our December 2012 royalty-bearing instrument financing arrangement, and interest incurred under our 3.5% exchangeable notes. Interest expense under our royalty-bearing instrument 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) income, net, consists primarily of foreign exchange losses and gains.

*(Provision for) Benefit from Income Taxes.* (Provision for) benefit from income taxes, deferred tax assets and liabilities, and reserves for unrecognized tax benefits reflect management's best assessment of estimated future taxes to be paid. We are subject to income taxes in both the United States and foreign jurisdictions. In applying the estimated annual effective tax rate approach prescribed under ASC 740-270 and based on present evidence and conclusions around the realizability of deferred tax assets, we determined that any tax benefit related to the pretax losses generated during the three and nine months ended September 30, 2018 and 2017 is neither more likely than not to be realized in the current year nor realizable as a deferred tax asset at the end of the year. Therefore, the appropriate amount of income tax benefit to recognize during the three and nine months ended September 30, 2018 and 2017 is zero.

## 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 market-specific and other relevant 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. Estimates are assessed each period and updated to reflect current information. 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. A summary of our critical accounting policies, significant judgments and estimates is presented in Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2017. There were no material changes to our critical accounting policies, significant judgments and estimates during the nine months ended September 30, 2018, other than as set forth below.

*Revenue Recognition*—In accordance with GAAP, under Accounting Standards Codification (“ASC”) Topic 606, *Revenue from Contracts with Customers*, which we adopted on a modified retrospective basis effective January 1, 2018, we recognize revenue when our Distributors obtain control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. To determine revenue recognition for arrangements that we determine are within the scope of Topic 606, we perform the following five steps: (i) identify the contract(s) with a Distributor; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy a performance obligation. We apply the five-step model to contracts only when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the Distributor. At contract inception, once the contract is determined to be within the scope of Topic 606, we assess the goods or services promised within each contract, determine those that are performance obligations and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. For a complete discussion of our accounting for net product revenue and licensing revenues, see Note 2—Significant Accounting Policies.

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. 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. In accordance with GAAP, we recognize revenue when the Distributor obtains control of our product, which occurs at a point in time, typically upon delivery to the Distributor. We recognized net product revenues of \$151.3 million and \$126.3 million based on sales to Distributors during the nine months ended September 30, 2018 and 2017, respectively.

We have written contracts with our Distributors, and transfer of control typically occurs upon delivery of our product to the Distributor. 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. 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 and IQVIA in estimating the level of inventory held in the distribution channel. A hypothetical 5% change in estimated aggregate bottles of channel inventory would result in a change of less than 1% in net product revenues reported during each of the nine months ended September 30, 2018 and 2017.

When evaluating licensing arrangements, we perform the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) we satisfy each performance obligation. In determining performance obligations, we evaluate whether the license is distinct from the other performance obligations with the collaborative partner based on the consideration of the relevant facts and circumstances for each arrangement. Factors considered in the determination of 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 us.

If the license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenues from non-refundable, up-front fees allocated to the license when the license is transferred to the

Distributor and the Distributor is able to use and benefit from the license. For licenses that are bundled with other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

At the inception of each arrangement that includes development, regulatory and commercial milestone payments, we evaluate whether the milestones are considered probable of being reached and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our control or the control of the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. We evaluate factors such as the scientific, clinical, regulatory, commercial and other risks that must be overcome to achieve the respective milestone as well as the level of effort and investment required. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which we recognize revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, we re-evaluate the probability of achievement of such development, regulatory and commercial milestones and any related constraint, and if necessary, adjust its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect licensing revenues and earnings in the period of adjustment.

We receive payments from our customers based on billing schedules established in each contract. Up-front payments and fees are recorded as deferred revenue upon receipt or when due and may require deferral of revenue recognition to a future period until we perform our obligations under these arrangements. Amounts are recorded as accounts receivable when our right to consideration is unconditional. We do not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the customer and the transfer of the promised goods or services to the customer will be one year or less.

### **Recent Accounting Pronouncements**

For a discussion of recent accounting pronouncements, see Note 2—Significant Accounting Policies in the accompanying Notes to Condensed Consolidated Financial Statements included in Item 1 of this Quarterly Report on Form 10-Q for additional information.

### **Results of Operations**

#### ***Comparison of Three Months Ended September 30, 2018 and September 30, 2017***

*Product Revenue, net.* We recorded net product revenue of \$55.0 million and \$47.1 million during the three months ended September 30, 2018 and 2017, respectively, an increase of \$7.9 million, or 17%. This increase in revenue was driven primarily by an increase in estimated normalized total Vascepa prescriptions in the United States. Based on data provided by Symphony Health and IQVIA, estimated normalized total Vascepa prescriptions in the United States increased by approximately 74,000 and 83,000, respectively, over the three months ended September 30, 2017, representing growth of 19% and 22%, respectively.

All of our product revenue in the three months ended September 30, 2018 and 2017 was derived from product sales of 1-gram and 0.5-gram size capsules of Vascepa, net of allowances, discounts, incentives, rebates, chargebacks and returns. The FDA-approved dosing for Vascepa continues to be 4 grams per day and, as expected, the majority of new and existing patients taking Vascepa continue to be prescribed the 1-gram size Vascepa capsules. Timing of shipments to wholesalers, as used for revenue recognition, and timing of prescriptions as estimated by third-party sources such as Symphony Health and IQVIA may differ from period to period.

During the quarters ended September 30, 2018 and 2017, our net product revenue included 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, 2018 and 2017 was up to \$70 per 30-day prescription filled and, beginning in March 2017, included up to \$140 per 90-day 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, 2018 and 2017 was \$0.4 million and \$0.3 million, respectively. Licensing revenue relates to the amortization of amounts received in connection with a Vascepa licensing agreement for the China Territory, specifically a \$15.0 million up-front payment received in February 2015 and a \$1.0 million

milestone payment achieved in March 2016, as well as amortization of amounts received in connection with a Vascepa licensing agreement for Canada, specifically a \$5.0 million up-front payment which was received upon closing of the agreement in September 2017 and a \$2.5 million milestone payment that was receivable following achievement of the REDUCE-IT trial primary endpoint in September 2018. The up-front and milestone payments are being recognized over the estimated period in which we are required to provide regulatory and development support pursuant to the agreements. The amount of licensing revenue is expected to vary from period to period based on timing of milestones achieved and changes in estimates of the timing and level of support required. We do not anticipate significant revenues from international sources in 2018.

*Cost of Goods Sold.* Cost of goods sold during the three months ended September 30, 2018 and 2017 was \$13.5 million and \$11.9 million, respectively, an increase of \$1.6 million, or 14%. 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 quarters ended September 30, 2018 and 2017 was sourced from three API suppliers. These suppliers compete with each other based on cost, consistent quality, capacity, timely delivery and other factors. In the future, we may see the average cost of supply change based on numerous potential factors including increased volume purchases, continued improvement in manufacturing efficiency, the mix of purchases made among suppliers, currency exchange rates and other factors. We currently anticipate API average cost in 2018 to be similar to 2017. 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 each of the three months ended September 30, 2018 and 2017 was 75%.

*Selling, General and Administrative Expense.* Selling, general and administrative expense for the three months ended September 30, 2018 and 2017 was \$50.0 million and \$33.2 million, respectively, an increase of \$16.8 million, or 51%. Selling, general and administrative expenses for the three months ended September 30, 2018 and 2017 are summarized in the table below:

<i>In thousands</i>	<b>Three months ended September 30,</b>	
	<b>2018</b>	<b>2017</b>
Selling, general and administrative expense (1)	\$ 33,200	\$ 24,295
Co-promotion fees (2)	11,157	5,928
Non-cash stock-based compensation expense (3)	5,603	2,971
Total selling, general and administrative expense	<u>\$ 49,960</u>	<u>\$ 33,194</u>

- (1) Selling, general and administrative expense, excluding co-promotion fees and non-cash compensation charges for stock compensation, for the three months ended September 30, 2018 and 2017 was \$33.2 million and \$24.3 million, respectively, an increase of \$8.9 million, or 37%. This increase is due primarily to increased promotional activities, including commercial spend in preparation for successful REDUCE-IT results (announced on September 24, 2018), including costs for pilot direct-to-consumer activities of approximately \$5 million.
- (2) Co-promotion fees payable to Kowa Pharmaceuticals America, Inc. for the three months ended September 30, 2018 and 2017 were \$11.2 million and \$5.9 million, respectively, an increase of \$5.2 million, or 88%. The increase is due primarily to an accrual for co-promotion tail payments of \$3.9 million in the third quarter of 2018 as well as an increase in gross margin on product sales, upon which the co-promotion fees are calculated for the third quarter of 2018 compared to the same period in 2017.
- (3) Non-cash stock-based compensation expense for each of the three months ended September 30, 2018 and 2017 was \$5.6 million and \$3.0 million, respectively, an increase of \$2.6 million, or 89%. Non-cash stock-based compensation expense represents the estimated costs associated with equity awards issued to internal staff supporting our selling, general and administrative functions.

*Research and Development Expense.* Research and development expense for the three months ended September 30, 2018 and 2017 was \$14.1 million and \$10.7 million, respectively, an increase of \$3.4 million, or 32%. Research and development expenses for the three months ended September 30, 2018 and 2017 are summarized in the table below:

<i>In thousands</i>	<b>Three months ended September 30,</b>	
	<b>2018</b>	<b>2017</b>
REDUCE-IT study (1)	\$ 9,414	\$ 7,696
Regulatory filing fees and expenses (2)	419	442
Internal staffing, overhead and other (3)	3,191	2,032
Research and development expense, excluding non-cash expense	13,024	10,170
Non-cash stock-based compensation expense (4)	1,048	524
Total research and development expense	<u>\$ 14,072</u>	<u>\$ 10,694</u>

The increase in research and development expenses for the quarter ended September 30, 2018, as compared to the prior year period, is primarily due to timing of REDUCE-IT and related costs.

- (1) In September 2018, we announced landmark positive topline results of the REDUCE-IT cardiovascular outcomes trial. The REDUCE-IT study met its primary endpoint demonstrating an approximately 25% relative risk reduction in composite of major adverse cardiovascular events with high statistical significance. This result was supported by robust demonstrations of efficacy across multiple secondary endpoints. The REDUCE-IT study results have been accepted for presentation at the 2018 Scientific Sessions of the American Heart Association (AHA) on November 10, 2018. We managed the study through a contract research organization (CRO) through which all costs for this outcomes study were incurred with the exception of costs for clinical trial material (CTM) and costs for internal management. We expense costs for CTM when allocated to clinical research. For the three months ended September 30, 2018 and 2017, we incurred expenses through our CRO in connection with this trial of approximately \$6.8 million and \$6.6 million, respectively. Inclusive of CTM costs, the combined CRO and CTM costs during the three months ended September 30, 2018 and 2017 for REDUCE-IT were approximately \$9.4 million and \$7.7 million, respectively. Our internal personnel are responsible for managing multiple projects and their costs are not specifically allocated to REDUCE-IT or any other individual project. The increase in expenses in the third quarter of 2018 as compared to the same period in 2017 is primarily due to costs associated with data collection and analysis related to the REDUCE-IT study. We anticipate that our costs for this outcomes study, including publication of study results and submission of an sNDA seeking expanded labeling for Vascepa in the United States and potential international regulatory submissions, will continue to represent the most significant component of our research and development expenditures through the balance of 2018 and 2019.
- (2) The regulatory filing fees in each of the quarters ended September 30, 2018 and 2017 included annual FDA fees for maintaining manufacturing sites. Such fees primarily represent fees for qualification of new suppliers, including increasing capacity capabilities, and fees for sites used for the manufacture of product used in the REDUCE-IT clinical outcomes study.
- (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. These costs increased in 2018 compared to 2017 in support of publishing results of the REDUCE-IT study and preparing potential regulatory filings based on the results of the study.
- (4) Non-cash stock-based compensation expense represents the estimated costs associated with equity awards issued to internal staff supporting our research and development and regulatory functions.



*Interest Expense, net.* Net interest expense for the three months ended September 30, 2018 and 2017 was \$2.2 million and \$2.4 million, respectively, a decrease of \$0.2 million, or 10%. Net interest expense for the three months ended September 30, 2018 and 2017 is summarized in the table below:

<i>In thousands</i>	Three months ended September 30,	
	2018	2017
Exchangeable senior notes (1):		
Amortization of debt discounts	\$ 56	\$ 54
Contractual coupon interest	263	260
Total exchangeable senior notes interest expense	319	314
Long-term debt from royalty-bearing instrument (2):		
Cash interest	1,377	1,599
Non-cash interest	491	535
Total long-term debt from royalty-bearing instrument interest expense	1,868	2,134
Other interest expense	74	1
Total interest expense	2,261	2,449
Interest income (3)	(98)	(48)
Total interest expense, net	\$ 2,163	\$ 2,401

- (1) Cash and non-cash interest expense related to the exchangeable senior notes for the three months ended September 30, 2018 and 2017 was \$0.3 million in each period.
- (2) Cash and non-cash interest expense related to the December 2012 royalty-bearing instrument for the three months ended September 30, 2018 and 2017 was \$1.9 million and \$2.1 million, respectively. These amounts reflect the assumption that our Vascepa net revenue levels will not be high enough to support repayment in accordance with the contractual repayment schedule without the optional reduction which is allowed to be elected by us if the threshold revenue levels are not achieved. To date, our revenues have been below the contractual threshold amount each quarter such that each payment reflects the calculated optional reduction amount as opposed to the contractual threshold payments for each quarterly period.
- (3) Interest income for the three months ended September 30, 2018 and 2017 was \$0.1 million and less than \$0.1 million, respectively. Interest income represents income earned on cash balances.

*Other (Expense) Income, net.* Other (expense) income, net, for the three months ended September 30, 2018 and 2017 was expense of \$0.1 million and income of less than \$0.1 million, respectively. Other (expense) income, net, primarily consists of gains and losses on foreign exchange transactions.

#### **Comparison of Nine Months Ended September 30, 2018 and September 30, 2017**

*Product Revenue, net.* We recorded net product revenue of \$151.3 million and \$126.3 million during the nine months ended September 30, 2018 and 2017, respectively, an increase of \$24.9 million, or 20%. This increase in revenue was driven primarily by an increase in estimated normalized total Vascepa prescriptions in the United States. Based on data provided by Symphony Health and IQVIA, estimated normalized total Vascepa prescriptions in the United States increased by approximately 229,000 and 251,000, respectively, over the nine months ended September 30, 2017, representing growth of 22% and 24%, respectively.

All of our product revenue in the nine months ended September 30, 2018 and 2017 was derived from product sales of 1-gram and 0.5-gram size capsules of Vascepa, net of allowances, discounts, incentives, rebates, chargebacks and returns. The FDA-approved dosing for Vascepa continues to be 4 grams per day and, as expected, the majority of new and existing patients taking Vascepa continue to be prescribed the 1-gram size Vascepa capsules. Timing of shipments to wholesalers, as used for revenue recognition, and timing of prescriptions as estimated by third-party sources such as Symphony Health and IQVIA may differ from period to period.

During the nine months ended September 30, 2018 and 2017, our net product revenue included 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, 2018 and 2017 was up to \$70 per 30-day prescription filled and, beginning in March 2017, included up to \$140 per 90-day 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, 2018 and 2017 was \$0.6 million and \$0.9 million, respectively, a decrease of \$0.3 million, or 33%. Licensing revenue relates to the amortization of amounts received in connection with a Vascepa licensing agreement for the China Territory, specifically a \$15.0 million up-front payment received in February 2015 and a \$1.0 million milestone payment achieved in March 2016, as well as amortization of amounts received in connection with a Vascepa licensing agreement for Canada, specifically a \$5.0 million up-front payment which was received upon closing of the agreement in September 2017 and a \$2.5 million milestone payment that was receivable following achievement of the REDUCE-IT trial primary endpoint in September 2018. The up-front and milestone payments are being recognized over the estimated period in which we are required to provide regulatory and development support pursuant to the agreements. The amount of licensing revenue is expected to vary from period to period based on timing of milestones achieved and changes in estimates of the timing and level of support required. We do not anticipate significant revenues from international sources in 2018.

*Cost of Goods Sold.* Cost of goods sold during the nine months ended September 30, 2018 and 2017 was \$37.0 million and \$31.5 million, respectively, an increase of \$5.5 million, or 17%. 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, 2018 and 2017 was sourced from three API suppliers. These suppliers compete with each other based on cost, consistent quality, capacity, timely delivery and other factors. In the future, we may see the average cost of supply change based on numerous potential factors including increased volume purchases, continued improvement in manufacturing efficiency, the mix of purchases made among suppliers, currency exchange rates and other factors. We currently anticipate API average cost in 2018 to be similar to 2017. 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, 2018 and 2017 was 76% and 75%, respectively.

*Selling, General and Administrative Expense.* Selling, general and administrative expense for the nine months ended September 30, 2018 and 2017 was \$147.3 million and \$98.9 million, respectively, an increase of \$48.4 million, or 49%. Selling, general and administrative expenses for the nine months ended September 30, 2018 and 2017 are summarized in the table below:

<i>In thousands</i>	<b>Nine months ended September 30,</b>	
	<b>2018</b>	<b>2017</b>
Selling, general and administrative expense (1)	\$ 104,927	\$ 74,315
Co-promotion fees (2)	30,512	15,729
Non-cash stock-based compensation expense (3)	11,871	8,866
Total selling, general and administrative expense	<u>\$ 147,310</u>	<u>\$ 98,910</u>

- (1) Selling, general and administrative expense, excluding co-promotion fees and non-cash compensation charges for stock compensation, for the nine months ended September 30, 2018 and 2017 was \$104.9 million and \$74.3 million, respectively, an increase of \$30.6 million, or 41%. This increase is due primarily to increased promotional activities, including commercial spend in preparation for successful REDUCE-IT results (announced on September 24, 2018), including costs for pilot direct-to-consumer activities of approximately \$18 million, as well as payment of \$2.0 million made in connection with the settlement agreement reached with Teva Pharmaceuticals USA, Inc. in May 2018.
- (2) Co-promotion fees payable to Kowa Pharmaceuticals America, Inc. for the nine months ended September 30, 2018 and 2017 were \$30.5 million and \$15.7 million, respectively, an increase of \$14.8 million, or 94%. The increase is due primarily to an accrual for co-promotion tail payments of \$10.7 million in 2018 as well as an increase in gross margin on product sales, upon which the co-promotion fees are calculated for the nine months ended September 30, 2018 compared to the same period in 2017.
- (3) Non-cash stock-based compensation expense for the nine months ended September 30, 2018 and 2017 was \$11.9 million and \$8.9 million, respectively, an increase of \$3.0 million, or 34%. Non-cash stock-based compensation expense represents the estimated costs associated with equity awards issued to internal staff supporting our selling, general and administrative functions.

*Research and Development Expense.* Research and development expense for the nine months ended September 30, 2018 and 2017 was \$44.0 million and \$35.2 million, respectively, an increase of \$8.8 million, or 25%. Research and development expenses for the nine months ended September 30, 2018 and 2017 are summarized in the table below:

<i>In thousands</i>	<b>Nine months ended September 30,</b>	
	<b>2018</b>	<b>2017</b>
REDUCE-IT study (1)	\$ 29,650	\$ 25,824
Regulatory filing fees and expenses (2)	888	778
Internal staffing, overhead and other (3)	11,294	7,004
Research and development expense, excluding non-cash expense	41,832	33,606
Non-cash stock-based compensation expense (4)	2,161	1,605
Total research and development expense	<u>\$ 43,993</u>	<u>\$ 35,211</u>

The increase in research and development expenses for the nine months ended September 30, 2018, as compared to the prior year period, is primarily due to timing of REDUCE-IT and related costs.

- (1) In September 2018, we announced landmark positive topline results of the REDUCE-IT cardiovascular outcomes trial. The REDUCE-IT study met its primary endpoint demonstrating an approximately 25% relative risk reduction in composite of major adverse cardiovascular events with high statistical significance. This result was supported by robust demonstrations of efficacy across multiple secondary endpoints. The REDUCE-IT study results have been accepted for presentation at the 2018 Scientific Sessions of the American Heart Association (AHA) on November 10, 2018. We managed the study through a contract research organization (CRO) through which all costs for this outcomes study were incurred with the exception of costs for clinical trial material (CTM) and costs for internal management. We expense costs for CTM when allocated to clinical research. For the nine months ended September 30, 2018 and 2017, we incurred expenses through our CRO in connection with this trial of approximately \$22.7 million and \$22.4 million, respectively. Inclusive of CTM costs, the combined CRO and CTM costs during the nine months ended September 30, 2018 and 2017 for REDUCE-IT were approximately \$29.7 million and \$25.8 million, respectively. Our internal personnel are responsible for managing multiple projects and their costs are not specifically allocated to REDUCE-IT or any other individual project. The increase in expenses in 2018 as compared to 2017 is primarily due to costs associated with last patient study visits and data collection and analysis related to the REDUCE-IT study. We anticipate that our costs for this outcomes study, including publication of study results and submission of an sNDA seeking expanded labeling for Vascepa in the United States and potential international regulatory submissions, will continue to represent the most significant component of our research and development expenditures through the balance of 2018 and 2019.
- (2) The regulatory filing fees in each of the nine months ended September 30, 2018 and 2017 included annual FDA fees for maintaining manufacturing sites. Such fees primarily represent fees for qualification of new suppliers, including increasing capacity capabilities, and fees for sites used for the manufacture of product used in the REDUCE-IT clinical outcomes study.
- (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. These costs increased in 2018 compared to 2017 in support of publishing results of the REDUCE-IT study and preparing potential regulatory filings based on the results of the study. Other research and development expenses for the nine months ended September 30, 2018 also include a non-refundable, non-creditable upfront payment of approximately \$2.7 million related to our strategic collaboration with Mochida Pharmaceutical Co., Ltd.
- (4) Non-cash stock-based compensation expense represents the estimated costs associated with equity awards issued to internal staff supporting our research and development and regulatory functions.

*Interest Expense, net.* Net interest expense for the nine months ended September 30, 2018 and 2017 was \$6.2 million and \$7.1 million, respectively, a decrease of \$0.9 million, or 13%. Net interest expense for the nine months ended September 30, 2018 and 2017 is summarized in the table below:

<i>In thousands</i>	<b>Nine months ended September 30,</b>	
	<b>2018</b>	<b>2017</b>
Exchangeable senior notes (1):		
Amortization of debt discounts	\$ 166	\$ 146
Contractual coupon interest	788	743
Total exchangeable senior notes interest expense	954	889
Long-term debt from royalty-bearing instrument (2):		
Cash interest	4,332	4,835
Non-cash interest	1,520	1,591
Total long-term debt from royalty-bearing instrument interest expense	5,852	6,426
Other interest expense	74	5
Total interest expense	6,880	7,320
Interest income (3)	(692)	(223)
Total interest expense, net	<u>\$ 6,188</u>	<u>\$ 7,097</u>

- (1) Cash and non-cash interest expense related to the exchangeable senior notes for the nine months ended September 30, 2018 and 2017 was \$1.0 million and \$0.9 million, respectively.
- (2) Cash and non-cash interest expense related to the December 2012 royalty-bearing instrument for the nine months ended September 30, 2018 and 2017 was \$5.9 million and \$6.4 million, respectively. These amounts reflect the assumption that our Vascepa net revenue levels will not be high enough to support repayment in accordance with the contractual 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, 2018 and 2017 was \$0.7 million and \$0.2 million, respectively. Interest income represents income earned on cash balances.

*Other (Expense) Income, net.* Other (expense) income, net, for the nine months ended September 30, 2018 and 2017 was expense of \$0.1 million and income of \$0.1 million, respectively. Other (expense) income, net, primarily consists of gains and losses on foreign exchange transactions.

#### Liquidity and Capital Resources

Our sources of liquidity as of September 30, 2018 include cash and cash equivalents of \$81.9 million. In February 2018, we completed a public offering of 19,178,082 ADSs and, in March 2018, we issued an additional 1,438,356 ADSs upon the underwriter's partial exercise of a 30-day option to purchase additional shares. The underwriter purchased the ADSs from us at a price of \$3.41 per ADS after commission, resulting in net proceeds to us of approximately \$70.0 million, after deducting estimated offering expenses payable by us. Our projected uses of cash include expansion of our sales force and initiatives for medical education and market awareness following successful REDUCE-IT results, increasing inventory purchases, and general corporate and working capital purposes. 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:

<i>In millions</i>	<b>Nine months ended September 30,</b>	
	<b>2018</b>	<b>2017</b>
Cash (used in) provided by:		
Operating activities	\$ (62.4)	\$ (30.7)
Investing activities	(0.1)	—
Financing activities	70.7	11.5
Increase (decrease) in cash and cash equivalents	<u>\$ 8.3</u>	<u>\$ (19.2)</u>

Net cash used in operating activities during the nine months ended September 30, 2018 increased compared to the same period in 2017 primarily as a result of commercial and R&D activities associated with preparation for completion of the REDUCE-IT study, including payment for increased levels of Vascepa inventory, partially offset by higher collections from product sales.

In December 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 \$100.0 million received at the closing of the agreement which closing occurred in December 2012. In December 2017, BioPharma assigned all rights under this agreement to

CPPIB. We have agreed to repay up to \$150.0 million of future revenue and receivables. As of September 30, 2018, the net remaining amount to be repaid to CPPIB is \$94.1 million. To date, our net 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. As of September 30, 2018, there are no quarterly contractual threshold payments remaining, such that the maximum amount payable is subject only to the calculated threshold limitation based on quarterly Vascepa net revenues. In accordance with the agreement, quarterly differences between the calculated optional reduction amounts and the contractual threshold amounts were rescheduled for payment beginning in the second quarter of 2017 and any such deferred payments will remain subject to continued application of the quarterly ceiling in amounts due established by the calculated threshold for royalty based on quarterly Vascepa net revenues. No additional interest expense or liability is incurred as a result of such deferred repayments. The agreement does not expire until \$150.0 million in aggregate has been repaid. We can prepay an amount equal to \$150.0 million less any previously repaid amount.

In January 2017, we, through our wholly-owned subsidiary Corsicanto II DAC, or Corsicanto II, a private designated activity company incorporated under the laws of Ireland, entered into separate, privately negotiated purchase agreements with certain investors pursuant to which we issued and sold \$30.0 million in aggregate principal amount of 3.5% exchangeable senior notes due 2047, or the 2017 Notes. The net proceeds we received from the January 2017 offering were approximately \$28.8 million, after deducting placement agent fees and estimated offering expenses.

The 2017 Notes were issued pursuant to an indenture dated as of January 25, 2017, by and among Corsicanto II, us as guarantor, and Wilmington Trust, National Association, as trustee. The 2017 Notes are the senior unsecured obligations of the Issuer and are guaranteed by us. The 2017 Notes bear interest at a rate of 3.5% per annum from, and including, January 25, 2017, payable semi-annually in arrears on January 15 and July 15 of each year, beginning on July 15, 2017. The 2017 Notes will mature on January 15, 2047, unless earlier repurchased, redeemed or exchanged. On or after January 19, 2021, we may redeem for cash all or a portion of the 2017 Notes at a redemption price of 100% of the aggregate principal amount of the 2017 Notes to be redeemed, plus accrued and unpaid interest. On January 19, 2022, holders of the 2017 Notes may require that we repurchase in cash all or any portion of the 2017 Notes at a price equal to 100% of the aggregate principal amount of the 2017 Notes to be repurchased, plus accrued and unpaid interest. At any time prior to January 15, 2047, the holders may exchange their 2017 Notes for ADSs at their option, and we may mandatorily exchange the 2017 Notes if the price of our shares trades above 130% of the exchange price then in effect for 20 VWAP trading days in any 30 consecutive VWAP trading day period (as defined in the indenture). The initial exchange rate for such conversion is 257.2016 ADSs per \$1,000 principal amount of the 2017 Notes (equivalent to an initial exchange price of approximately \$3.89 per ADS), subject to adjustment upon the occurrence of certain events, including the payment of cash dividends. Upon exchange, the 2017 Notes are to be settled in ADSs. On October 19, 2018, we announced that we exercised our option to mandatorily exchange the entirety of the 2017 Notes into ADSs. When completed on November 2, 2018, the mandatory exchange will result in extinguishment of the debt and issuance of an aggregate amount of 7,716,048 ADSs, subject to certain adjustments as provided in the 2017 Notes, such that we will have no outstanding debt or related interest obligations.

During 2018, we increased our inventory balance by approximately \$9 million to build in preparation for anticipated revenue growth resulting from positive REDUCE-IT results.

As of September 30, 2018, we had cash and cash equivalents of \$81.9 million, an increase of \$8.3 million from December 31, 2017. The increase is primarily due to proceeds from the public offering financing and accounts receivable collections, partially offset by net cash used in operating activities in support of the commercialization of Vascepa and funding of REDUCE-IT. As of September 30, 2018, we had accounts receivable, net, of \$47.6 million and other receivables of \$25.7 million. We have incurred annual operating losses since our inception and, as a result, we had an accumulated deficit of \$1.4 billion as of September 30, 2018. We anticipate that quarterly net cash outflows in future periods will continue to be variable as a result of the timing of certain items, including our purchases of API, payments to our Vascepa co-promotion partner, and expanded Vascepa promotional activities resulting from positive REDUCE-IT results. We believe that our cash and cash equivalents of \$81.9 as of September 30, 2018 will be sufficient to fund our projected operations through planned expansion of our sales force and the anticipated submission in early 2019 of a supplemental new drug application (sNDA) with the FDA based on REDUCE-IT study results. Depending on the level of cash generated from operations, and in light of the recently announced successful results of the REDUCE-IT study, additional capital may be required to support planned expansion of Vascepa promotion and potential Vascepa promotion beyond which we are currently executing. If additional capital is required and we are unable to obtain additional capital, we may be forced to delay, limit or eliminate certain promotional activities. We anticipate that quarterly net cash outflows in future periods will be variable.

### **Contractual Obligations**

We have Vascepa API supply agreements with three independent companies from which we purchase qualified API supply: Nisshin, Chemport, and Finorga SAS, or Novasep. We also have encapsulation agreements with three FDA-approved commercial API encapsulators for Vascepa manufacturing: Patheon, Inc. (formerly Banner Pharmacaps, now part of Thermo Fisher Scientific), Catalent Pharma Solutions, and Capsugel Plöerme SAS, (now a Lonza company), or Capsugel. Our agreements with Chemport, Novasep, and Capsugel contain minimum annual purchase levels to enable us to maintain certain supply exclusivity and also contain a

provision that any shortfall in the minimum purchase commitments is payable in cash. Each supplier is required to meet certain performance obligations and the agreements may be terminated by us in the event of non-performance. In the ordinary course, pursuant to the results of the REDUCE-IT study, we are increasing our orders for API from these manufacturers while taking steps to help qualify at least one additional potential API manufacturer.

We have certain marketing commitments, consisting of communication costs related to our direct-to-consumer activities, totaling approximately \$8.6 million.

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

Under the terms of the agreement with CPPIB, as successor in interest to BioPharma, we agreed to repay up to \$150.0 million of future revenue and receivables. As of September 30, 2018, the net remaining amount to be repaid is \$94.1 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. As of September 30, 2018, there are no quarterly contractual threshold payments remaining, such that the maximum amount payable is subject only to the calculated threshold limitation based on quarterly Vascepa net revenues. In accordance with the agreement, quarterly differences between the calculated optional reduction amounts and the contractual threshold amounts were rescheduled for payment beginning in the second quarter of 2017 and 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 net 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 \$150.0 million in aggregate has been repaid. We can prepay an amount equal to \$150.0 million less any previously repaid amount.

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, 2018 and 2017. 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 \$9.8 million as of September 30, 2018). 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, 2018) for each of the two potential market approvals (i.e. £10 million maximum, or approximately \$13.0 million as of September 30, 2018).

We do not enter into financial instruments for trading or speculative purposes. As of September 30, 2018, 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 27, 2018.

#### **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, 2018 (the “Evaluation Date”), 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, 2018, 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, 2018, we implemented certain internal controls in connection with our adoption of ASC Topic 606. There were no other 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.

## 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, 2017 and “Item 1. Legal Proceedings” of our Quarterly Report on Form 10-Q for the quarters ended March 31, 2018 and June 30, 2018 include discussions of our current legal proceedings. There have been no material changes to those disclosures as of the date of this filing.

### 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 effects of tax reform, and other risks set forth below.*

*Those risk factors below denoted with a “\*” are newly added or have been materially updated from our Annual Report on 10-K for the year ended December 31, 2017 filed with the SEC on February 27, 2018.*

#### **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 do not meet expectations, our business could 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. If we seek to diversify our development programs or product offerings through licensing or acquisitions, such transactions are also time-consuming, dilutive to existing shareholdings, and can be disruptive to operations. These dynamics can restrict our ability to respond rapidly to adverse business conditions for Vascepa. If demand for Vascepa does not meet expectations and we are not successful with development, 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.

##### ***Factors out of our control make it more difficult for Vascepa 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 the U.S. Food and Drug Administration, or 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. Guidelines for the management of very high triglyceride levels suggest that the primary goal of reducing triglyceride levels in this patient population is reduction in 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 severe hypertriglyceridemia has not been determined and our FDA-approved labeling and promotional efforts state these facts.

In August 2015, based on a federal court order, we began communicating promotional information beyond the MARINE indication to healthcare professionals in the United States 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. 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 benefits. 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.

In September 2018, we announced topline results from the REDUCE-IT™ (Reduction of Cardiovascular Events with EPA—Intervention Trial) cardiovascular (CV) outcomes study of Vascepa. REDUCE-IT was a multinational, prospective, randomized, double-blind, placebo-controlled study, enrollment for which started in November 2011. REDUCE-IT investigated the effects of Vascepa on CV risk in statin-treated adults with well-controlled LDL-C 41-100 mg/dL (median baseline LDL-C: 75 mg/dL) and other CV risk factors, including persistent elevated TG 150-499 mg/dL (median baseline TG: 216 mg/dL). REDUCE-IT topline results showed the trial met its primary endpoint demonstrating an approximately 25% relative risk reduction, to a high degree of statistical significance ( $p < 0.001$ ), in major adverse cardiovascular events (MACE) in the intent-to-treat patient population with use of Vascepa 4 grams/day as compared to placebo. MACE events were defined as a composite of cardiovascular death, nonfatal myocardial infarction (MI), nonfatal stroke, coronary revascularization, or unstable angina requiring hospitalization. This result was supported by robust demonstrations of efficacy across multiple secondary endpoints. Vascepa was well tolerated in REDUCE-IT with a safety profile consistent with clinical experience associated with omega-3 fatty acids and current FDA-approved labelling. The proportions of patients experiencing adverse events and serious adverse events in REDUCE-IT were similar between the active and placebo treatment groups. Based on the final positive results of REDUCE-IT, we plan to seek additional indicated uses for Vascepa in the United States and to continue to develop Vascepa commercially in major markets around the world.

Even though we have released topline results from the REDUCE-IT trial, our approved label for Vascepa in the United States currently remains unchanged pending additional interactions and review by the FDA. A failure to obtain an expanded label may 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 in any future indications and uses based on the REDUCE-IT trial or otherwise will depend on a number of factors, including:

- the perceived efficacy and safety of Vascepa by prescribing healthcare professionals, as compared to no treatment and as compared to alternative treatments in various at risk patient populations, both as studied in clinical trials of Vascepa such as MARINE, ANCHOR and REDUCE-IT and not studied but for which the benefit/risk profile may be viewed as positive;
- peer review of REDUCE-IT results and publication of results in one or more medical journals over time;
- the FDA's review and analysis of the results of the REDUCE-IT;
- 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 or related settlement;
- natural disasters that can inhibit our ability to promote Vascepa regionally and can negatively affect product demand by creating obstacles for patients to seek treatment and fill prescriptions;
- new policies or laws affecting Vascepa sales, such as state and federal efforts to affect drug pricing and provide or remove healthcare coverage that includes reimbursement for prescription drugs; 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.

***As with any topline cardiovascular outcomes trial result announcement, further REDUCE-IT data assessment and data release will yield additional useful information to inform greater understanding of study outcome. That additional data may exceed, meet or not meet investor expectations. If the additional data do not meet expectations, the perception of REDUCE-IT results and Vascepa may suffer and our stock price may decline.***

In September 2018, we announced topline results from the REDUCE-IT trial showing that the trial met its primary endpoint demonstrating an approximately 25% relative risk reduction, to a high degree of statistical significance ( $p < 0.001$ ), in MACE in the intent-to-treat patient population with use of Vascepa 4 grams/day as compared to placebo. After announcement of favorable topline results from REDUCE-IT, additional data assessment and data release will yield additional useful information to inform greater understanding of study outcome. Generally, detailed trial data assessment may take several months and even years to complete and publish. More detailed presentation of REDUCE-IT results are scheduled first at the 2018 Scientific Sessions of the American Heart Association (AHA) on November 10, 2018 in Chicago, Illinois. That presentation and additional data may exceed, match or may not meet investor expectations.

Aspects that could change and impact the final evaluation of the totality of the efficacy and safety data from REDUCE-IT may include some or all of the following:

- the magnitude of the treatment benefit on the primary composite endpoint, its components, secondary endpoints and the primary and secondary risk prevention cohorts;
- consideration of which components of the composite or secondary endpoints have the most clinical significance;
- the consistency of the primary and secondary outcomes;
- the consistency of findings across cohorts and important subgroups;
- safety considerations and risk/benefit considerations;
- consideration of REDUCE-IT results in the context of other clinical studies; and
- study conduct and data quality, integrity and consistency.

If release of additional data do not meet expectations, the perception of REDUCE-IT results and the perceived value of Vascepa may suffer. If this occurs our business could suffer and our stock price could significantly decline.

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

Prior to REDUCE-IT results topline announcement in September 2018, our sales team consisted of approximately 170 sales professionals, including sales representatives and their managers. We are currently increasing the size of our sales force to a planned total of over 400 sales professionals in the United States and expanding our promotion of Vascepa. This sales team promotes Vascepa to a limited group of physicians and other healthcare professionals in select geographies in the United States. Even after planned expansion, this sales team is not large enough to call upon all physicians.

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, which we amended in July 2017. Under the agreement, Kowa Pharmaceuticals America, Inc. co-promotes Vascepa in conjunction with its promotion of its primary product, a branded statin for patients with high cholesterol, along with our sales professionals based on a plan designed to focus on select sales territories that we believe have demonstrated the greatest potential for Vascepa sales growth, increasing 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, and we have very limited experience as a company operating in this area and co-promoting a pharmaceutical product with a partner. Furthermore, our agreement with Kowa Pharmaceuticals America, Inc. is designed such that its co-promotion of Vascepa ceases at the end of 2018. If we do not extend this co-promotion agreement, enter into a co-promotion agreement with an equally capable company or hire equally capable sales representatives as part of our current sales force expansion plans, our sales may be negatively impacted.

In addition to sales force expansion in the United States, Amarin plans to work with its international partners to support regulatory efforts outside the United States based on REDUCE-IT results. We will again need to overcome challenges associated with rapidly hiring and training personnel and managing larger teams of people.

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.

***Our past and future 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 and the U.S. government to make it illegal for pharmaceutical companies to promote their FDA-approved products for uses that have not been approved by the FDA. Companies that market drugs for off-label uses or indications have been subject to related costly litigation, criminal penalties and civil liability under the FDCA and the False Claims Act. However, recent case law has called into question the extent to which government in the United States, including FDA, can, and is willing to seek to, prevent truthful and non-misleading speech related to off-label uses of FDA-approved products such as Vascepa.

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 the ANCHOR population 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 reflected 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 an off-label use has generally been 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. 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 treated 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 was already and currently is 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 communicate promotional information beyond the MARINE indication to healthcare professionals in the United States 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. As part of the settlement, given, as expressed in the court's opinion, that the dynamic nature of science and medicine is that knowledge is ever-advancing and that a statement that is fair and balanced one day may become incomplete or otherwise misleading in the future as new studies are done and new data is acquired, we agreed that we bear the responsibility to ensure that our communications regarding off-label use of Vascepa remain truthful and non-misleading, consistent with the federal court ruling.

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 the FDA's review and analysis of our final positive results from the REDUCE-IT outcomes study will be required for FDA-approved label expansion for Vascepa. However, we proactively communicate results from the REDUCE-IT trial in a manner we believe is truthful and non-misleading and thus protected under the freedom of speech clause of the First Amendment to the United States Constitution.

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. Data arising from studies of drug products are complex, such as the many studies that we believe show supportive but not conclusive research on the potential connection between the effects of EPA, the active ingredient in Vascepa, and cardiovascular risk reduction (e.g., the JELIS trial of a highly-pure EPA product in Japan by Mochida Pharmaceutical Co., Ltd., or Mochida, and other data using a variety of levels of evidence that connect EPA to favorable effects toward reduced cardiovascular risk. We, the FDA, the U.S. government, our competitors and other interested parties may not agree on the truthfulness and non-misleading nature of our promotional materials with respect to the outcome of these trials or other direct or indirect claims we make about Vascepa. Likewise, the FDA, the U.S. government, our competitors and other interested parties may not agree on the truthfulness and non-misleading nature of our promotional materials related to the REDUCE-IT results. Federal and state governments or agencies 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. Also, if governmental parties or our competitors view our claims as misleading or false, we could also be subject to liability based on fair competition-based statutes, such as the Lanham Act. Any of such negative circumstances could adversely affect our ability to operate our business and our results of operations.

***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 abroad include large, well-established pharmaceutical and generic companies, specialty and generic pharmaceutical sales and marketing companies, and specialized cardiovascular treatment companies. GlaxoSmithKline plc currently sells Lovaza<sup>®</sup>, a prescription-only omega-3 fatty acid indicated for patients with severe hypertriglyceridemia, which was approved by FDA in 2004 and has been on the market in the United States since 2005. Multiple generic versions of Lovaza are 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 high-density lipoprotein cholesterol, or HDL-C, but is also used to lower triglycerides. Multiple generic versions of Tricor, Trilipix, and Niaspan are also available in the United States. We compete with these drugs, and in particular, multiple low-cost generic versions of these drugs, in our FDA-approved indicated use and in off-label uses, such as to beneficially affect lipid levels in patients with persistent high triglyceride levels after statin therapy with the aim of potentially lowering cardiovascular risk beyond statin therapy.

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.

Results of pending low dose omega-3 and other cardiovascular outcomes studies may negatively affect sales of Vascepa. For example, results of VITamin D and Omega-3 Trial (VITAL) are expected to be announced immediately before the presentation of REDUCE-IT results at the 2018 Scientific Sessions of the American Heart Association (AHA) on November 10, 2018 in Chicago, Illinois. VITAL is an NIH funded randomized double-blind, placebo-controlled, 2x2 factorial trial of 2000 IU per day of vitamin D3 and 1 gram per day of omega-3 fatty acid supplementation (Lovaza) for the primary prevention of cancer and cardiovascular disease in a nationwide USA cohort of 25,874 adults not selected for elevated cardiovascular or cancer risk. Positive results due to the omega-3 component in VITAL may influence greater utilization of 1 gram daily of dietary supplements or Lovaza in a broad low cardiovascular risk population and in studied patients and may potentially cause an update of AHA recommendation for 1 gram per day of EPA and DHA based on trial results.

Likewise, earlier this year, results from A Study of Cardiovascular Events in Diabetes (ASCEND) trial were released and showed negligible results for omega-3 fatty acids 1 gram daily. ASCEND was a British Heart Foundation funded 2x2 factorial design, randomized study to assess whether aspirin 100 mg daily versus placebo and separately, omega-3 fatty acids 1 gram daily versus placebo, reduce the risk of cardiovascular events in a nationwide UK cohort of over 15,000 individuals with diabetes who do not have atherosclerotic cardiovascular disease. Negative results from such studies could create misleading impressions about the use of omega-3s generally, including Vascepa, despite REDUCE-IT positive results and the highly-pure EPA active ingredient in Vascepa and its higher dose regimen.

Also, AstraZeneca is currently conducting a long-term outcomes study to assess Statin Residual Risk Reduction With Epanova in High Cardiovascular Risk Patients With Hypertriglyceridemia (STRENGTH). The study is a randomized, double-blind, placebo-controlled (corn oil), parallel group design that is believed to have enrolled approximately 13,000 patients with hypertriglyceridemia and low HDL and high risk for cardiovascular disease randomized 1:1 to either corn oil plus statin or Epanova plus statin, once daily, for approximately 3-5 years as determined when the number of major adverse cardiovascular event outcomes is reached. The STRENGTH study estimated completion date is in November 2019, but it could be stopped earlier if, for example, it generates an overwhelming efficacy result. In addition, Kowa Research Institute (a subsidiary of the Japanese company Kowa Co., Ltd) announced in March 2017 that it is initiating a phase III cardiovascular outcomes trial titled PROMINENT examining the effect of pemafibrate (experimental name K-877) in reducing cardiovascular events in Type II diabetic patients with hypertriglyceridemia. Kowa Research Institute has publicly estimated study completion in May 2022, and if successful, U.S. regulatory approval is estimated in mid-2023.

We are also aware of other pharmaceutical companies that are developing products that, if successfully developed, approved and marketed, would compete with Vascepa. 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® (omega-3 phospholipid), 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 initiated a Phase 3 clinical program (TRILOGY) to assess the safety and efficacy of CaPre in patients with very high ( $\geq 500$  mg/dL) triglycerides in the first quarter of 2018. Acasti expects enrollment to be completed in Q4 2018 and study completion is expected by the end of 2019. We believe Micelle BioPharma Inc., or Micelle, is also developing potential treatments for hypertriglyceridemia based on omega-3 fatty acids. To our knowledge, Micelle, after acquiring SC401 from Sancilio & Company, or 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 pharmacokinetic studies and Phase 2 bioavailability studies (FASTR I&II), with one comparing SC401 to Lovaza. We expect the company or a potential partner to initiate a pivotal clinical Phase 3 study as the next step in development.

Matinas BioPharma, Inc. is developing an omega-3-based therapeutic (MAT9001) for the treatment of severe hypertriglyceridemia and mixed dyslipidemia. In the fourth quarter of 2014 Matinas BioPharma, Inc. filed an IND with the FDA to conduct a human study in the treatment of severe hypertriglyceridemia and, in June 2015, the company announced topline results for its head-to-head comparative pharmacokinetic and pharmacodynamic study of MAT9001 versus Vascepa. In September 2017, Matinas announced that it will be seeking a partner company to develop and commercialize MAT9001. Akcea Therapeutics/Ionis Pharmaceuticals (formerly Isis Pharmaceuticals), or Akcea/Ionis, in August 2018 announced the receipt of a complete response letter from the FDA for WAYLIVRA™ (volanesorsen), a drug candidate administered through weekly subcutaneous injections, for the treatment of familial chylomicronemia syndrome (FCS). Akcea will continue to work with the FDA on the path forward for Waylivra for the treatment of FCS. Waylivra continues to be developed for the treatment of familial partial lipodystrophy (FPL).

A Phase 3 trial is currently ongoing studying Waylivra (volanesorsen) in patients with FPL (BROADEN trial). Akcea/Ionis expects to file an NDA for FPL in 2019. In January 2017, Akcea/Ionis announced a strategic collaboration and option agreement with Novartis whereby Novartis will help develop (including funding cardiovascular outcomes studies) and commercialize products

emerging from this collaboration, including Waylivra (volanesorsen). In June 2018, Gemphire Therapeutics announced positive topline results from a Phase 2b trial (INDIGO-1) of its drug candidate, gemcabene, in patients with severe hypertriglyceridemia. Gemcabene is an oral, once-daily pill for a number of hypercholesterolemic populations and severe hypertriglyceridemia. Gemphire announced plans to initiate a Phase III study for homozygous familial hypercholesterolemia (HoFH), heterozygous familial hypercholesterolemia (HeFH) and non-familial hypercholesterolemia in ASCVD patients in the second half of 2018. In August 2018, the FDA requested that Gemphire conduct an additional long-term toxicity study before commencing any further clinical testing, thereby effectively placing gemcabene on clinical hold. Zydus Cadila has a Phase 2 development program for its lead molecule, Saroglitazar, in various indications, including severe hypertriglyceridemia in the United States. Study completion is expected in 2018. In August 2018, the company announced that it had suspended the Phase 2 trial in the severe hypertriglyceridemia indication due to study enrollment issues, while it continues development activities in other indications. The product is approved in India under the name Lipaglyn® for the treatment of hypertriglyceridemia and diabetic dyslipidemia.

***Generic company competitors are seeking FDA approval of generic versions of Vascepa. We are now engaged in related patent litigation and could face other challenges to our exclusivity.***

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.

As an alternate path to FDA approval for modifications of products previously approved by the FDA, an applicant may submit a new drug application, or NDA, under Section 505(b)(2) of the FDCA (enacted as part of the Hatch-Waxman Amendments). This statutory provision permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference from the owner of the data. The Hatch-Waxman Amendments permit the applicant to rely upon the FDA findings of safety and effectiveness of a drug that has obtained FDA approval based on preclinical or clinical studies conducted by others. In addition to relying on FDA prior findings of safety and effectiveness for a referenced drug product, the FDA may require companies to perform additional preclinical or clinical studies to support approval of the modification to the referenced product.

If an application for a generic version of a branded product or a Section 505(b)(2) application relies on a prior FDA finding of safety and effectiveness of a previously-approved product including an alternative strength thereof, the applicant is required to certify to the FDA concerning any patents listed for the referenced product in the FDA publication called “Approved Drug Products with Therapeutic Equivalence Evaluations,” otherwise known as the “Orange Book.” Specifically, the applicant must certify in the application that:

- (I) there is no patent information listed for the reference drug;
- (II) the listed patent has expired for the reference drug;
- (III) the listed patent for the reference drug has not expired, but will expire on a particular date and approval is sought after patent expiration; or
- (IV) the listed patent for the reference drug is invalid, unenforceable, or will not be infringed by the manufacture, use or sale of the product for which the ANDA or 505(b)(2) NDA is submitted.

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 both claim Vascepa and are listed in the Orange Book. 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 the relevant patents are invalid, or both. After receipt of a valid notice, the branded product manufacturer has 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, the Hatch-Waxman Amendments provide for a 30-month stay on FDA’s ability to give final approval to the proposed generic product, which period begins on the date the paragraph IV notice is received. Generally, during a period of time in which generic applications may be submitted for a branded product based on a product’s regulatory exclusivity status, if no patents are listed in the Orange Book before the date on which a complete ANDA application for a product (excluding an amendment or

supplement to the application) is submitted, an ANDA application could be approved by FDA without regard to a stay. For products entitled to five-year exclusivity status, the Hatch-Waxman Amendments provide that an ANDA application may be submitted after four years following FDA approval of the branded product if it contains a certification of patent invalidity or non-infringement to a patent listed in the Orange Book. In such a case, the 30-month stay runs from the end of the five-year exclusivity period. Statutory stays 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 ANDA 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 the Vascepa 1-gram dose strength 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 new chemical entity, or 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, in July 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.

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 ran from its date of FDA approval on July 26, 2012 and extended until July 26, 2017. We believe the statutory NCE-related 30-month stay triggered by the 1-gram dose patent litigation following generic application submissions permitted on July 26, 2016 is scheduled to continue until January 26, 2020, seven-and-a-half years from FDA approval, unless such patent litigation is resolved against us sooner.

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 the 1-gram dose strength 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 patent infringement lawsuits against three of these four ANDA applicants. In October 2016, Amarin filed a lawsuit against Roxane Laboratories, Inc. and related parties, collectively, 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.). According to a stipulation filed with the Nevada court, in December 2016, Roxane transferred its ANDA to West-Ward Pharmaceuticals International Limited, which then designated West-Ward Pharmaceuticals Corp. (or together with West-Ward Pharmaceuticals International Limited, West-Ward) as its agent for FDA communications. In view of the ANDA transfer, in February 2017, West-Ward replaced Roxane and related parties as Defendants in the above-referenced case. The case against West-Ward is now captioned *Amarin Pharma, Inc. et al. v. West-Ward Pharmaceuticals Corp. et al.*, Civ. A. No. 2:16-cv-02525 (D. Nev.). In November 2016, Amarin filed a lawsuit against Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd., collectively, DRL, in the U.S. District Court for the District of Nevada. The case against DRL is captioned *Amarin Pharma, Inc. et al. v. Dr. Reddy's Laboratories, Inc. et al.*, Civ. A. No. 2:16-cv-02562 (D. Nev.). In November 2016, Amarin filed a lawsuit against Teva Pharmaceuticals USA, Inc. and Teva Pharmaceuticals Industries Limited, or collectively, Teva, in the U.S. District Court for the District of Nevada. The case against Teva was captioned *Amarin Pharma, Inc. et al. v. Teva Pharmaceuticals USA, Inc. et al.*, Civ. A. No. 2:16-cv-02658. In all three lawsuits, we are seeking, among other remedies, an order enjoining each defendant from marketing

generic versions of the 1-gram dose strength of Vascepa before the last to expire of the asserted patents in 2030. The three lawsuits have been consolidated for pretrial proceedings.

The fourth ANDA applicant referenced above is Apotex Inc., or Apotex, which sent us a paragraph IV certification notice in September 2016. The notice reflected that Apotex made a paragraph IV notice as to some, but not all, of the patents listed in the Orange Book for Vascepa. Because Apotex did not make a paragraph IV certification as to all listed patents, Apotex cannot market a generic version of Vascepa before the last to expire of the patents for which Apotex did not make a paragraph IV certification, which is in 2030. At a later date, Apotex may elect to amend its ANDA in order to make a paragraph IV certification as to additional listed patents. If and when Apotex does make such an amendment, it would be required to send Amarin an additional paragraph IV certification notice, and Amarin would then have the ability to file a lawsuit against Apotex pursuant to the Hatch-Waxman Amendments.

In October 2016, we introduced to the market a 0.5-gram dose strength of Vascepa. In August 2017, as anticipated, we received a paragraph IV certification notice from Teva contending 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 the 0.5-gram dose strength of Vascepa, as described in the Teva ANDA. This Teva ANDA was filed as an amendment to the 1-gram Teva ANDA and is related to patents already at issue in the 1-gram Vascepa patent litigation. This certification followed the related listing in the Orange Book of patents associated with the 0.5-gram product in June 2017. This June 2017 listing was within the five-year, post NDA-approval period during which the Hatch-Waxman Amendments require a paragraph IV certification of patent invalidity or non-infringement under the Hatch-Waxman, five-year, NCE regulatory scheme. Accordingly, in October 2017, we filed a patent infringement lawsuit against Teva in the U.S. District Court for the District of Nevada. The case is captioned *Amarin Pharma, Inc. et al. v. Teva Pharmaceuticals USA, Inc. et al.*, Civ. A. No. 2:17-cv-2641 (D. Nev.). In this lawsuit, we sought, among other remedies, an order enjoining Teva from marketing generic versions of the 0.5-gram dose strength of Vascepa before the last to expire of the asserted patents in 2030.

On May 24, 2018, we entered into a settlement agreement with Teva that resolves our ANDA patent litigation as it relates to Teva's as amended ANDA for both the 1-gram and 0.5-gram dose strengths of Vascepa. As part of this settlement agreement, Teva may first begin selling its generic version of Vascepa in the United States on August 9, 2029, or earlier under certain customary circumstances, including commercial launch by another generic manufacturer under certain circumstances, in which event Teva would pay us certain royalties on its generic Vascepa products. The ANDA patent litigation continues in the United States District Court for the District of Nevada with parties West-Ward and DRL.

In July 2018, as anticipated, we received a paragraph IV certification notice from DRL contending 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 the 0.5-gram dose strength of Vascepa, as described in the DRL ANDA. This DRL ANDA was filed as an amendment to the 1-gram DRL ANDA and is related to patents already at issue in the 1-gram Vascepa patent litigation. This certification followed the related listing in the Orange Book of patents associated with the 0.5-gram product in June 2017. This June 2017 listing was within the five-year, post NDA-approval period during which the Hatch-Waxman Amendments require a paragraph IV certification of patent invalidity or non-infringement under the Hatch-Waxman, five-year, NCE regulatory scheme. Accordingly, in August 2018, we filed a patent infringement lawsuit against DRL in the U.S. District Court for the District of Nevada. The case is captioned *Amarin Pharma, Inc. et al. v. Dr. Reddy's Laboratories, Inc. et al.*, Civ. A. No. 2:18-cv-01596 (D. Nev.). In this lawsuit, we are seeking, among other remedies, an order enjoining DRL from marketing generic versions of the 0.5-gram dose strength of Vascepa before the last to expire of the asserted patents in 2030. In light of the overlap between the cases, DRL and Amarin have stipulated that the final judgment on the merits of the parties' contentions in the consolidated 1-gram action shall also be binding in the 0.5-gram case. Subject to the Court's approval, the stipulation would stay the 0.5-gram case pending the Court's final decision in the 1-gram cases.

We may also face challenges to the validity of our patents through a procedure known as *inter partes* review. *Inter partes* review is a trial proceeding conducted through the Patent Trial and Appeal Board, or PTAB, of the US Patent and Trademark Office. Such a proceeding could be introduced against us within the statutory one-year window triggered by service of a complaint for infringement or at any time by an entity not served with a complaint. Such proceedings may review the patentability of one or more claims in a patent on specified substantive grounds such as allegations that a claim is obvious on the basis of certain prior art.

We intend to vigorously enforce our intellectual property rights relating to Vascepa, but we cannot predict the outcome of the pending lawsuits or any subsequently filed lawsuits or *inter partes* review.

If an ANDA filer meets the approval requirements for a generic version of Vascepa to the satisfaction of the FDA under its ANDA, FDA may grant tentative approval to the ANDA during a Hatch-Waxman 30-month stay period. A tentative approval is issued to an ANDA applicant when its application is approvable prior to the expiration of any exclusivities applicable to the branded, reference listed drug product. A tentative approval does not allow the applicant to market the generic drug product and postpones the final ANDA approval until any exclusivity protections, such as a 30-month stay, have expired.



As a result of the statutory stays associated with the filing of these lawsuits under the Hatch-Waxman Amendments, we believe the FDA cannot grant final approval to West-Ward, DRL, or Teva's respective ANDAs for the 1-gram strength of Vascepa before January 26, 2020, unless there is an earlier court decision holding that the subject patents are not infringed and/or are invalid.

If final approval is granted and an ANDA filer is able to supply the product in significant commercial quantities, the generic company could introduce a generic version of Vascepa. Any such introduction of a generic version of Vascepa would also be subject to current patent infringement claims including those being litigated in the above-detailed patent litigations, and any court order we may seek and be granted to prevent any such launch based on our patent claims prior to any adverse court judgment or PTAB finding against us.

Any generic market entry would limit our U.S. sales, which would have a significant 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's five-year, NCE and related exclusivity benefits could be challenged by companies seeking to introduce generic versions of Vascepa.***

The timelines and conditions under the ANDA process that permit the start of patent litigation and allow the FDA to approve generic versions of brand name drugs like Vascepa differ based on whether a drug receives three-year, or five-year, NCE marketing exclusivity. In May 2016, after significant litigation, FDA determined that Vascepa is eligible for NCE marketing exclusivity. Accordingly, we believe a related 30-month stay is currently in place with respect to our 1-gram dose strength of Vascepa that is scheduled to continue until January 26, 2020, seven-and-a-half years from FDA approval of Vascepa, unless related patent litigation is resolved against us sooner.

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 could 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 such case, the pioneer drug company is afforded the benefit of a 30-month stay against the launch of such a competitive product that extends from the end of the five-year exclusivity period. A pioneer company could also be afforded extensions to the stay under applicable regulations, including a six-month pediatric exclusivity extension or a judicial extension if applicable requirements are met. A drug sponsor could also gain a form of marketing exclusivity under 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. We believe this determination provides Vascepa with the benefits of NCE exclusivity afforded by statute. NCE exclusivity for Vascepa ran from its date of FDA approval on July 26, 2012 and extended until July 26, 2017. We believe the statutory NCE-related 30-month stay triggered by the 1-gram dose patent litigation following generic application submissions permitted on July 26, 2016 is scheduled to continue until January 26, 2020, seven-and-a-half years from FDA approval, unless such patent litigation is resolved against us sooner.

It is possible that FDA's NCE determination and related 30-month stay could be challenged by interested parties. If challenged, we plan to vigorously defend exclusivity for Vascepa. Any such challenge could have a negative impact on our company and create uncertainty around the continued benefits associated with exclusivity that we believe are applicable to us under the Hatch-Waxman Amendments.

Regulatory exclusivity is in addition to exclusivity afforded by issued patents related to Vascepa.

***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 product, Vascepa, is a prescription-only form of EPA, an omega-3 fatty acid in ethyl ester form. Mixtures of omega-3 fatty acids in triglyceride form are naturally occurring substances contained in various foods, including fatty fish. Omega-3 fatty acids are marketed by others in a number of chemical forms as non-prescription dietary supplements. We cannot be sure physicians will view the pharmaceutical grade purity and proven efficacy and safety of Vascepa as having a superior therapeutic profile to unproven and loosely regulated omega-3 fatty acid dietary supplements. In addition, the FDA has not yet enforced to the full extent of its regulatory authority what we view as illegal claims made by certain omega-3 fatty acid product manufacturers to the extent we believe appropriate under applicable law and regulations, for example, claims that certain of such chemically altered products are dietary supplements and that certain of such products reduce triglyceride levels or could reduce cardiovascular risk.

Also, for more than a decade now, subject to certain limitations, 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 compete with Vascepa to a certain degree. Although we have taken steps to address these competitive issues, and plan to continue to do so vigorously, we may not be successful in such efforts. For example, on August 30, 2017, Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Limited, each wholly-owned subsidiaries of Amarin Corporation plc, filed a lawsuit with the United States International Trade Commission, or the ITC, against manufacturers, importers, and distributors of products containing synthetically produced omega-3 products in ethyl ester or re-esterified triglyceride form that contain more EPA than DHA or any other single component for use in or as dietary supplements. The lawsuit sought an investigation by the ITC regarding potentially unfair methods of competition and unfair acts involving the importation and sale of articles in the United States that injure or threaten injury to a domestic industry. On October 27, 2017, the ITC determined to not institute our requested investigation. We are currently appealing this determination in federal court and plan to pursue it vigorously. We have also recently sued several omega-3 dietary supplement manufacturers for making claims that we believe make them unfairly competitive to 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. Also, insurance plans may increasingly impose policies that favor supplement use over Vascepa. While Vascepa is highly price-competitive for patients generally, and in particular when covered by insurance—cheaper in many cases—any 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. or in replacing this co-promotion effort after it expires at the end of 2018.***

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 Kowa Pharmaceuticals America, Inc. co-promotes Vascepa in conjunction with its promotion of its primary product, a branded statin for patients with high cholesterol. 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 for an extended period of time, depending on Vascepa revenues, we may have to 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.

Furthermore, our agreement with Kowa Pharmaceuticals America, Inc. is designed such that its co-promotion of Vascepa ceases at the end of 2018. If we do not extend this co-promotion agreement, enter into a co-promotion agreement with an equally capable company or hire equally capable sales representatives, our sales may be negatively impacted.

***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.

***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 proposed REDUCE-IT indications.***

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 MARINE trial, the ANCHOR trial and the REDUCE-IT trial were conducted based on 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. 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.

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 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 (Asia) Macao Commercial Offshore Limited, or Eddingpharm, obtain marketing approval in Mainland China, Hong Kong, Macau and Taiwan, or 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, there is a degree of unpredictability with regard to the eventual pricing and reimbursement levels of medications in markets outside the United States. If the pricing and reimbursement levels of Vascepa are lower than we anticipate, then affordability of, and market access to, Vascepa may be adversely affected and thus market potential in these territories would suffer. Furthermore, 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. 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, or collectively the PPACA, enacted in March 2010, 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 subject to U.S. federal and state consumer protection and unfair competition laws, non-compliance with which could subject us to significant liability. 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 in 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.

***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 changes the way healthcare is financed by both governmental and private insurers. Among other cost-containment measures, PPACA establishes:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents;
- a new Medicare Part D coverage gap discount program, in which pharmaceutical manufacturers who wish to have their drugs covered under Part D must offer discounts to eligible beneficiaries during their coverage gap period;
- a new formula that increases the rebates a manufacturer must pay under the Medicaid Drug Rebate Program; and
- new policies or laws affecting Vascepa sales, such as state and federal efforts to affect drug pricing and provide healthcare coverage that includes reimbursement for prescription drugs.

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. It appears likely that the Affordable Care Act will continue the pressure on pharmaceutical pricing, especially under the Medicare and Medicaid programs, and may also increase our regulatory burdens and operating costs. Legislative changes to the Affordable Care Act remain possible under the Trump Administration.

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. For example, the State of California recently enacted legislation that requires notice for exceeding specified limits on annual drug price increases and other legislation that seeks to limit the use of co-pay cards in certain situations. These and other measures at the federal and state levels, to the extent applicable to us, could negatively affect our revenue and results from operations.

In addition, it is 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. For example, proposals are being considered to expand the use of dietary supplements in addition to or in place of drugs in government and private payor plans. In addition, 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.

***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, efficacy or safety 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 FDCA, 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 commercialization partners outside the United States. 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.

***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 but not limited to:

- the lack of efficacy during clinical trials;
- the inability to manufacture sufficient quantities of qualified materials under cGMPs for use in clinical trials;
- slower than expected rates of patient recruitment;
- the inability to observe patients adequately after treatment;
- changes in regulatory requirements for clinical 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.

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. Questions can also arise on the quality of study data or its reliability. For example, during the public advisory committee meeting held by FDA as part of its review of our ANCHOR sNDA, a discussion regarding observed, nominally statistically significant changes from baseline in an adverse direction, while on background statin therapy, in certain lipid parameters, including triglycerides, in the placebo group, raised questions about the possibility that the mineral oil placebo used in the ANCHOR trial (and in the REDUCE-IT trial) might not be biologically inert and might be viewed as artificially exaggerating the clinical effect of Vascepa when measured against placebo in the ANCHOR trial. Ultimately, no strong evidence for biological activity of mineral oil was identified by the FDA before its approval of Vascepa after review of the MARINE and ANCHOR trials and consideration of other data regarding mineral oil. It was ultimately concluded that the between-group differences likely provided the most appropriate descriptions of the treatment effect of Vascepa and that whatever factor(s) led to the within-group changes over time in the placebo group were likely randomly distributed to all treatment groups. Thus, the FDA approved Vascepa for use in the MARINE indication in July 2012, FDA did not dispute the veracity of the ANCHOR trial data and, in connection with the March 2016 agreement we reached with the FDA allowing us to promote the results of the ANCHOR study, the FDA did not seek to require that we include any qualification related to this earlier question regarding the mineral oil placebo. The FDA, early on in the course of the REDUCE-IT trial, directed the DMC for REDUCE-IT to periodically review unblinded lipid data to monitor for signals that the placebo might not be inert. After each such quarterly unblinded safety analysis and review meeting to date, the DMC recommended to continue the REDUCE-IT study as planned. Each of these DMC recommendations has been shared with FDA. This matter illustrates that concerns such as this may arise in the future that could affect our product development, regulatory review or the public perception of our products and our future prospects, including REDUCE-IT results.

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 gain approval for new indications and affect revenues from the sale of our 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 clinical trial or product, or in connection with the manufacturer of products, may result in regulatory issues that prevent past or proposed future approvals of a product and/or restrictions on that product or manufacturer, including withdrawal of an indication or the product from the market, which would have a negative impact on our potential revenue stream.

***As we continue to 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.***

The process of establishing a commercial infrastructure is difficult, expensive and time-consuming. Prior to REDUCE-IT results topline announcement in September 2018, our sales team consisted of approximately 170 sales professionals, including sales representatives and their managers. We are currently increasing the size of our sales force to a planned total of over 400 sales professionals in the United States and expanding our promotion of Vascepa. This sales team promotes Vascepa to a limited group of physicians and other healthcare professionals in select geographies in the United States. Even after planned expansion, this sales team is not large enough to call upon all physicians.

In addition to sales force expansion in the United States, Amarin plans to work with its international partners to support regulatory efforts outside the United States based on REDUCE-IT results. 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 ensure 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. 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/or 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), or Vascepa API, 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 NDA 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 qualified third-parties.

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 to manufacture the API for Vascepa, Novasep, Nisshin and Chemport currently supply all of our API for Vascepa. Our strategy in adding API suppliers has been to expand manufacturing capacity, maintain competitive advantages, and mitigate the risk of reliance on any single supplier.

Expanding manufacturing capacity and qualifying such capacity is complex 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/or 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, now part of Thermo Fisher Scientific), Catalent Pharma Solutions, and Capsugel Plöerme SAS (now a Lonza company). These companies have qualified and validated 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 may 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 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 regulations 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 and International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, or ICH, regulations who are both capable of manufacturing Vascepa and willing to do so. Failure by us or our third-party manufacturers to comply with applicable regulations, requirements, or guidelines could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our products, delays, suspension or withdrawal of approvals, license revocation, seizures or 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 pre-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 under ICH guidelines. 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 demonstrated 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 or our approved suppliers are unable to comply, we may be subject to regulatory, civil actions or penalties which could significantly and adversely affect our business.

***Our commercialization of Vascepa outside the United States is substantially dependent on third parties.***

We have expanded our Vascepa commercialization activities outside of the United States through several contractual arrangements in territories including China, the Middle East, North Africa and Canada. We continue to assess other opportunities to develop Vascepa commercialization outside of the United States through similar arrangements.

In February 2015, we entered into a Development, Commercialization and Supply Agreement, or the DCS Agreement, with Eddingpharm related to the development and commercialization of Vascepa in the China Territory. Under the DCS Agreement, Eddingpharm is responsible for development and commercialization activities in the China Territory and associated expenses. Additionally, Eddingpharm is required to conduct clinical trials in the China Territory to secure regulatory approval in certain territories. For example, in December 2017, Eddingpharm commenced a pivotal clinical trial aimed to support the regulatory approval of the first indication of Vascepa in a patient population with severe hypertriglyceridemia in Mainland China. Additional clinical development efforts may be necessary in this market. 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.

In March 2016, we entered into an agreement with Biologix FZCo, or Biologix, to register and commercialize Vascepa in several Middle Eastern and North African countries. Under the terms of the distribution agreement, we granted to Biologix a non-exclusive license to use our trademarks in connection with the importation, distribution, promotion, marketing and sale of Vascepa in the Middle East and North Africa territory. Commercialization across the Middle East and North Africa is several years away, if at all, in the most commercially significant territories and subject to similar risks as in the China Territory.

In September 2017, we entered into an agreement with HLS Therapeutics Inc., or HLS, to register, commercialize and distribute Vascepa in Canada. Under the agreement, HLS is responsible for regulatory and commercialization activities and associated costs. Amarin is responsible for providing assistance towards local filings, supplying finished product under negotiated supply terms, maintaining intellectual property, and continuing the development and funding of REDUCE-IT-related activities. Significant commercialization of Vascepa in Canada is several years away, if at all. If HLS Therapeutics is not able to effectively register and commercialize Vascepa in Canada, we may not be able to generate revenue from the agreement as a result of the sale of Vascepa in Canada.

We have limited experience working with partners outside the United States to develop and market our products in non-U.S. jurisdictions. In order for our partners 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 our partners to obtain approval for Vascepa in non-U.S. jurisdictions in a timely manner may limit the commercial success of Vascepa and our ability to grow our revenues.

***Our dependence on third parties in the distribution channel from our manufacturers to patients subject us to risk that limit our profitability and could limit our ability to supply Vascepa to large market segments.***

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. These parties exercise a substantial amount of bargaining power over us given their control over large segments of the market for Vascepa. This bargaining power has led us to bear increasingly higher discounts in the sale of Vascepa. In addition, payors have broad latitude to change individual products' formulary position or to implement other barriers that inhibit patients from receiving therapies prescribed by their healthcare professionals. These payor barriers include requirements that patients try another drug before Vascepa, known as step edits, and the requirement that prior authorization be obtained by a healthcare provider after a prescription is written before a patient will be reimbursed by their health plan for the cost of a Vascepa prescription. Further, pharmacy benefit managers implement plans that act as disincentives for Vascepa use, such as increasingly higher deductibles. One practical impact of higher deductibles is that they cause patients to delay filling prescriptions for asymptomatic, chronic care medications such as hypertriglyceridemia earlier in the year, until patients meet their deductible and the cost of Vascepa is then borne more by their insurance carrier. Collectively, these dynamics negatively affect our profitability for the sale of Vascepa and could increase over time further impacting our operating results. Consolidation among these industry participants could increase the pressure from these market dynamics.

***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 ensure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Our reliance on third parties does not relieve us of these responsibilities and requirements. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be delayed in obtaining regulatory approvals for our product candidates and may be delayed in our efforts to successfully commercialize our product candidates for targeted diseases.

## Risks Related to Our Intellectual Property

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

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

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

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 65 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 65 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;
- 39 U.S. patents covering or related to the use of Vascepa in either the MARINE or ANCHOR populations that have terms that expire in 2030 or later;
- 7 U.S. patents covering or related to the use of Vascepa in the REDUCE-IT population with terms expiring in 2033 or later;
- 4 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 or later;
- 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;
- 2 additional patents related to the use of a pharmaceutical composition comprised of free fatty acids to treat the REDUCE-IT population expiring 2033;
- 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;
- 2 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 2034;
- 2 additional patents covering a pharmaceutical composition comprised of EPA and a hydroxyl compound with a term that expires in 2034; and
- 2 additional patents covering a new combination therapy comprised of EPA and another drug.

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, including, for example, under our collaboration with Mochida. It is possible that third parties will obtain patents or other proprietary rights that might be necessary or useful to us. In cases where third parties are first to invent a particular product or technology, or first to file after various provisions of the America Invents Act of 2011 went into effect on March 16, 2013, it is possible that those parties will obtain patents that will be sufficiently broad so as to prevent us from utilizing such technology or commercializing our current and future products.

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

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

We anticipate that competitors may from time to time oppose our efforts to obtain patent protection for new technologies or to submit patented technologies for regulatory approvals. Competitors may seek to oppose our patent applications to delay the approval process or to challenge our granted patents, for example, by requesting a reexamination of our patent at the USPTO, or by filing an opposition in a foreign patent office, even if the opposition or challenge has little or no merit. 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.

***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 2018, we issued financial and business guidance, including expected fiscal year 2018 total net revenue and expectations regarding improved cash flow from commercial operations and timing of the REDUCE-IT outcomes trial. In April 2018, we issued revised revenue guidance following the impact of what we believe were trends related to third-party medical insurance coverage for patients prescribed Vascepa and other seasonal factors experienced in the first quarter of 2018. All such guidance is based on estimates and the judgment of management. Because of the inherent nature of estimates, there could be significant differences between our estimates and the actual amount of product demand. If, for any reason, we are unable to realize our currently projected 2018 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.

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

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

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

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

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

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

In 2007, we purchased Ester Neurosciences Limited, or Ester, 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, or Yissum. 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 undergoing federal and state tax audits, including audit by the United States Internal Revenue Service (IRS) for the years 2013 to 2014. 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 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. Three customers individually accounted for 10% or more of our gross product sales. Customers A, B, and C accounted for 26%, 31%, and 31%, respectively, of gross product sales for the nine months ended September 30, 2018, and represented 37%, 33%, and 17%, respectively, of the gross accounts receivable balance as of September 30, 2018. Customers A, B, and C accounted for 28%, 27%, and 35%, respectively, of gross product sales for the nine months ended September 30, 2017, and represented 36%, 27%, and 24%, respectively, of the gross accounts receivable balance as of September 30, 2017. 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, 2017, 2016, and 2015, we reported losses of approximately \$67.9 million, \$86.4 million, and \$149.1 million, respectively, and we had an accumulated deficit as of December 31, 2017 of \$1.3 billion. For the nine months ended September 30, 2018 and 2017, we reported losses of approximately \$82.8 million and \$34.6 million, respectively, and we had an accumulated deficit as of September 30, 2018 of \$1.4 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, and costs related to the commercialization of Vascepa. 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. We have been generating product revenue from sales of Vascepa since January 2013, 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 effectively market and sell Vascepa through our strategic collaborations.

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 in the near term due to high costs associated with our REDUCE-IT study and commercialization efforts, for example. If we are unable to continue to generate robust product revenues, we will not become profitable in the near term, if ever, 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 the REDUCE-IT cardiovascular outcomes study. Accordingly, our historical financial results reflect a substantially different business from that currently being conducted and from that expected in the future. In addition, we have a limited history of obtaining regulatory approval for, and no demonstrated ability to successfully commercialize, a product candidate. Consequently, any predictions about our future performance may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.

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

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

- the continuing evolution of the medical community's and the public's perception of the REDUCE-IT study results;
- the level of demand for Vascepa, due to changes in prescriber sentiment, quarterly changes in Distributor purchases, and other factors;
- 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 and the timing and extent to which such coverage and reimbursement changes;
- 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 co-promotion partner, Kowa Pharmaceuticals America, Inc.;

- the timing and ability of commercialization partners outside the United States to develop, register and commercialize Vascepa in the China Territory, several Middle Eastern and North African countries, and Canada, for example, including obtaining necessary regulatory approvals and establishing marketing channels;
- additional developments regarding our intellectual property portfolio and regulatory exclusivity protections, if any;
- outcomes of litigation and other legal proceedings; 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 \$81.9 million as of September 30, 2018 will be sufficient to fund our projected operations through planned expansion of our sales force and the anticipated submission in early 2019 of a supplemental new drug application (sNDA) with the FDA based on REDUCE-IT study results. Depending on the level of cash generated from operations, and in light of the recently announced successful results of the REDUCE-IT study, additional capital may be required to support planned expansion of Vascepa promotion and potential Vascepa promotion beyond which we are currently executing. If additional capital is required and we are unable to obtain additional capital, we may be forced to delay, limit or eliminate certain promotional activities. 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.

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, including expenditures such as potential direct-to-consumer advertising and increased sales force sizing, 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 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;
- continued costs associated with litigation and other legal proceedings;
- the time and costs involved in obtaining additional regulatory approvals for Vascepa based on REDUCE-IT results;
- 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.

***The potential future benefit of our substantial net operating loss carryforwards could be lost and our prospects for profitability could be materially diminished if tax regulations or rates change or if we are deemed to not have active operations in Ireland.***

Tax law and policies in the United States and Ireland are subject to change based on adjustments in political perspectives. In the United States and internationally, how to tax entities with international operations, like Amarin, has been subject to significant re-evaluation. We developed Vascepa in and from Ireland. In recent years, particularly since 2013 when commercial sale of Vascepa commenced in the United States, the majority of our consolidated operations have been in the United States. Ownership to Vascepa continues to reside with our wholly-owned Ireland-based subsidiary, Amarin Pharmaceuticals Ireland Ltd., and oversight and operations of that entity are structured to be maintained in Ireland. In order to effectively utilize our accumulated net operating loss carryforwards for tax purposes in Ireland, our operations, particularly for this subsidiary, need to be active in Ireland. In addition, utilization of these accumulated net operating loss carryforwards assumes that tax treaties between Ireland and other countries, particularly the United States, do not change in a manner which limit our future ability to offset earnings with these operating loss carryforwards for tax purposes.



Similarly, a change in our Irish tax residence could materially affect our ability to obtain profitability, if at all. Changes in tax law and tax rates, particularly in the United States and Ireland, could also impact our assessment of deferred taxes. Any change in our assessment of the realizability or the timing for realizing deferred taxes could have a negative impact on our future profitability.

***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 December 2012 Purchase and Sale Agreement with CPPIB Credit Europe S.à r.l., or CPPIB, as successor in interest to BioPharma Secured Debt Fund II Holdings Cayman LP, 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, Corsicanto DAC (in liquidation) (formerly Corsicanto Limited), or Corsicanto, issued \$150.0 million in aggregate principal amount of 3.5% exchangeable senior notes due 2032, or the 2012 Notes. 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. In November 2015, we issued \$31.3 million in aggregate principal amount of 3.5% exchangeable senior notes due 2032, or the 2015 Notes, and used \$16.2 million of the proceeds to repay a portion of the 2012 Notes, such that \$15.1 million of 2012 Notes remained outstanding. In September 2016, we mandatorily exchanged the entirety of the 2014 Notes and 2015 Notes, in accordance with their respective terms, into 60,311,188 ADSs. In January 2017, approximately \$15.0 million of the 2012 Notes were put to us and in March 2017, we redeemed the entirety of the remaining \$0.1 million of outstanding principal amount of 2012 Notes plus accrued but unpaid interest, such that no 2012 Notes remain outstanding. A liquidator was appointed to Corsicanto on September 7, 2017 pursuant to a resolution of Amarin Corporation plc as sole shareholder.

In January 2017, Corsicanto II DAC, or Corsicanto II, issued \$30.0 million in aggregate principal amount of 3.5% exchangeable senior notes due 2047, or the 2017 Notes. On October 19, 2018, we announced that Corsicanto II exercised its option to mandatorily exchange the entirety of the 2017 Notes into ADSs. When completed on November 2, 2018, the mandatory exchange will result in extinguishment of the debt and issuance of an aggregate amount of 7,716,048 ADSs, subject to certain adjustments as provided in the 2017 Notes.

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 October 30, 2018, we had 307,461,189 common shares outstanding including 303,882,906 shares held as ADSs and 358,685 held as ordinary 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 seek to sell substantial amounts of our ADSs, particularly if these sales are in a rapid or disorderly manner, or other investors perceive that these sales could occur, the market price of our ADSs could decrease significantly.

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

- developments or disputes concerning ongoing patent prosecution efforts and any future patent or proprietary rights;
- litigation and regulatory developments in the United States affecting our Vascepa promotional rights, and regulatory developments in 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 and during the three months ended September 30, 2018, 38,867,180 preferred shares were converted, resulting in the issuance of 3,886,718 ordinary shares. The consolidation and redesignation of the Series A Preference Shares currently outstanding would result in an additional 28,931,746 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.

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.

***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 through 2017. Our status as a PFIC is subject to change in 2018 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 December 2012 Purchase and Sale Agreement could adversely affect our financial results and liquidity.***

Pursuant to our December 2012 Purchase and Sale Agreement with CPPIB, which was assigned to CPPIB by BioPharma Secured Debt Fund II Holdings Cayman LP in December 2017, we are obligated to make payments 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 CPPIB'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 CPPIB.

Upon a transaction resulting in a change of control of Amarin, as defined in the agreement, CPPIB 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 CPPIB and (iii), unless CPPIB 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 CPPIB 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 CPPIB 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 as of September 30, 2018 consisted of \$30.0 million in aggregate principal amount of 3.5% exchangeable senior notes due 2047, or the 2017 Notes. On October 19, 2018, we announced that we exercised our option to mandatorily exchange the entirety of the 2017 Notes into ADSs. When completed on November 2, 2018, the mandatory exchange will result in extinguishment of the debt and issuance of an aggregate amount of 7,716,048 ADSs, subject to certain adjustments as provided in the 2017 Notes, such that we will have no outstanding debt or related interest obligations.

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 2017 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.

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.

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

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

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

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

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

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

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

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

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

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

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

*Issuer Purchases of Equity Securities*

Shares purchased in the second quarter of 2018 are as follows:

<i>Period</i>	<b>Total Number of Shares Purchased (1)</b>	<b>Average Price Paid per Share (2)</b>
July 1 – 31, 2018	—	\$ —
August 1 – 31, 2018	—	—
September 1 – 30, 2018	806,071	3.67
Total	806,071	\$ 3.67

(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.

(2) Based on the closing market price per NASDAQ on the date of transaction.

**Item 6. Exhibits**

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

<b>Exhibit Number</b>	<b>Description</b>
<a href="#"><u>31.1</u></a>	<a href="#"><u>Certification of President and Chief Executive Officer (Principal Executive Officer) pursuant to Section 302 of Sarbanes-Oxley Act of 2002</u></a>
<a href="#"><u>31.2</u></a>	<a href="#"><u>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</u></a>
<a href="#"><u>32.1</u></a>	<a href="#"><u>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</u></a>
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

**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 1, 2018



## CERTIFICATION

I, John F. Thero, certify that:

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

Date: November 1, 2018

/s/ John F. Thero

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

## CERTIFICATION

I, Michael W. Kalb, certify that:

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

Date: November 1, 2018

/s/ Michael W. Kalb

Michael W. Kalb

Senior Vice President and Chief Financial Officer  
(Principal Financial Officer and Principal Accounting Officer)

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

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

- (1) The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2018, to which this Certification is attached as Exhibit 32.1 (the "Quarterly Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Quarterly Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 1, 2018

/s/ John F. Thero

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

Date: November 1, 2018

/s/ Michael W. Kalb

Michael W. Kalb  
Senior Vice President and Chief Financial Officer  
(Principal Financial Officer and Principal Accounting Officer)

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

