AMARIN CORP PLC\UK
Form 10-Q
May 03, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended March 31, 2017

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

Commission File No. 000-21392

Amarin Corporation plc

(Exact Name of Registrant as Specified in its Charter)

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

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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		Accelerated filer
Non-accelerated filer	(Do not check if smaller reporting company)	Smaller reporting company
Emerging growth company		

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

272,291,602 shares were outstanding as of May 1, 2017, including 269,557,267 shares held as American Depositary Shares (ADSs), each representing one Ordinary Share, 50 pence par value per share and 2,734,335 Ordinary Shares. In addition, 32,818,464 ordinary share equivalents were issuable in exchange for outstanding preferred shares as of May 1, 2017, for a total of 305,110,066 ordinary shares and ordinary share equivalents outstanding as of May 1, 2017.

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PART I

AMARIN CORPORATION PLC

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited, in thousands, except share amounts)

	March 31, 2017	December 31, 2016
ASSETS		
Current Assets:		
Cash and cash equivalents	$96,076	$98,251
Restricted cash	600	600
Accounts receivable, net	29,450	19,985
Inventory	23,879	20,507
Prepaid and other current assets	4,785	6,983
Total current assets	154,790	146,326
Property, plant and equipment, net	69	78
Deferred tax assets	11,082	11,082
Other long-term assets	652	741
Intangible asset, net	8,610	8,772
TOTAL ASSETS	$175,203	$166,999
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current Liabilities:		
Accounts payable	$15,117	$6,062
Accrued expenses and other current liabilities	44,434	37,720
Current portion of exchangeable senior notes, net of discount	192	15,351
Current portion of long-term debt from royalty-bearing instrument	17,004	15,944
Deferred revenue, current	1,197	1,172
Total current liabilities	77,944	76,249
Long-Term Liabilities:		
Exchangeable senior notes, net of discount	28,831	—
Long-term debt from royalty-bearing instrument	82,405	85,155
Deferred revenue, long-term	13,625	13,943
Other long-term liabilities	1,167	710
Total liabilities	203,972	176,057
Commitments and contingencies (Note 6)		
Stockholders' Deficit:		
Series A Convertible Preferred Stock, £0.05 par, unlimited authorized; 328,184,640 shares issued and outstanding as of March 31, 2017 and December 31, 2016 (equivalent to 32,818,464 ordinary shares upon future consolidation and redesignation at a 10:1 ratio)	24,364	24,364
Common stock, £0.50 par, unlimited authorized; 272,261,602 issued, 270,695,420	208,465	207,166

outstanding as of March 31, 2017; 270,183,201 issued, 269,363,696 outstanding as of December 31, 2016		
Additional paid-in capital	967,073	964,914
Treasury stock; 1,566,182 shares as of March 31, 2017; 819,505 shares as of December 31, 2016	(3,726)	(1,498)
Accumulated deficit	(1,224,945)	(1,204,004)
Total stockholders' deficit	(28,769)	(9,058)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	$175,203	$166,999

See notes to condensed consolidated financial statements.

AMARIN CORPORATION PLC

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited, in thousands, except per share amounts)

	Three months ended March 31,	
	2017	2016
Product revenue, net	$34,344	$25,307
Licensing revenue	293	236
Total revenue, net	34,637	25,543
Less: Cost of goods sold	8,198	6,896
Gross margin	26,439	18,647
Operating expenses:		
Selling, general and administrative	34,171	28,020
Research and development	10,823	13,730
Total operating expenses	44,994	41,750
Operating loss	(18,555)	(23,103)
Loss on change in fair value of derivative liabilities	—	(1,250)
Interest expense, net	(2,381)	(5,586)
Other expense, net	(5)	(121)
Loss from operations before taxes	(20,941)	(30,060)
Benefit from income taxes	—	289
Net loss	$(20,941)	$(29,771)
Loss per share:		
Basic	$(0.08)	$(0.16)
Diluted	$(0.08)	$(0.16)
Weighted average shares:		
Basic	270,163	184,052
Diluted	270,163	184,052

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
December 31, 2016	328,184,640	270,183,201	(819,505)	$24,364	$207,166	$964,914	$(1,498)	$(1,204,004)	$(9,058)
Exercise of stock options	—	172,027	—	—	107	189	—	—	296
Vesting of restricted stock units	—	1,906,374	(746,677)	—	1,192	(1,192)	(2,228)	—	(2,228)
Stock-based compensation	—	—	—	—	—	3,162	—	—	3,162
Loss for the period	—	—	—	—	—	—	—	(20,941)	(20,941)
March 31, 2017	328,184,640	272,261,602	(1,566,182)	$24,364	$208,465	$967,073	$(3,726)	$(1,224,945)	$(28,769)

See notes to condensed consolidated financial statements.

AMARIN CORPORATION PLC

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited, in thousands)

	Three Months Ended March 31,	
	2017	2016
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$(20,941)	$(29,771)
Adjustments to reconcile loss to net cash used in operating activities:		
Depreciation and amortization	21	44
Loss on sale of fixed assets	—	48
Stock-based compensation	3,351	3,597
Amortization of debt discount and debt issuance costs	563	2,473
Amortization of intangible asset	162	161
Loss on change in fair value of derivative liabilities	—	1,250
Deferred income taxes	—	(446)
Changes in assets and liabilities:		
Accounts receivable, net	(9,465)	(1,193)
Inventory	(3,372)	(2,359)
Prepaid and other current assets	2,198	(2,953)
Other long-term assets	89	—
Accrued interest payable	(2,267)	(2,015)
Deferred revenue	(293)	1,763
Accounts payable and other current liabilities	15,580	4,531
Other long-term liabilities	457	(35)
Net cash used in operating activities	(13,917)	(24,905)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of equipment	(12)	(21)
Net cash used in investing activities	(12)	(21)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of convertible debt	30,000	—
Payment of debt issuance costs	(1,207)	—
Proceeds from exercise of stock options, net of transaction costs	296	22
Repurchase of exchangeable senior notes	(15,107)	—
Taxes paid related to stock-based awards	(2,228)	(694)
Net cash provided by (used in) financing activities	11,754	(672)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(2,175)	(25,598)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	98,251	106,961
CASH AND CASH EQUIVALENTS, END OF PERIOD	$96,076	$81,363
Supplemental disclosure of cash flow information:		
Cash paid during the year for:		
Interest	$4,111	$5,138
Income taxes	$64	$267

See notes to condensed consolidated financial statements.

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AMARIN CORPORATION PLC

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

(1) Nature of Business and Basis of Presentation

Nature of Business

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

The Company’s lead product, Vascepa® (icosapent ethyl) capsules, is approved by the U.S. Food and Drug Administration, or FDA, for use as an adjunct to diet to reduce triglyceride levels in adult patients with severe (TG >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 size capsule. 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 >200 mg/dL and <500 mg/dL), which the Company also refers to as persistently high triglycerides. This expanded promotion of Vascepa commenced pursuant to a federal court order and is continuing pursuant to an agreement among the Company, the FDA and the U.S. government. The Company sells Vascepa principally to a limited number of major wholesalers, as well as selected regional wholesalers and specialty pharmacy providers, or collectively, its Distributors or its customers, that in turn resell Vascepa to retail pharmacies for subsequent resale to patients and healthcare providers. The Company markets Vascepa through its direct sales force of approximately 150 sales professionals, including sales representatives and their managers. In May 2014, Kowa Pharmaceuticals America, Inc. commenced co-promotion of Vascepa in accordance with a co-promotion agreement with the Company. Kowa Pharmaceuticals America, Inc. co-promotes Vascepa through its no less than 250 sales representatives who now devote a substantial portion of their time to promoting Vascepa in conjunction with the promotion of Kowa Pharmaceutical America, Inc.’s primary product, a branded statin for patients with high cholesterol. The Company operates in one business segment.

The Company is also developing Vascepa for FDA approval of potential additional indications for use. In particular, the Company is conducting a cardiovascular outcomes study of Vascepa, titled REDUCE-IT (Reduction of Cardiovascular Events with EPA—Intervention Trial). The REDUCE-IT study, which commenced in 2011 and completed patient enrollment and randomization of 8,175 individual patients in 2016, is designed to evaluate the efficacy of Vascepa in reducing major cardiovascular events in a high-risk patient population on statin therapy.

Basis of Presentation

The condensed consolidated financial statements included herein have been prepared by the Company, without audit, in accordance with accounting principles generally accepted in the United States of America (the “U.S.” or the “United States”) and pursuant to the rules and regulations of the Securities and Exchange Commission, or the SEC. Certain information in the footnote disclosures of the financial statements has been condensed or omitted where it substantially duplicates information provided in the Company’s latest audited consolidated financial statements, in accordance with the rules and regulations of the SEC. These condensed consolidated financial statements should be read in conjunction with the Company’s audited consolidated financial statements and notes included in its Annual Report on Form 10-K for the fiscal year ended December 31, 2016, or the 2016 Form 10-K, filed with the SEC. The balance sheet amounts at December 31, 2016 in this report were derived from the Company’s audited 2016 consolidated financial statements included in the 2016 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 months ended March 31, 2017 and 2016, respectively, are not necessarily indicative of the results for the entire fiscal year or any future period. Certain numbers presented throughout this document may not add precisely to the totals provided due to rounding. Absolute and percentage changes are calculated using the underlying amounts in thousands. Certain prior year balances have been reclassified to conform to current year presentation due primarily to the Company's adoption of recent accounting pronouncements related to the cash flow presentation of excess tax benefits. These reclassifications do not have a material impact on the Company's condensed consolidated financial statements.

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.

At March 31, 2017, the Company had cash and cash equivalents of $96.1 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 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 long-term debt and exchangeable senior notes do not represent a short-term claim on the liquid assets of the Company as of March 31, 2017. The terms of the Company's January 2012 3.5% exchangeable senior notes due 2032, or the 2012 Notes, which were repaid in full during the first quarter of 2017, allowed for repurchase in cash by the Company at the option of the holders on January 19, 2017, as well as redemption by the Company for cash of all or part of the 2012 Notes on or after January 19, 2017, both at a price equal to 100% of the principal amount of the 2012 Notes to be repurchased or redeemed, plus accrued and unpaid interest to, but excluding, the repurchase or redemption date. Accordingly, $15.1 million in principal amount of 2012 Notes represents a short-term claim on the liquid assets of the Company as of December 31, 2016.

The Company believes its cash and cash equivalents will be sufficient to fund its projected operations through the results of the REDUCE-IT study, which we anticipate will be available mid-2018. Depending on the level of cash generated from operations, additional capital may be required to sustain operations, fund debt obligations or expand promotion of Vascepa as contemplated following anticipated successful results of the REDUCE-IT study. The Company anticipates that annual 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

The Company sells Vascepa principally to a limited number of major wholesalers, as well as selected regional wholesalers and specialty pharmacy providers, or collectively, its Distributors or its customers, that in turn resell Vascepa to retail pharmacies for subsequent resale to patients and healthcare providers. Patients are required to have a prescription in order to purchase Vascepa. In accordance with GAAP, the Company's revenue recognition policy requires that: (i) there is persuasive evidence that an arrangement

exists between the Company and the Distributor, (ii) delivery has occurred, (iii) collectability is reasonably assured and (iv) the price is fixed or determinable.

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

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

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

Product Returns: The Company’s Distributors have the right to return unopened unprescribed Vascepa during the 18-month period beginning six months prior to the labeled expiration date and ending twelve months after the labeled expiration date. The expiration date for Vascepa is three years after it has been converted into capsule form, which is the last step in the manufacturing process for Vascepa and generally occurs within a few months before Vascepa is delivered to Distributors. The Company estimates future product returns on sales of Vascepa based on: (i) data provided to the Company by its Distributors (including weekly reporting of Distributors’ sales and inventory held by Distributors that provided the Company with visibility into the distribution channel in order to determine what quantities were sold to retail pharmacies and other providers), (ii) information provided to the Company from retail pharmacies, (iii) data provided to the Company by a third-party data provider which collects and publishes prescription data, and other third parties, (iv) historical industry information regarding return rates for similar pharmaceutical products, (v) the estimated remaining shelf life of Vascepa previously shipped and currently being shipped to Distributors and (vi) contractual agreements intended to limit the amount of inventory maintained by the Company’s Distributors.

Other Incentives: Other incentives that the Company offers to indirect customers include co-pay mitigation rebates provided by the Company to commercially insured patients who have coverage for Vascepa and who reside in states that permit co-pay mitigation programs. The Company’s co-pay mitigation program is intended to reduce each participating patient’s portion of the financial responsibility for Vascepa’s purchase price to a specified dollar amount. Based upon the terms of the program and information regarding programs provided for similar specialty

pharmaceutical products, the Company estimates the average co-pay mitigation amounts and the percentage of patients that it expects to participate in the program in order to establish its accruals for co-pay mitigation rebates and deducts these estimated amounts from its gross product revenues at the time the revenues are recognized. The Company adjusts its accruals for co-pay mitigation rebates based on actual redemption activity and estimates regarding the portion of issued co-pay mitigation rebates that it estimates will be redeemed.

The following tables summarize activity in each of the net product revenue allowance and reserve categories described above for the three months ended March 31, 2017 and 2016:

In thousands	Trade Allowances	Rebates, Chargebacks and Discounts	Product Returns	Other Incentives	Total
Balance at December 31, 2016	$ 3,743	$ 20,915	$ 859	$ 1,681	$ 27,198
Provision related to current period sales	6,621	19,670	1,028	3,107	30,426
Provision related to prior period sales	(298)	(702)	—	(82)	(1,082)
Credits/payments made for current period sales	(2,357)	(727)	—	(1,332)	(4,416)
Credits/payments made for prior period sales	(3,107)	(15,376)	(9)	(1,770)	(20,262)
Balance at March 31, 2017	$ 4,602	$ 23,780	$ 1,878	$ 1,604	$ 31,864

In thousands	Trade Allowances	Rebates, Chargebacks and Discounts	Product Returns	Other Incentives	Total
Balance at December 31, 2015	$ 4,296	$ 9,881	$ 535	$ 1,084	$ 15,796
Provision related to current period sales	4,218	11,455	107	2,529	18,309
Provision related to prior period sales	(274)	(435)	—	—	(709)
Credits/payments made for current period sales	(1,463)	(1,228)	—	(322)	(3,013)
Credits/payments made for prior period sales	(2,734)	(6,418)	(82)	(1,284)	(10,518)
Balance at March 31, 2016	$ 4,043	$ 13,255	$ 560	$ 2,007	$ 19,865

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

Multiple-Element Arrangements and Licensing Revenue

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

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

The Company may receive up-front, non-refundable payments when licensing its intellectual property in conjunction with research, development and commercialization agreements. In determining the units of accounting, management evaluates whether the license has stand-alone value from the undelivered elements to the collaborative partner based

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

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

Milestones

Contingent consideration from activities that is earned upon the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved. At the inception of each arrangement that includes milestone payments, the Company evaluates whether each milestone is substantive. This evaluation includes an assessment of whether: (a) the consideration is commensurate with either (1) the entity's performance to achieve the milestone, or (2) the enhancement of the value of the delivered

item(s) as a result of a specific outcome resulting from the entity's performance to achieve the milestone, (b) the consideration relates solely to past performance and (c) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. The Company evaluates factors such as the scientific, clinical, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement in making this assessment.

See Note 9—Development, Commercialization and Supply Agreements for further information regarding licensing revenue and milestones primarily related to the Company's multiple-element arrangement with Eddingpharm (Asia) Macao Commercial Offshore Limited.

Distribution Costs

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

Cash and Cash Equivalents and Restricted Cash

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

Accounts Receivable, net

Accounts receivable, net, comprised of trade receivables, are generally due within 30 days and are stated at amounts due from customers. The Company recognizes an allowance for losses on accounts receivable in an amount equal to the estimated probable losses net of any recoveries. The allowance is based primarily on assessment of specific identifiable customer accounts considered at risk or uncollectible, as well as an analysis of current receivables aging and expected future write-offs. The expense associated with the allowance for doubtful accounts is recognized as selling, general, and administrative expense. The Company has not historically experienced any credit losses.

The following table summarizes the impact of accounts receivable reserves on the gross trade accounts receivable balances as of March 31, 2017 and December 31, 2016:

In thousands	March 31, 2017	December 31, 2016
Gross trade accounts receivable	$34,468	$ 24,127
Trade allowances	(4,602)	(3,743)
Chargebacks	(404)	(387)
Allowance for doubtful accounts	(12)	(12)
Accounts receivable, net	$29,450	$ 19,985

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:

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

Upon retirement or sale of assets, the cost of the assets disposed and the related accumulated depreciation are removed from the 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.

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 accrued under the agreement with Kowa Pharmaceuticals America, Inc.

Income Taxes

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

The Company provides reserves for potential payments of tax to various tax authorities or does not recognize tax benefits related to uncertain tax positions and other issues. Tax benefits for uncertain tax positions are based on a determination of whether a tax benefit

taken by the Company in its tax filings or positions is more likely than not to be realized, assuming that the matter in question will be decided based on its technical merits. The Company's policy is to record interest and penalties in the provision for income taxes.

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

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. Prior to adoption of ASU No. 2016-09, Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting in April 2016, such amounts were recognized as an increase and decrease in additional paid-in capital. Excess income tax benefits and deficiencies are classified in 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. Due to adoption of ASU No. 2016-09 and retrospective application of the aspects of the standard related to cash flow presentation, the Company reclassified $0.1 million of excess tax provision from cash flows provided by financing activities to cash flows used in operating activities in the condensed consolidated statement of cash flows for the three months ended March 31, 2016, to conform to the current year presentation.

The Company's and its subsidiaries' income tax returns are periodically examined by various tax authorities. The Company is currently under audit by the United States Internal Revenue Service (IRS) for the years 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.

Derivative Instruments

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

Loss per Share

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

The Company's preferred stock is entitled to receive dividends on an as-if-converted basis in the same form as dividends actually paid on common shares. Accordingly, the preferred stock is considered a participating security and the Company is required to apply the two-class method to consider the impact of the preferred stock on the calculation

of basic and diluted earnings per share. The Company is currently in a net loss position and is therefore not required to present the two-class method, however, in the event the Company is in a net income position, the two-class method must be applied by allocating all earnings during the period to common shares and preferred stock based on their contractual entitlements assuming all earnings were distributed.

The calculation of net loss and the number of shares used to compute basic and diluted net loss per share for the three months ended March 31, 2017 and 2016 are as follows:

In thousands	March 31, 2017	March 31, 2016
Net loss—basic and diluted	$(20,941)	$(29,771)
Weighted average shares outstanding—basic and diluted	270,163	184,052
Net loss per share—basic and diluted	$(0.08)	$(0.16)

For the three months ended March 31, 2017 and 2016, the following potentially dilutive securities were not included in the computation of net loss per share because the effect would be anti-dilutive:

In thousands	March 31, 2017	March 31, 2016
Stock options	23,461	20,807
Restricted stock and restricted stock units	9,812	10,673
Exchangeable senior notes (if converted)	7,716	59,407
Preferred stock (if converted)	32,818	32,818

Debt Instruments

Debt instruments are initially recorded at fair value, with coupon interest and amortization of debt issuance discounts recognized in the condensed consolidated statement of operations as interest expense each period in which such instruments are outstanding. If the Company issues shares to discharge the liability, the debt obligation is derecognized and common stock and additional paid-in capital are recognized on the issuance of those shares.

The 2012 Notes could be settled in any combination of ADSs or cash, at the Company's discretion, upon conversion and were therefore accounted for in accordance with ASC 470-20. Under ASC 470-20, the fair value of the liability component of the 2012 Notes was determined and deducted from the initial proceeds to determine the proceeds allocated to the conversion option, which was recorded in equity. The difference between the initial fair value of the liability component and the amount repayable was fully amortized over the expected term of the instrument. The conversion feature in the 2012 Notes qualified for the exception from derivative accounting in accordance with ASC 815-40. The terms of the 2012 Notes also allowed 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. Consequently, in January 2017, holders of 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 March 31, 2017. The carrying value of the conversion option will remain in equity hereafter as a result of the repayment in full of the related debt instrument.

The 2017 Notes can only be settled in ADSs upon conversion and are therefore accounted for as part of the debt host. 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. 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 full discussion of the 2012 Notes and 2017 Notes.

Stock-Based Compensation

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

Concentration of Credit Risk

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

A significant portion of the Company's sales are to wholesalers in the pharmaceutical industry. The Company monitors the creditworthiness of customers to whom it grants credit terms and has not experienced any credit losses. The Company does not require collateral or any other security to support credit sales. The Company's top three customers accounted for 95% of gross product sales for each of the three months ended March 31, 2017 and 2016 and represented 97% and 95% of the gross accounts receivable balance as of March 31, 2017 and 2016, respectively. The Company has not experienced any write-offs of its accounts receivable.

Concentration of Suppliers

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

The Company cannot provide assurance that its efforts to procure uninterrupted supply of Vascepa API to meet market demand will continue to be successful or that it will be able to renew current API supply agreements on favorable terms or at all. Significant alteration to or termination of the Company's current API supply chain or its failure to enter into new and similar agreements 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 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, net in the condensed consolidated statements of operations. For transactions settled during the applicable period, gains and losses are included in other expense, net in the condensed consolidated statements of operations. Certain amounts payable pursuant to supply contracts are denominated in currencies other than the U.S. dollar.

Debt Issuance Costs

The Company records debt issuance costs related to a recognized debt liability in the condensed consolidated balance sheet as a direct deduction from the carrying amount of that debt liability and amortizes such costs 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, net in the condensed consolidated statements of operations.

Fair Value of Financial Instruments

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

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

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

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 March 31, 2017 and December 31, 2016 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:

	March 31, 2017			
In thousands	Total	Level 1	Level 2	Level 3
Asset:				
Cash equivalents—money market	$9,293	$9,293	$ —	$ —

	December 31, 2016			
In thousands	Total	Level 1	Level 2	Level 3
Asset:				
Cash equivalents—money market	$14,238	$14,238	$ —	$ —

The carrying amounts of cash, cash equivalents, accounts payable and accrued liabilities approximate fair value because of their short-term nature. The carrying amounts and the estimated fair values of debt instruments as of March 31, 2017 and December 31, 2016 are as follows:

	March 31, 2017		December 31, 2016	
In thousands	Carrying Value	Estimated Fair Value	Carrying Value	Estimated Fair Value
Current portion of long-term debt from royalty-bearing instrument, net of accrued interest	$11,713		$8,437	
Long-term debt from royalty-bearing instrument	82,405		85,155	
Total long-term debt from royalty-bearing instrument	$94,118	$ 90,600	$93,592	$ 90,500
2012 Notes	—	—	15,107	15,174
2017 Notes	28,831	31,900	—	—

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 2012 Notes as of December 31, 2016 does not include a debt discount, as it had been fully amortized as non-cash interest expense over the expected term of the 2012 Notes, which was calculated to be a period of twenty-four months. During the three months ended March 31, 2017, the Company repurchased $15.0 million in aggregate principal amount of 2012 Notes at the option of holders and redeemed the remaining $0.1 million in aggregate principal amount at the Company's option, such that no 2012 Notes remained outstanding as of March 31, 2017. The carrying value of the 2017 Notes as of March 31, 2017 includes a debt discount of $1.2 million, 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. The change in the estimated fair values of these liabilities from December 31, 2016 to March 31, 2017 is largely related to financing activities and changes in the quoted bond prices.

Derivative Liabilities

The Company's December 2012 financing agreement with BioPharma Secured Debt Fund II Holdings Cayman LP (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 March 31, 2017, the fair value of the derivative was determined to be nil based on current assumptions, and the debt was valued by comparing debt issues of similar companies with (i) remaining terms of between 2.1 and 4.7 years, (ii) coupon rates of between 8.1% and 11.1% and (iii) market yields of between 10.5% and 18.8%. As of December 31, 2016, 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 2.4 and 5.0 years, (ii) coupon rates of between 8.1% and 11.1% and (iii) market yields of between 11.9% and 18.4%. As such, the Company recognized no gain or loss on change in fair value of derivative liability for the three months ended March 31, 2017. As of March 31, 2016, the fair value of the derivative was determined to be $5.9 million and, as of December 31, 2015, the fair value of the derivative was determined to be $5.5 million. As such, the Company recognized a $0.4 million loss on change in fair value of derivative liability for the three months ended March 31, 2016.

The Company’s 2014 Notes and 2015 Notes each contained a redemption feature whereby, upon occurrence of a change in control, the Company would have been required to repurchase the notes. The Company determined these redemption features to be embedded derivatives, requiring bifurcation in accordance with ASC 815. The derivatives were carried at fair value and were classified as Level 3 in the fair value hierarchy due to the use of significant unobservable inputs. The fair value of each embedded derivative was calculated using a probability-weighted model incorporating management estimates of the probability of a change in control

occurring, and by determining the fair value of the debt with and without the change in control provision included. The difference between the two was determined to be the fair value of the embedded derivative. The fair value of these derivative liabilities was remeasured at each reporting period, with changes in fair value recognized in the condensed consolidated statement of operations. These derivative liabilities were derecognized in September 2016 and therefore no gain or loss on change in fair value of derivative liability was recognized for the three months ended March 31, 2017. As of March 31, 2016, the fair values of the derivatives related to the 2014 Notes and 2015 Notes were determined to be $2.8 million and $0.7 million, respectively, and, as of December 31, 2015, the fair values of the derivatives related to the 2014 Notes and 2015 Notes were determined to be $2.1 million and $0.6 million, respectively. As such, the Company recognized a $0.7 million loss and $0.1 million loss on change in fair value of derivative liability for the 2014 Notes and 2015 Notes, respectively, for the three months ended March 31, 2016.

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. The Company considered the following recent accounting pronouncements which were not yet adopted as of March 31, 2017:

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606), which will replace numerous requirements in U.S. GAAP, including industry-specific requirements. This guidance provides a five step model to be applied to all contracts with customers, with an underlying principle that an entity will recognize revenue to depict the transfer of goods or services to customers at an amount that the entity expects to be entitled to in exchange for those goods or services. ASU No. 2014-09 requires extensive quantitative and qualitative disclosures covering the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including disclosures on significant judgments made when applying the guidance. This guidance is effective for annual reporting periods beginning after December 15, 2017 and interim periods therein. Early adoption is permitted for reporting periods and interim periods therein, beginning after December 15, 2016. An entity can elect to apply the guidance under one of the following two methods: (i) retrospectively to each prior reporting period presented, referred to as the full retrospective method, or (ii) retrospectively with the cumulative effect of initially applying the standard recognized at the date of initial application in retained earnings, referred to as the modified retrospective method.

The Company has substantially completed an initial impact assessment of the potential changes from adopting ASU No. 2014-09. The impact assessment consisted of a review of a representative sample of contracts, discussions with key stakeholders, and a cataloging of potential impacts on its financial statements, accounting policies, financial control, and operations. The Company anticipates that the adoption of ASU No. 2014-09 will not have a material impact on product revenue from distributors and may have an impact on contract revenues generated by its license agreements:

(i) Changes in the model for distinct licenses of functional intellectual property which may result in a timing difference of revenue recognition. Whereas revenue from these arrangements was previously recognized over a

period of time pursuant to the multiple element arrangement guidance, revenue from these arrangements may now be recognized at a point in time under the new guidance.

(ii) Assessments of milestone payments, which are linked to events that are in the Company's control, will result in variable consideration that may be recognized at an earlier point in time under the new guidance, when it is probable that the milestone will be achieved without a significant future reversal of cumulative revenue expected.

The Company has not yet completed its final review of the impact of this guidance; however, the Company anticipates applying the modified retrospective method when implementing this guidance. The Company plans to adopt the new standard effective January 1, 2018. The Company continues to monitor additional changes, modifications, clarifications or interpretations being undertaken by the FASB, which may impact its current conclusions.

In January 2016, the FASB issued ASU No. 2016-01, Financial Instruments—Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities. The new guidance is intended to improve the recognition and

measurement of financial instruments by requiring separate presentation of financial assets and financial liabilities by measurement category and form of financial asset (i.e., securities or loans and receivables) within the balance sheet or the accompanying notes to the financial statements, eliminating the requirement for public business entities to disclose the method(s) and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost within the balance sheet, requiring public business entities to use the exit price notion when measuring the fair value of financial instruments for disclosure purposes, requiring equity investments (except those accounted for under the equity method of accounting, or those that result in consolidation of the investee) to be measured at fair value with changes in fair value recognized in net income, and requiring a reporting organization to present separately in other comprehensive income the portion of the total change in the fair value of a liability resulting from a change in the instrument-specific credit risk (also referred to as “own credit”) when the organization has elected to measure the liability at fair value in accordance with the fair value option for financial instruments, among others. The new guidance is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. The new guidance permits early adoption of the own credit provision. The Company is currently evaluating the accounting, transition and disclosure requirements of the standard and cannot currently estimate the financial statement impact of adoption.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842). The new guidance will require lessees to recognize a right-of-use asset and a lease liability for virtually all of their leases (other than leases that meet the definition of a short-term lease). The liability will be equal to the present value of lease payments. The asset will be based on the liability, subject to adjustment, such as for initial direct costs. Under the new guidance, lessor accounting is largely unchanged but certain targeted improvements were made to align, where necessary, lessor accounting with the lessee accounting model and Topic 606, Revenue from Contracts with Customers. The new lease guidance also simplified the accounting for sale and leaseback transactions primarily because lessees must recognize lease assets and lease liabilities and therefore, will no longer be provided with a source of off-balance sheet financing. The new guidance is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the accounting, transition and disclosure requirements of the standard and cannot currently estimate the financial statement impact of adoption.

In March 2016, the FASB issued ASU No. 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net), which clarifies that an entity is a principal when it controls the specified good or service before that good or service is transferred to the customer, and is an agent when it does not control the specified good or service before it is transferred to the customer. The new guidance is intended to improve the operability and understandability of the implementation guidance on principal versus agent considerations. In April 2016, the FASB issued ASU No. 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing, which clarifies the following two aspects of Topic 606: (a) identifying performance obligations; and (b) the licensing implementation guidance. Further, in May 2016, the FASB issued ASU No. 2016-12, Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients, which provides clarifying guidance in certain narrow areas and adds some practical expedients. The amendments do not change the core principles of the guidance in Topic 606 and are effective for the Company’s fiscal year beginning January 1, 2018. Early application is permitted only as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period. The Company is currently evaluating the accounting, transition and disclosure requirements of these standards and cannot currently estimate the financial statement impact of adoption.

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. For each of these ASUs, the new guidance is effective for fiscal years beginning after December 15, 2017, including interim periods within

those fiscal years, with early adoption permitted. The Company has evaluated the accounting, transition and disclosure requirements of these standards and does not expect them to have a material impact on the Company’s consolidated financial statements.

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

(3) Intangible Assets

Intangible assets consist of the historical acquisition cost of certain technology rights for Vascepa and have an estimated remaining useful life of 13.3 years. The carrying value as of March 31, 2017 and December 31, 2016 is as follows:

In thousands	March 31, 2017	December 31, 2016
Technology rights	$11,624	$ 11,624
Accumulated amortization	(3,014)	(2,852)
	$8,610	$ 8,772

(4) Inventory

The Company capitalizes its purchases of saleable inventory of Vascepa from suppliers that have been qualified by the FDA. Inventories as of March 31, 2017 and December 31, 2016 consist of the following:

In thousands	March 31, 2017	December 31, 2016
Raw materials	$12,391	$ 4,430
Work in process	2,815	10,716
Finished goods	8,673	5,361
Total inventory	$23,879	$ 20,507

(5) Debt

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

On December 6, 2012, the Company entered into an agreement with BioPharma Secured Debt Fund II Holdings Cayman LP, or BioPharma. Under this agreement, the Company granted to BioPharma a security interest in future receivables associated with the Vascepa patent rights, in exchange for $100.0 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 by BioPharma as collateral for repayment of the remaining unpaid balance under this agreement if the Company defaults on making required payments. In the agreement, the Company agreed to repay BioPharma up to $150.0 million with such repayment based on a portion of revenues and receivables generated from Vascepa.

As of March 31, 2017, the remaining amount to be repaid to BioPharma is $121.7 million. During the three months ended March 31, 2017, the Company made repayments under the agreement of $3.8 million to BioPharma and an additional $3.4 million is scheduled to be paid in May 2017 for the first quarter of 2017. All payments to date have been calculated based on the threshold limitation, as described below, as opposed to the contractual quarterly repayments scheduled through May 2017. Additional quarterly repayments are scheduled to be paid after May 2017, subject only to the threshold limitation. All such payments reduce the remainder of the $150.0 million in aggregate payments to BioPharma.

These quarterly payments are subject to a quarterly threshold amount whereby, if a calculated threshold, based on quarterly Vascepa revenues, is not achieved, the quarterly payment payable in that quarter can, at the Company's election, be reduced, with the reduction carried forward without interest for payment in a future period. The payment of any carried forward amount is subject to similarly calculated threshold repayment amounts based on Vascepa revenue levels. Except upon a change of control in Amarin, the agreement does not expire until $150.0 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.

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

The Company determined the redemption feature upon a change of control to be an embedded derivative requiring bifurcation. The fair value of the embedded derivative was calculated by determining the fair value of the debt with the change in control provision included and also without the change in control provision. The difference between the two fair values of the debt was determined to be the fair value of the embedded derivative, and upon closing the Company recorded a derivative liability of $14.6 million as a reduction to the note payable. The fair value of this derivative liability is remeasured at each reporting period, with changes in fair value recognized in the condensed consolidated statement of operations and any changes in the assumptions used in measuring the fair value of the derivative liability could result in a material increase or decrease in its carrying value. Based on current assumptions underlying the valuation, the Company recognized no gain or loss on change in fair value of derivative liability during the three months ended March 31, 2017, as compared to a loss on change in fair value of derivative liability of $0.4 million during the three months ended March 31, 2016.

As of March 31, 2017 and December 31, 2016, the carrying value of the BioPharma debt, net of the unamortized debt discount and issuance costs, was $94.1 million and $93.6 million, respectively. During the three months ended March 31, 2017, the Company recorded cash and non-cash interest expense of $1.6 million and $0.5 million, respectively, in connection with the BioPharma debt, compared to $1.7 million and $0.5 million, respectively, during the three months ended March 31, 2016. The Company will periodically evaluate the remaining term of the agreement and the effective interest rate is recalculated each period based on the Company's most current estimate of repayment.

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

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

January 2012, 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. As of March 31, 2017, all debt issued in these transactions was exchanged or redeemed such that none remained outstanding.

In January 2012, the Company, through its wholly-owned subsidiary Corsicanto Designated Activity Company (formerly Corsicanto Limited) ("Corsicanto"), issued $150.0 million in principal amount of 3.5% Exchangeable Senior Notes due 2032 (the "2012 Notes"), resulting in net proceeds of $144.3 million. In May 2014, the Company entered into separate, privately negotiated exchange agreements with certain holders of the 2012 Notes pursuant to which Corsicanto exchanged $118.7 million in aggregate principal amount of the existing 2012 Notes for $118.7 million in aggregate principal amount of new 3.5% May 2014 Exchangeable Senior Notes due 2032 (the "2014 Notes"), following which $31.3 million in aggregate principal amount of the 2012 Notes remained outstanding with terms unchanged. In November 2015, the Company entered into a privately negotiated subscription agreement with one of its existing investors, pursuant to which the investor agreed to purchase approximately $31.3 million in aggregate principal amount of new 3.5% November 2015 Exchangeable Senior Notes due 2032 (the "2015 Notes") for approximately $27.5 million. Approximately $15.9 million of such proceeds were used to finance the repayment of $16.2 million in aggregate principal amount of the 2012 Notes, following which $15.1 million in aggregate principal amount of the 2012 Notes remained outstanding with terms unchanged. The 2012 Notes, 2014 Notes, and 2015 Notes are referred to collectively as the "Notes."

In August 2016, Corsicanto gave notice to the holders of the 2014 Notes and 2015 Notes that certain equity conditions contained within the notes had been satisfied and exercised its option to mandatorily exchange $118.7 million of aggregate principal amount of 2014 Notes and $31.3 million of aggregate principal amount of 2015 Notes for equity with settlement in September 2016, such that all of the outstanding 2014 Notes and 2015 Notes were retired at that time. Consistent with the terms of the 2014 Notes and 2015 Notes, the final as-adjusted exchange rate was 402.0746 ADSs per $1,000 of principal amount, resulting in 47,739,925 ADSs and 12,571,263 ADSs being issued in exchange for the 2014 Notes and 2015 Notes, respectively. In total, the Company mandatorily exchanged $150.0 million in aggregate principal amount ($127.3 million in carrying value, net of unamortized debt discount and issuance costs) of outstanding 2014 Notes and 2015 Notes, resulting in the issuance of 60,311,188 ADSs and recognition of $40.1 million in common stock and $87.4 million in additional paid-in capital during the year ended December 31, 2016. Included within this $87.4 million is $0.8 million of accrued but unpaid interest as of the exchange date deemed satisfied and discharged in full upon delivery of the ADSs consistent with the terms of the notes and ASC 470-20, less $0.7 million of transaction costs.

The terms of the 2012 Notes allowed for repurchase in cash by the Company at the option of the holders on each of January 19, 2017, January 19, 2022, and January 19, 2027, as well as redemption by the Company for cash of all or part of the 2012 Notes on or after

January 19, 2017, both at a price equal to 100% of the principal amount of the 2012 Notes to be repurchased or redeemed, plus accrued and unpaid interest to, but excluding, the repurchase or redemption date. Consequently, in January 2017, holders of 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 March 31, 2017.

The 2012 Notes were exchangeable under certain circumstances into cash, ADSs, or a combination of cash and ADSs, at the Company's election. At the time of issuance, the Company calculated the fair value of the liability component of the 2012 Notes to be $126.2 million and the excess of the principal amount of the debt over the liability component of $23.8 million was allocated to the conversion option, resulting in a discount on the debt and corresponding increase in equity as a result of the cash settlement feature. The Company also recorded a debt discount to reflect the value of the underwriter's discounts and offering costs. The debt discount from underwriter's discounts and offering costs was allocated to the equity and liability components of the 2012 Notes in proportion to the proceeds allocated to each component. The $23.8 million equity component allocated to the conversion option was reduced by the portion of offering costs allocated to the equity component, $10.1 million upon extinguishment of the 2012 Notes as part of the 2014 Notes exchange and $1.3 million upon extinguishment of the 2012 Notes as part of the 2015 Notes issuance, such that $11.5 million remained in equity as of both March 31, 2017 and December 31, 2016. The conversion option was not remeasured each reporting period as it continued to meet the criteria for equity classification, and will remain in equity hereafter as a result of the repayment in full of the related debt instrument during the first quarter of 2017.

The portion of the debt discount from underwriter's discounts and offering costs allocated to the liability component as well as the discount created from allocating proceeds to the conversion option were amortized as interest expense over the estimated life of the 2012 Notes of twenty-four months. Such discounts were fully amortized prior to 2016. The carrying value of the 2012 Notes was nil and $15.1 million as of March 31, 2017 and December 31, 2016, respectively, included within current portion of exchangeable senior notes, net of discount, due to the holders' January 19, 2017 optional put date.

The 2014 Notes were recorded at fair value of $90.8 million representing a $27.9 million discount to par. In addition the Company recognized a discount of $2.5 million in underwriter's fees and offering costs. The 2015 Notes were recorded at fair value of $27.5 million representing a $3.8 million discount to par. In addition, the Company recognized a discount of $0.1 million in offering costs. These discounts were amortized as interest expense over the expected terms of the 2014 Notes and 2015 Notes, which was expected to be through the first optional put date in January 2019 for each. The carrying value of the 2014 Notes and 2015 Notes was nil as of March 31, 2017 and December 31, 2016.

The 2014 Notes and 2015 Notes contained a provision that if a fundamental change (as defined in the 2014 Notes and 2015 Notes) had occurred prior to the notes being exchanged, holders may have required the Company to repurchase all or part of their notes for cash at a fundamental change repurchase price equal to 100% of the aggregate principal amount of the 2014 Notes and 2015 Notes to be repurchased, plus accrued and unpaid interest to, but not including, the fundamental change repurchase date. The Company determined that these fundamental change redemption features represented embedded derivatives requiring bifurcation from the respective debt liabilities and allocated $3.5 million of the $90.8 million fair value of the 2014 Notes and $0.5 million of the $27.5 million fair value of the 2015

Notes to derivative liabilities. The fair value of these derivative liabilities was remeasured at each reporting period, with changes in fair value recognized in the statement of operations. During the three months ended March 31, 2016, the Company recognized a $0.7 million loss and a $0.1 million loss on the change in fair value of the redemption features of the 2014 Notes and 2015 Notes, respectively.

The Notes had a stated interest rate of 3.5% per year, payable semiannually in arrears on January 15 and July 15 of each year. During the three months ended March 31, 2016, the Company recognized aggregate interest expense of $3.4 million related to the Notes, of which $2.0 million represents non-cash interest and $1.4 million represents contractual coupon interest. During the three months ended March 31, 2017, the Company recognized cash interest expense of less than $0.1 million related to the Notes. As of March 31, 2017 and December 31, 2016, the Company had total accrued interest on the Notes of nil and $0.2 million, respectively, which is included in current portion of exchangeable senior notes, net of discount. The Company made the contractual interest payments due on the Notes during the three months ended March 31, 2017 and 2016 of $0.3 million and $2.5 million, respectively.

January 2017 Exchangeable Senior Notes

On January 20, 2017, the Company and Corsicanto II Designated Activity Company (“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.

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. Based on the closing price of the Company's stock at March 31, 2017, the principal amount of the 2017 Notes would exceed the value of the shares if converted on that date by $5.3 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 has agreed to use its 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 will be 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 sheet. 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 March 31, 2017, the carrying value of the 2017 Notes, net of unamortized discount, was $28.8 million.

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 three months ended March 31, 2017, the Company recognized interest expense of $0.2 million related to the 2017 Notes, of which less than $0.1 million represents non-cash interest and $0.2 million represents contractual coupon interest. As of March 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 sheet.

(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, 2016 includes a discussion of the Company’s current legal proceedings. There have been no material changes to those disclosures as of the date of this filing.

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 March 31, 2017, the Company has no royalty, milestone or minimum purchase commitments with Nisshin.

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 $9.4 million at March 31, 2017). 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 $6.2 million at March 31, 2017) for each of the two potential market approvals (i.e. £10 million maximum, or approximately $12.5 million at March 31, 2017).

The Company has no provision for any of the obligations above since the amounts are either not probable or able to be estimated at March 31, 2017.

(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. In 2015, at the request of the holders, a portion of the Series A Preference Shares were consolidated and redesignated, resulting in the issuance of 6,283,333 ADSs such that a maximum of 32,818,464 ordinary shares remain issuable upon future consolidation and redesignation of the remaining Series A Preference Shares as of March 31, 2017, inclusive of the shares issued in July 2015 as discussed below, subject to certain adjustments for dilutive events.

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

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

The restricted American Depositary Shares and Series A Preference Shares were sold in a transaction exempt from the registration requirements under the Securities Act of 1933, as amended (the "Securities Act"). The Company filed a registration statement with the SEC covering the resale of the restricted American Depositary Shares and the ADSs representing ordinary shares created by the consolidation and redesignation of the Series A Preference Shares (the "Registrable Securities") on April 9, 2015, which was declared effective by the SEC on May 1, 2015. In addition, the Company agreed to use its commercially reasonable best efforts to keep the registration, and any qualification, exemption or compliance under state securities laws which the Company determines to obtain, continuously effective,

and to keep the Registration Statement free of any material misstatements or omissions, until the earlier of (a) March 11, 2017 or (b) the date on which all Registrable Securities held by Purchasers may be sold or transferred in compliance with Rule 144 under the Securities Act, without any volume or manner of sale restrictions.

The Series A Preference Shares contain a contingent beneficial conversion feature ("BCF") because they contain a conversion feature at a fixed rate that was in-the-money when issued. The BCF was recorded in the quarter 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 may be consolidated and redesignated from time to time up to a maximum of 3,886,718 ordinary shares, each ordinary share to be represented by one ADS. For each restricted ADS, Sofinnova paid a negotiated price of $0.15 (equating to $1.50 on an as-if-converted-to-ordinary-shares basis) resulting in gross proceeds to the Company of $5.8 million. 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. 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.

Incentive Equity Awards

As of March 31, 2017, there were an aggregate of 23,461,406 stock options and 9,811,802 restricted stock units ("RSUs") outstanding, representing approximately 7% and 3%, respectively, of outstanding shares (including common and preferred shares) on a fully diluted basis.

During the three months ended March 31, 2017 and 2016, the Company issued 172,027 and 21,369 shares, respectively, as a result of the exercise of stock options, resulting in gross and net proceeds of $0.3 million during the three months ended March 31, 2017 and $22 thousand during the three months ended March 31, 2016.

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. The issuance of 989,000 of these RSUs is contingent upon shareholder approval to increase the aggregate number of shares authorized for issuance under the 2011 Plan, which will be put to a vote at the Company's Annual General Meeting of Shareholders to be held on May 15, 2017.

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

On February 1, 2016, the Company granted a total of 1,607,500 RSUs and 2,442,000 stock options to employees under the 2011 Plan. The RSUs vest annually over a three-year period and the stock options vest monthly over a four-year period. During the three months

ended March 31, 2017, the Company issued 494,885 common shares related to the vesting of these RSUs, of which 191,899 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 through 2018.

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

In exchange for Kowa Pharmaceuticals America, Inc.'s co-promotional services, Kowa Pharmaceuticals America, Inc. is entitled to a quarterly co-promotion fee based on aggregate Vascepa gross margin that increases during the term. The percentage of aggregate Vascepa gross margin earned by Kowa Pharmaceuticals America, Inc. was fifteen percent (15%) in 2015, nineteen percent (19%) in 2016, twenty percent (20%) in 2017, and is scheduled to increase to low twenty percent levels in 2018, subject to certain adjustments. The co-promotion fee also varies based on sales levels and whether the FDA has approved an ANCHOR indication labeling expansion for Vascepa or has permitted the use of data generated to support obtaining FDA approval of the ANCHOR indication in the promotion of Vascepa, in which case the co-promotion fee would be decreased if specified requirements are met. In certain circumstances, upon the earlier of the expiration or termination of the Agreement in accordance with its terms, Kowa Pharmaceuticals America, Inc. may be eligible for up to three years of co-promotion tail royalties equal to declining percentages of the co-promotion fee earned prior to such agreement expiration.

As of March 31, 2017 and December 31, 2016, the Company had a net accrual of $8.9 million and $2.5 million, respectively, to Kowa Pharmaceuticals America, Inc. representing co-promotion fees accrued under the agreement with Kowa Pharmaceuticals America, Inc. net of reimbursable amounts incurred for samples and other marketing expenses.

(9) Development, Commercialization and Supply Agreements

On February 26, 2015, the Company entered into a Development, Commercialization and Supply Agreement (the "DCS Agreement") with Eddingpharm (Asia) Macao Commercial Offshore Limited ("Eddingpharm") related to the development and commercialization of Vascepa in Mainland China, Hong Kong, Macau and Taiwan, 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 ongoing REDUCE-IT clinical trials of Vascepa.

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

competitive products in the China Territory.

The Company and Eddingpharm agreed to form a joint development committee to oversee regulatory and development activities for Vascepa in the China Territory in accordance with a negotiated development plan and to form a separate joint commercialization committee to oversee Vascepa commercialization activities in the China Territory. Development costs will be paid by Eddingpharm to the extent such costs are incurred in connection with the negotiated development plan or otherwise incurred by Eddingpharm. Eddingpharm will be responsible for preparing and filing regulatory applications in all countries of the China Territory at Eddingpharm's cost with the Company's assistance. The DCS Agreement also contains customary provisions regarding indemnification, 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, which it will recognize as revenue over the estimated period in which the Company is required to provide initial and on-going regulatory and development support and clinical supply for obtaining regulatory approvals in the China Territory and through the estimated period in which the Company is required to provide commercial supply, which is currently estimated to be a period of approximately 16 years. In March 2016, Eddingpharm submitted its clinical trial application ("CTA") with respect to the MARINE indication for Vascepa to the Chinese regulatory authority. Following the CTA submission, the Company received a non-refundable $1.0 million milestone payment, which it will recognize as revenue over the estimated period in which the Company is required to provide on-going development support needed to support the successful approval for a new drug application, which is currently estimated to be a period of approximately four years. In March 2017, the CTA was approved by the Chinese regulatory authority, and Eddingpharm expects to initiate clinical trials by the end of 2017.

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 $1.0 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 recognizes contingent consideration from activities that is earned upon the achievement of a substantive milestone in the period in which the milestone is achieved.

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 payments based on product sales at an agreed-upon transfer price, which represents a percentage of gross selling price, subject to a minimum floor price.

Licensing and deferred revenues currently consist of revenue attributable to receipt of up-front, non-refundable payments and milestone payments related to the Eddingpharm and Biologix agreements. Up-front and milestone payments under such agreements are typically recognized as licensing revenue over the estimated period in which the Company is required to provide regulatory and development support and clinical and commercial supply pursuant to the agreements. During the three months ended March 31, 2017 and 2016, the Company recognized $0.3 million and $0.2 million of up-front and milestone payments as licensing revenue, respectively, and recorded $14.8 million as deferred revenue as of March 31, 2017.

(10) Subsequent Events

The Company has evaluated subsequent events from March 31, 2017 through the date of the issuance of these condensed consolidated financial statements.

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," "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, 2016 and below under Part II, Item IA, "Risk Factors".

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

Overview

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

Our lead product, Vascepa® (icosapent ethyl) capsules, is approved by the U.S. Food and Drug Administration, or FDA, for use as an adjunct to diet to reduce triglyceride levels in adult patients with severe (TG >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 >200 mg/dL and <500 mg/dL) who are also on statin therapy for elevated low-density lipoprotein cholesterol, or LDL-C, levels which condition we refer to as mixed dyslipidemia or persistently high triglycerides. This study is known as the ANCHOR study. Safety data from both the MARINE and ANCHOR studies are reflected in FDA-approved labeling for Vascepa. In January 2013, we began selling and marketing Vascepa in the United States based on the FDA-approved MARINE indication. In August 2015, we also began 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 of approximately 150 sales professionals, including sales representatives and their managers. In March 2014, we entered into a co-promotion agreement in the United States with Kowa Pharmaceuticals America, Inc. under which no less than 250 Kowa Pharmaceuticals America, Inc. sales representatives began to devote a substantial portion of their time to promoting Vascepa starting in May 2014.

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

Triglycerides are the main constituent of body fat in humans. Hypertriglyceridemia refers to a condition in which patients have high levels of triglycerides in the bloodstream. It is estimated that over 75 million adults in the United States have elevated triglyceride levels (TG >150 mg/dL), approximately 40 million adults in the United States have high triglyceride levels (TG >200 mg/dL), and approximately 4.0 million people in the United States have severely high triglyceride levels (TG >500 mg/dL), commonly known as very high triglyceride levels. Many patients with high 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 are currently focused on completing the ongoing REDUCE-IT (Reduction of Cardiovascular Events with EPA—Intervention Trial) cardiovascular outcomes study of Vascepa, which we started in December 2011. REDUCE-IT, a multinational, prospective, randomized, double-blind, placebo-controlled study, is the first prospective cardiovascular outcomes study of any drug in a population of patients who, despite stable statin therapy, have elevated triglyceride levels. Based on the results of REDUCE-IT, we plan to seek additional indicated uses for Vascepa. In REDUCE-IT, cardiovascular event rates for patients on stable statin therapy plus four (4) grams per day of Vascepa will be compared to cardiovascular event rates for patients on stable statin therapy plus placebo. In 2016, we completed patient enrollment and randomization of 8,175 individual patients into the REDUCE-IT study, exceeding the 8,000 patients targeted for the trial.

The REDUCE-IT study is designed to be completed after reaching 1,612 aggregate primary cardiovascular events. Based on projected event rates, we estimate the onset of the target aggregate number of cardiovascular events to be reached near the end of 2017 with study results then expected to be available and published in 2018. In addition, since its inception in 2011, our REDUCE-IT special protocol assessment (SPA) agreement with the FDA has provided for periodic safety reviews and an interim efficacy and safety analysis by the study’s independent data monitoring committee (DMC) at approximately 60% of the target aggregate number of primary cardiovascular events. In August 2016, we announced an amendment to our REDUCE-IT SPA agreement with FDA that reaffirmed FDA concurrence on key elements of the study, defined details of the statistical analysis plan for the study, expanded to greater than 30 the pre-specified secondary and tertiary endpoints in the study, and added a second interim efficacy and safety analysis by the DMC at approximately 80% of the target aggregate number of primary cardiovascular events. The periodic safety reviews and interim efficacy and safety analyses are conducted confidentially by the study’s DMC. We remain blinded to all data from the study. Since patient enrollment commenced in 2011, more than 28,000 patient years of study experience have been accumulated in the REDUCE-IT study. Following each periodic review of safety data to date, the DMC has communicated to us that we should continue the study as planned.

In March 2016, we announced that the onset of approximately 60% of the target aggregate number of primary cardiovascular events had triggered preparation for the first pre-specified interim analysis of efficacy and safety results. Such analysis included the first review of unblinded efficacy data by the independent DMC. The DMC completed its review of the interim analysis in September 2016 and, consistent with previously stated expectations, recommended that the trial continue as planned without modification. In March 2017, we announced that the onset of approximately 80% of the target aggregate number of primary cardiovascular events has triggered preparation for a pre-specified interim efficacy and safety analysis by the study’s independent DMC. We currently expect the independent interim analysis to be conducted before the end of the third calendar quarter of 2017. As is typical, the statistical threshold for defining overwhelming efficacy on the primary endpoint at interim analyses is considerably higher than the threshold for defining statistical significance at the end of the study. In addition, we have requested the DMC to not recommend stopping the study early based only upon the achievement of statistical significance for the

primary endpoint, but to ensure that supportive trends of benefit are also consistently observed in certain secondary endpoints and subpopulations before recommending that the study be stopped early for overwhelming efficacy. This is the same approach we asked the DMC to employ in connection with the REDUCE-IT study 60% interim analysis. It is our expectation that the 80% interim analysis will also result in a recommendation by the DMC to continue the trial.

In the successful Phase 3 MARINE and ANCHOR clinical trials, Vascepa was studied at a daily dose of 2 grams and 4 grams. We sought approval of Vascepa at the more efficacious 4-gram dose for use in each patient population. These trials demonstrated favorable results in their respective patient populations, particularly with the 4-gram dose of Vascepa, in reducing triglyceride levels without increasing LDL-C levels in the MARINE trial and with a statistically significant decrease in LDL-C levels in the ANCHOR trial, in each case, relative to placebo. These trials also showed favorable results, particularly with the 4-gram dose of Vascepa, in other important lipid and inflammation biomarkers, including apolipoprotein B (apo B), non-high-density lipoprotein cholesterol (non-HDL-C), total-cholesterol (TC), very low-density lipoprotein cholesterol (VLDL-C), lipoprotein-associated phospholipase A2 (Lp-PLA2), and high sensitivity C-reactive protein (hs-CRP). In these trials, the most commonly reported adverse reaction (incidence >2% and greater than placebo) in Vascepa-treated patients was arthralgia (joint pain) (2.3% for Vascepa vs. 1.0% for placebo).

In April 2015, we received a Complete Response Letter, or CRL, from the FDA in response to our supplemental new drug application, or sNDA, that sought approval of Vascepa for use in patients with mixed dyslipidemia, based on the successful ANCHOR study. The CRL followed an October 2013 rescission by the FDA of a special protocol assessment, or SPA, agreement and three failed attempts by us to appeal that rescission at FDA. The FDA has acknowledged the success of the ANCHOR study, which met all primary and secondary endpoints. However, FDA determined that there were insufficient data to conclude that drug-induced changes in serum triglycerides could be recognized by the FDA as a valid surrogate for reducing cardiovascular risk in the ANCHOR population for the purpose of regulatory approval of a drug targeted at a triglyceride-lowering indication in this population. The FDA has acknowledged that the standard of proof required by the FDA for approval of a new drug indication is higher than that generally used to inform patient treatment guidelines and that used by physicians in clinical practice. The FDA did not determine that the drug-induced effects of Vascepa, which go beyond triglyceride-lowering, would not actually reduce cardiovascular risk in this population and the FDA has encouraged us to complete the REDUCE-IT outcomes study. Based on our communications with the FDA, we expect that final positive results from the REDUCE-IT outcomes study will be required for label expansion for Vascepa.

In May 2015, we and a group of independent physicians filed a lawsuit in federal court to permit us to promote to healthcare professionals the use of Vascepa in patients with mixed dyslipidemia so long as the promotion is truthful and non-misleading. This use reflects recognized medical practice but is not covered by current FDA-approved labeling for the drug. Historically, FDA has considered promotion of drug uses not covered by FDA-approved labelling to be illegal off-label promotion, even if such promotion is truthful and non-misleading. In August 2015, we were granted preliminary relief in the form of a declaratory judgment in this lawsuit. The court declaration 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. 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. We currently market Vascepa in the United States through our direct sales force of approximately 150 sales professionals, including

sales representatives and their managers. Commencing in May 2014, in addition to Vascepa promotion by our sales representatives, no less than 250 Kowa Pharmaceuticals America, Inc. sales representatives began devoting a substantial portion of their time to promoting Vascepa. We also employ various 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 we expect that the majority of patients taking Vascepa will continue to be prescribed the 1-gram size Vascepa capsule. We also expect that the majority of new patients will 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, including no less than 250 Kowa Pharmaceuticals America, Inc. sales representatives and the achievement of minimum levels of Vascepa revenue in 2015 and beyond. First position refers to when a sales representative's primary purpose in detailing is related to Vascepa, while second position refers to when a sales representative's primary purpose in detailing is to promote another product, but they also devote time in the same sales call to promote Vascepa. Kowa Pharmaceuticals America, Inc. has also agreed to continue to bear the costs incurred for its sales force associated with the commercialization of Vascepa and to pay for certain incremental costs associated with the use of its sales force, such as sample costs and costs for promotional and marketing materials. We will continue to recognize all revenue from sales of Vascepa. In exchange for Kowa Pharmaceuticals America, Inc.'s co-promotional services, Kowa Pharmaceuticals America, Inc. is entitled to a quarterly co-promotion fee based on a percentage of aggregate Vascepa gross margin that increases during the term. The percentage of aggregate Vascepa gross margin earned by Kowa Pharmaceuticals America, Inc. was fifteen percent (15%) in 2015, nineteen percent (19%) in 2016, twenty percent (20%) in 2017, and is scheduled to increase to low twenty percent levels in 2018, subject to certain adjustments. The term of this co-promotion agreement expires on December 31, 2018, following which our agreement with Kowa Pharmaceuticals America, Inc. provides for up to three years of tail royalties equal to declining percentages of the co-promotion fee earned prior to agreement expiration.

Based on monthly compilations of data provided by a third party, Symphony Health Solutions, the estimated number of normalized total Vascepa prescriptions for the three months ended March 31, 2017 and 2016 was approximately 305,000 and 201,000, respectively. According to data from another third party, IMS Health, the estimated number of normalized total Vascepa prescriptions for the three months ended March 31, 2017 and 2016 was approximately 335,000 and 212,000, respectively. Normalized total prescriptions represent the estimated total number of Vascepa prescriptions shipped to patients, calculated on a normalized basis (i.e., one month's supply, or total capsules shipped 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. During 2016, predominantly in the second quarter, wholesaler inventory levels increased based on estimated days of inventory on hand. In addition, regional stocking of Vascepa expanded at certain retail pharmacies, likely due to higher volume sales of Vascepa.

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 7, 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.

Commercialization – Outside the United States

In February 2015, we announced an exclusive agreement with Eddingpharm to develop and commercialize Vascepa capsules in what we refer to as the China Territory, consisting of the territories of Mainland China, Hong Kong, Macau and Taiwan, for uses that are currently commercialized and under development by us in the United States based on the MARINE, ANCHOR and ongoing REDUCE-IT clinical trials of Vascepa. Under the agreement, Eddingpharm is responsible for development and commercialization activities in the China Territory and associated expenses. We will provide development assistance and be responsible for supplying the product. Terms of the agreement include up-front and milestone payments to us of up to $169.0 million, including a non-refundable $15.0 million up-front payment received at closing, a non-refundable milestone payment of $1.0 million received upon successful submission of a clinical trial application with respect to the MARINE indication for Vascepa to the Chinese regulatory authority in March 2016, and future 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 $1.0 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 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 are entitled to receive payments based on product sales at an agreed-upon transfer price, which represents a percentage of gross selling price, subject to a minimum floor price.

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 is 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 is designed to test the hypothesis that the clinical effects of Vascepa, including 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 results of REDUCE-IT, we may seek additional indications for Vascepa beyond the indications studied in the ANCHOR or MARINE trials.

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

Completion of the REDUCE-IT study is designed to occur after reaching an aggregate number of cardiovascular events. Based on projected event rates, we estimate the onset of the target aggregate number of cardiovascular events to be reached near the end of 2017 with study results then expected to be available in 2018. In addition, since its

inception in 2011, our REDUCE-IT SPA agreement with the FDA has provided for periodic safety reviews and an interim efficacy and safety analysis by the independent DMC at approximately 60% of the target aggregate number of primary cardiovascular events. In August 2016, we announced an amendment to our REDUCE-IT SPA agreement with FDA that reaffirmed FDA concurrence on key elements of the study, defined details of the statistical analysis plan for the study, expanded to greater than 30 the pre-specified secondary and tertiary endpoints in the study, and added a second interim efficacy and safety analysis by the DMC at approximately 80% of the target aggregate number of primary cardiovascular events.

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

Since patient enrollment commenced in 2011, more than 28,000 patient years of study experience have been accumulated in REDUCE-IT. The DMC has reviewed unblinded safety data on a quarterly basis since 2013 and, after each such review of unblinded safety data to date, the DMC has recommended to us that the study be continued as planned.

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

Commercial Supply

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

Financial Position

We believe that our cash and cash equivalents of $96.1 million as of March 31, 2017 will be sufficient to fund our projected operations through results of the REDUCE-IT study, which we anticipate will be available mid-2018. Depending on the level of cash generated from operations, additional capital may be required to sustain operations, fund debt obligations or expand promotion of Vascepa as contemplated following anticipated successful results of the REDUCE-IT study. We anticipate that quarterly net cash outflows in future periods will be variable.

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 size capsule in October 2016. In accordance with U.S. Generally Accepted Accounting Principles, or GAAP, during 2013, before we had the ability to reliably estimate returns of Vascepa from our Distributors, revenue was recognized based on the resale of Vascepa for the purposes of filling patient prescriptions, and not based on our sales to such Distributors. In 2014, we concluded that we had developed sufficient history such that we can reliably estimate returns and as a result, began to recognize revenue based on sales to our Distributors.

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

Cost of Goods Sold. Cost of goods sold includes the cost of API for Vascepa on which revenue was recognized during the period, as well as the associated costs for encapsulation, packaging, shipment, supply management, quality assurance, 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 accrued under the agreement with 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 as well as costs of product supply received from suppliers when such receipt by us is prior to regulatory approval of the supplier. We expense research and development costs as incurred.

Loss on Change in Fair Value of Derivative Liabilities. Loss on change in fair value of derivative liabilities is comprised of: (i) the change in fair value of the derivative liability related to the change in control provision associated with the December 2012 financing with BioPharma Secured Debt Fund II Holdings Cayman LP, or BioPharma, and (ii) the change in fair value of the derivative liabilities related to the change in control provisions associated with the May 2014 and November 2015 exchangeable senior notes.

Interest and Other Expense, Net. Interest expense consists of interest incurred under lease obligations, interest incurred under our December 2012 financing arrangement with BioPharma and interest incurred under our 3.5% exchangeable notes. Interest expense under our BioPharma financing arrangement is calculated based on an estimated repayment schedule. Interest expense under our exchangeable notes includes the amortization of the conversion option related to

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

Critical Accounting Policies and Significant Judgments and Estimates

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

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

We began recognizing revenue from the sale of Vascepa following our commercial launch in the United States in January 2013. Prior to 2013, we recognized no revenue from Vascepa sales. We sell Vascepa to Distributors. In accordance with GAAP, during 2013, before we had the ability to reliably estimate returns of Vascepa from our Distributors, revenue was recognized based on the resale of Vascepa for the purposes of filling patient prescriptions, and not based on our sales to such Distributors. In 2014, we concluded that we had developed sufficient history such that we can reliably estimate returns and as a result, began to recognize revenue based on sales to our Distributors. Consequently, we recognized net product revenue of $34.3 million and $25.3 million based on sales to Distributors during the three months ended March 31, 2017 and 2016, respectively.

We have written contracts with our Distributors, and delivery occurs when a Distributor receives Vascepa. We evaluate the creditworthiness of each of our Distributors to determine whether revenues can be recognized upon delivery, subject to satisfaction of the other requirements, or whether recognition is required to be delayed until receipt of payment. In order to conclude that the price is fixed or determinable, we must be able to (i) calculate our gross product revenues from the sales to Distributors and (ii) reasonably estimate our net product revenues. We calculate gross product revenues based on the wholesale acquisition cost that we charge our Distributors for Vascepa. We estimate our net product revenues by deducting from our gross product revenues (a) trade allowances, such as invoice discounts for prompt payment and distributor fees, (b) estimated government and private payor rebates, chargebacks and discounts, such as Medicaid reimbursements, (c) reserves for expected product returns and (d) estimated costs of incentives offered to certain indirect customers, including patients. The gross to net deductions are estimated based on available actual information, historical data, known trends, and levels of inventory in the distribution channel. We rely on resale data provided by our Distributors as well as prescription data provided by Symphony Health Solutions and IMS Health in estimating the level of inventory held in the distribution channel. A hypothetical 5% change in estimated aggregate bottles of channel inventory would result in a change of less than 1% in net product revenues reported during each of the three months ended March 31, 2017 and 2016.

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

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

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

Derivative Financial Liabilities—Derivative financial liabilities are initially recorded at fair value. They are subsequently held at fair value, with gains and losses arising for changes in fair value recognized in the statement of operations. The fair value of derivative financial liabilities is determined using various valuation techniques. We use our judgment to select a variety of methods and make assumptions that are mainly based on market conditions existing at each balance sheet date, which include our projections for future estimated revenues, management estimates of the probability of a change in control occurring, and the terms of debt issues of similar companies. Fluctuations in the assumptions used in the valuation model would result in adjustments to the fair value of the derivative liabilities reflected on our balance sheet and, therefore, our statement of operations. If we issue shares to discharge the liability, the derivative financial liability is derecognized and common stock and additional paid-in capital are recognized on the issuance of those shares. For options and warrants treated as derivative financial liabilities, at settlement date the carrying value of the options and warrants are transferred to equity. The cash proceeds received from shareholders for additional shares are recorded in common stock and additional paid-in capital. We have recorded financial derivatives related to the change in control provision associated with our December 2012 royalty-bearing debt financing and the change in control provisions associated with our May 2014 and November 2015 exchangeable senior notes (both derecognized upon exchange of the debt hosts into equity during the third quarter of 2016).

Inventory—We capitalize purchases of saleable inventory of Vascepa from suppliers that have been qualified by the FDA. During the periods presented, the API purchased for Vascepa was sourced from three API suppliers. If we add a new API supplier, all Vascepa API purchased from such supplier is included as a component of research and development expense until the new API supplier is approved. Upon sNDA approval of each additional supplier, we capitalize subsequent Vascepa API purchases from such supplier as inventory. We state 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, quantities in excess of expected demand, changes in price levels or other causes, then we will reduce the carrying value of such inventory to net realizable value and recognize the difference as a component of cost of goods sold in the period in which it occurs. We expense inventory identified for use as marketing samples when they are packaged. The average cost reflects the actual purchase price of Vascepa API. Additionally, the determination of the classification of our inventory requires the use of estimates in order to determine the portion of inventories anticipated to be utilized within twelve months of the balance sheet date.

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

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

We assess our ability to realize deferred tax assets at each reporting period. The realization of deferred tax assets depends on generating future taxable income during the periods in which the tax benefits are deductible or creditable. We have historically generated annual positive taxable income in the United States. When making our assessment about the realization of our U.S. deferred tax assets at March 31, 2017, we considered all available evidence, placing particular weight on evidence that could be objectively verified. The evidence considered included the (i) historical profitability of our U.S. operations, (ii) sources of future taxable income, giving weight to sources according to the extent to which they can be objectively verified, and (iii) the risks to our business related to the commercialization and

development of Vascepa. Based on our assessment, we concluded that the recorded net U.S. deferred tax assets of $11.1 million are more likely than not to be realizable as of March 31, 2017. The majority of our deferred tax assets are held outside of the United States, for which we have established a full valuation allowance. Changes in historical earnings performance and future earnings projections, among other factors, may cause us to adjust our valuation allowance on deferred tax assets, which would impact our income tax expense in the period in which we determine that these factors have changed. In the event sufficient taxable income is not generated in future periods, additional valuation allowances could be required relating to these U.S. deferred tax assets.

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.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board, or FASB, and are early adopted by us or adopted as of the specified effective date. We considered the following recent accounting pronouncements which were not yet adopted as of March 31, 2017:

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606), which will replace numerous requirements in U.S. GAAP, including industry-specific requirements. This guidance provides a five step model to be applied to all contracts with customers, with an underlying principle that an entity will recognize revenue to depict the transfer of goods or services to customers at an amount that the entity expects to be entitled to in exchange for those goods or services. ASU No. 2014-09 requires extensive quantitative and qualitative disclosures covering the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including disclosures on significant judgments made when applying the guidance. This guidance is effective for annual reporting periods beginning after December 15, 2017 and interim periods therein. Early adoption is permitted for reporting periods and interim periods therein, beginning after December 15, 2016. An entity can elect to apply the guidance under one of the following two methods: (i) retrospectively to each prior reporting period presented, referred to as the full retrospective method, or (ii) retrospectively with the cumulative effect of initially applying the standard recognized at the date of initial application in retained earnings, referred to as the modified retrospective method.

We have substantially completed an initial impact assessment of the potential changes from adopting ASU No. 2014-09. The impact assessment consisted of a review of a representative sample of contracts, discussions with key stakeholders, and a cataloging of potential impacts on its financial statements, accounting policies, financial control, and operations. We anticipate that the adoption of ASU No. 2014-09 will not have a material impact on product revenue from distributors and may have an impact on contract revenues generated by our license agreements:

(i) Changes in the model for distinct licenses of functional intellectual property which may result in a timing difference of revenue recognition. Whereas revenue from these arrangements was previously recognized over a period of time pursuant to the multiple element arrangement guidance, revenue from these arrangements may now be recognized at a point in time under the new guidance.
(ii) Assessments of milestone payments, which are linked to events that are in our control, will result in variable consideration that may be recognized at an earlier point in time under the new guidance, when it is probable that the milestone will be achieved without a significant future reversal of cumulative revenue expected.

We have not yet completed our final review of the impact of this guidance; however, we anticipate applying the modified retrospective method when implementing this guidance. We plan to adopt the new standard effective January 1, 2018. We continue to monitor additional changes, modifications, clarifications or interpretations being undertaken by the FASB, which may impact our current conclusions.

In January 2016, the FASB issued ASU No. 2016-01, Financial Instruments—Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities. The new guidance is intended to improve the recognition and measurement of financial instruments by requiring separate presentation of financial assets and financial liabilities by measurement category and form of financial asset (i.e., securities or loans and receivables) within the balance sheet or the accompanying notes to the financial statements, eliminating the requirement for public business entities to disclose the method(s) and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost within the balance sheet, requiring public business entities to use the exit price notion when measuring the fair value of financial instruments for disclosure purposes, requiring equity investments (except those accounted for under the equity method of accounting, or those that result in consolidation of the investee) to be measured at fair value with changes in fair value recognized in net income, and requiring a reporting organization to present separately in other comprehensive income the portion of the total change in the fair value of a liability resulting from a change in the instrument-specific credit risk (also referred to as “own credit”) when the organization has elected to measure the liability at fair value in accordance with the fair value option for financial instruments, among others. The new guidance is effective for fiscal years beginning after

December 15, 2017, including interim periods within those fiscal years. The new guidance permits early adoption of the own credit provision. We are currently evaluating the accounting, transition and disclosure requirements of the standard and cannot currently estimate the financial statement impact of adoption.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842). The new guidance will require lessees to recognize a right-of-use asset and a lease liability for virtually all of their leases (other than leases that meet the definition of a short-term lease). The liability will be equal to the present value of lease payments. The asset will be based on the liability, subject to adjustment, such as for initial direct costs. Under the new guidance, lessor accounting is largely unchanged but certain targeted improvements were made to align, where necessary, lessor accounting with the lessee accounting model and Topic 606, Revenue from Contracts with Customers. The new lease guidance also simplified the accounting for sale and leaseback transactions primarily because lessees must recognize lease assets and lease liabilities and therefore, will no longer be provided with a source of off-balance sheet financing. The new guidance is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted. We are currently evaluating the accounting, transition and disclosure requirements of the standard and cannot currently estimate the financial statement impact of adoption.

In March 2016, the FASB issued ASU No. 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net), which clarifies that an entity is a principal when it controls the specified good or service before that good or service is transferred to the customer, and is an agent when it does not control the specified good or service before it is transferred to the customer. The new guidance is intended to improve the operability and understandability of the implementation guidance on principal versus agent considerations. In April 2016, the FASB issued ASU No. 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing, which clarifies the following two aspects of Topic 606: (a) identifying performance obligations; and (b) the licensing implementation guidance. Further, in May 2016, the FASB issued ASU No. 2016-12, Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients, which provides clarifying guidance in certain narrow areas and adds some practical expedients. The amendments do not change the core principles of the guidance in Topic 606 and are effective for our fiscal year beginning January 1, 2018. Early application is permitted only as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period. We are currently evaluating the accounting, transition and disclosure requirements of these standards and cannot currently estimate the financial statement impact of adoption.

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments, which is intended to reduce diversity in practice regarding how certain cash receipts and cash payments 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. For each of these ASUs, the new guidance is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years, with early adoption permitted. We have evaluated the accounting, transition and disclosure requirements of these standards and do not expect them to have a material impact on our consolidated financial statements.

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

Results of Operations

Comparison of Three Months Ended March 31, 2017 and March 31, 2016

Product Revenue, net. We recorded product revenue of $34.3 million and $25.3 million during the three months ended March 31, 2017 and 2016, respectively, an increase of $9.0 million, or 36%. This increase in revenue was driven primarily by an increase in estimated normalized total Vascepa prescriptions. Based on data provided by Symphony Health Solutions and IMS Health, estimated normalized total Vascepa prescriptions increased by approximately

104,000 and 123,000, respectively, over the three months ended March 31, 2016, representing growth of 52% and 58%, respectively. During the first quarter of 2017, overall wholesaler inventory levels decreased from year-end 2016 levels calculated based on estimated days of Vascepa sales on hand. Consequently, we estimate that this decrease in wholesaler inventory levels adversely impacted net product revenue by approximately $2.8 million to $3.1 million for the first quarter of 2017. During the first quarter of 2016, a decrease in wholesaler inventory levels adversely impacted net product revenue by approximately $1.2 million to $1.5 million calculated based on estimated days of Vascepa sales on hand. We believe that changes in channel inventory at these independent wholesalers and retail pharmacies are common and are impacted by numerous factors, including holiday timing and recent order trends. We also believe, based on information available to us, that channel inventory levels at the end of the first quarters of 2017 and 2016 are within ordinary ranges.

All of our product revenue in the three months ended March 31, 2017 and 2016 was derived from product sales of Vascepa, net of allowances, discounts, incentives, rebates, chargebacks and returns. Included in 2017 net product revenue are sales of 0.5-gram size Vascepa capsules, which were introduced in October 2016, for the subset of patients who prefer a smaller capsule. Sales of Vascepa 0.5-gram size capsules have not been significant to date. The FDA-approved dosing for Vascepa continues to be 4 grams per day and we expect that the majority of patients taking Vascepa will continue to be prescribed the 1-gram size Vascepa capsules. We also expect that the majority of new patients will be prescribed the 1-gram size Vascepa capsule. Timing of shipments to wholesalers, as used for revenue recognition, and timing of prescriptions as estimated by third-party sources such as Symphony Health Solutions and IMS Health may differ from period to period.

During the quarters ended March 31, 2017 and 2016, our net product revenue included an adjustment for co-pay mitigation rebates provided by us to commercially insured patients. Such rebates are intended to offset the differential for patients of Vascepa not covered by commercial insurers at the time of launch on Tier 2 for formulary purposes, resulting in higher co-pay amounts for such patients. Our cost for these co-payment mitigation rebates during the quarters ended March 31, 2017 and 2016 was up to $70 per 30-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 March 31, 2017 and 2016 was $0.3 million and $0.2 million, respectively, an increase of $0.1 million, or 24%. Licensing revenue relates to the amortization of a $15.0 million up-front payment received in February 2015 and a $1.0 million milestone payment achieved in March 2016, both associated with a Vascepa licensing agreement for the China Territory. The up-front and milestone payments are being recognized over the estimated period in which we are required to provide regulatory and development support and clinical and commercial supply under the agreement. The amount of licensing revenue recorded may be variable from period to period based on changes in estimates of the timing and level of support required. We do not anticipate significant revenues related to the Biologix agreement in 2017.

Cost of Goods Sold. Cost of goods sold during the three months ended March 31, 2017 and 2016 was $8.2 million and $6.9 million, respectively, an increase of $1.3 million, or 19%. 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 March 31, 2017 and 2016 was sourced from three API suppliers. The contracted cost of supply from our initial API supplier was higher than the contracted cost from our other API suppliers. In the future, we anticipate making continued purchases from this initial supplier and to make additional lower unit cost purchases of Vascepa API from other API suppliers, with the amount of such purchases dependent on the rate of our revenue growth. The average cost may be variable from period to period depending upon the timing and quantity of API purchased from each supplier.

Our gross margin on product sales for the three months ended March 31, 2017 and 2016 was 76% and 73%, respectively. This improvement was primarily driven by lower unit cost API purchases.

Selling, General and Administrative Expense. Selling, general and administrative expense for the three months ended March 31, 2017 and 2016 was $34.2 million and $28.0 million, respectively, an increase of $6.2 million, or 22%. Selling, general and administrative expenses for the three months ended March 31, 2017 and 2016 are summarized in

the table below:

In thousands	Three Months Ended March 31, 2017	2016
Selling, general and administrative expense (1)	$26,111	$21,638
Co-promotion fees (2)	5,232	3,498
Non-cash stock-based compensation expense (3)	2,828	2,884
Total selling, general and administrative expense	$34,171	$28,020

(1) Selling, general and administrative expense, excluding co-promotion fees and non-cash compensation charges for stock compensation and warrants, for the three months ended March 31, 2017 and 2016 was $26.1 million and $21.6 million, respectively, an increase of $4.5 million, or 21%. The increase is due primarily to increased promotional activities and increased legal costs, which are subject to quarterly variability.

(2) Co-promotion fees accrued under our agreement with Kowa Pharmaceuticals America, Inc. for the three months ended March 31, 2017 and 2016 were $5.2 million and $3.5 million, respectively, an increase of $1.7 million, or 50%. The increase is

due primarily to an increase in gross margin on product sales for the first quarter of 2017 compared to the same period in 2016, coupled with an increase in the percentage of aggregate Vascepa gross margin earned by Kowa Pharmaceuticals America, Inc. from 19% in 2016 to 20% in 2017.

(3) Non-cash stock-based compensation expense for the three months ended March 31, 2017 and 2016 was $2.8 million and $2.9 million, respectively, a decrease of $0.1 million, or 1.9%.

Research and Development Expense. Research and development expense for the three months ended March 31, 2017 and 2016 was $10.8 million and $13.7 million, respectively, a decrease of $2.9 million, or 21%. Research and development expenses for the three months ended March 31, 2017 and 2016 are summarized in the table below:

	Three Months Ended March 31,	
In thousands	2017	2016
REDUCE-IT study (1)	$7,683	$9,363
Regulatory filing fees and expenses (2)	202	707
Internal staffing, overhead and other (3)	2,415	2,947
Research and development expense, excluding non-cash expense	10,300	13,017
Non-cash stock-based compensation expense (4)	523	713
Total research and development expense	$10,823	$13,730

The decrease in research and development expenses for the quarter ended March 31, 2017, as compared to the prior year period, is primarily due to quarterly variability in costs related to the REDUCE-IT study.

(1) In December 2011, we announced commencement of patient dosing in our cardiovascular outcomes study of Vascepa, titled REDUCE-IT, which is designed to evaluate the efficacy of Vascepa, including its impact on triglyceride lowering and its other clinical effects, in reducing major adverse cardiovascular events compared to placebo in patients who despite statin therapy have risk factors for cardiovascular disease, including elevated triglyceride levels. 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 study duration is dependent on the rate of clinical events in the study, which rate may be affected by the epidemiology of the patients enrolled in the study and the length of time that the enrolled patients are followed. We manage the study through a contract research organization (CRO) through which all costs for this outcomes study are incurred with the exception of costs for clinical trial material (CTM) and costs for internal management. Our internal personnel are responsible for managing multiple projects and their costs are not specifically allocated to REDUCE-IT or any other individual project. For the three months ended March 31, 2017 and 2016, we incurred expenses through our CRO in connection with this trial of approximately $6.7 million and $7.6 million, respectively. Inclusive of CTM costs, the combined CRO and CTM costs during the three months ended March 31, 2017 and 2016 for REDUCE-IT were approximately $7.7 million and $9.4 million, respectively. The decrease in expenses in 2017 as compared to 2016 is primarily the result of timing variability for REDUCE-IT costs. We expense costs for CTM when allocated to clinical research. The aggregate cost of this outcomes study will depend on the rate of clinical events in the study. We currently estimate that we will incur $30 million to $40 million in annual costs through study completion and the rate at which we incur such costs will vary from quarter to quarter. The study is designed to be completed after reaching 1,612 aggregate primary cardiovascular events. Based on projected event rates, we estimate the onset of the target aggregate number of cardiovascular events to be reached near the end of 2017 with study results then expected to be available and published in 2018. We anticipate that our costs for this outcomes study will continue to represent the most significant component of our research and development expenditures.

(2) The regulatory filing fees in each of the quarters ended March 31, 2017 and 2016 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.

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

Loss on Change in Fair Value of Derivative Liabilities. Loss on change in fair value of derivative liabilities for the three months ended March 31, 2017 was nil versus a loss of $1.3 million in the prior year period. Loss on change in fair value of derivative liabilities for the three months ended March 31, 2017 and 2016 is comprised of (i) the change in fair value of the derivative liability related to the change in control provision associated with the December 2012 BioPharma financing, and (ii) the change in fair value of the derivative liabilities related to the change in control provisions associated with the May 2014 and November 2015 exchangeable senior notes.

Our December 2012 financing agreement with BioPharma contains a redemption feature whereby, upon a change of control, we would be required to repay $150.0 million, less any previously repaid amount, which net remaining unpaid amount as of March 31, 2017 was $121.7 million. Unless this early redemption feature is triggered, the remaining amount, without additional interest accumulation, is anticipated to be paid based on the royalty provisions of the agreement. The fair value of the derivative liability is recalculated at each reporting period using a probability-weighted model incorporating management estimates for potential change in control, and by determining the fair value of the debt with and without the change in control provision included. The difference between the two fair values of the debt was determined to be the fair value of the embedded derivative. No gain or loss on change in fair value of derivative liability was recognized for the three months ended March 31, 2017 as the fair value of the derivative was determined to be nil based on underlying assumptions as of both December 31, 2016 and March 31, 2017. As of December 31, 2015, the fair value of the derivative was determined to be $5.5 million, and as of March 31, 2016, the fair value of the derivative was determined to be $5.9 million. As such, we recognized a $0.4 million loss on change in fair value of derivative liability for the three months ended March 31, 2016.

Our 3.5% May 2014 Exchangeable Senior Notes due 2032, or 2014 Notes, contained a redemption feature whereby, upon occurrence of a change in control, we would have been required to repurchase the notes. The fair value of the embedded derivative was calculated using a probability-weighted model incorporating management estimates of the probability of a change in control occurring, and by determining the fair value of the debt with and without the change in control provision included. The difference between the two was determined to be the fair value of the embedded derivative. In September 2016, we exercised our optional exchange rights upon satisfaction of specified equity conditions set forth in the 2014 Notes indenture to mandatorily exchange the 2014 Notes into ADSs (see Note 5—Debt). As such, the related derivative liability was derecognized at that time and therefore no gain or loss on change in fair value of derivative liability was recognized for the three months ended March 31, 2017. As of December 31, 2015, the fair value of the derivative was determined to be $2.1 million, and as of March 31, 2016, the fair value of the derivative was determined to be $2.8 million. As such, we recognized a $0.7 million loss on change in fair value of derivative liability for the three months ended March 31, 2016.

Our 3.5% November 2015 Exchangeable Senior Notes due 2032, or 2015 Notes, contained the same redemption feature as the 2014 Notes and the related derivative liability was calculated utilizing the same methodology. In September 2016, we exercised our optional exchange rights upon satisfaction of specified equity conditions consistent with the terms of the 2015 Notes to mandatorily exchange the 2015 Notes into ADSs (see Note 5—Debt). As such, the related derivative liability was derecognized at that time and therefore no gain or loss on change in fair value of derivative liability was recognized for the three months ended March 31, 2017. As of December 31, 2015, the fair value of the derivative was determined to be $0.6 million and as of March 31, 2016, the fair value of the derivative was determined to be $0.7 million. As such, we recognized a $0.1 million loss on change in fair value of derivative liability for the three months ended March 31, 2016.

The change in fair value of the derivative liability related to the BioPharma financing agreement is largely related to our projections for future estimated revenues, management estimates of the probability of a change in control occurring, and the terms of debt issues of similar companies. The change in fair value of the derivative liabilities related to the 2014 Notes and 2015 Notes was largely related to changes in quoted bond prices. Any changes in the assumptions used to value the derivative liabilities could result in a material change to the carrying value of such liabilities.

Interest Expense, net. Net interest expense for the three months ended March 31, 2017 and 2016 was $2.4 million and $5.6 million, respectively, a decrease of $3.2 million, or 57%. Net interest expense for the three months ended March 31, 2017 and 2016 is summarized in the table below:

In thousands	Three Months Ended March 31, 2017	2016
Exchangeable senior notes (1):		
Amortization of debt discounts	$39	$1,969
Contractual coupon interest	220	1,445
Total exchangeable senior notes interest expense	259	3,414
Long-term debt from royalty-bearing instrument (2):		
Cash interest	1,625	1,678
Non-cash interest	526	505
Total long-term debt from royalty-bearing instrument interest expense	2,151	2,183
Other interest expense	2	5
Total interest expense	2,412	5,602
Interest income (3)	(31)	(16)
Total interest expense, net	$2,381	$5,586

(1) Cash and non-cash interest expense related to the exchangeable senior notes for the three months ended March 31, 2017 and 2016 was $0.3 million and $3.4 million, respectively. The decrease in cash and non-cash interest expense is the result of the decrease in principal amount of exchangeable senior notes from $165.1 million outstanding as of March 31, 2016 to $30.0 million outstanding as of March 31, 2017.

(2) Cash and non-cash interest expense related to the BioPharma royalty-bearing instrument for the three months ended March 31, 2017 and 2016 was $2.2 million in each period. These amounts reflect the assumption that our Vascepa revenue levels will not be high enough to support repayment to BioPharma in accordance with the repayment schedule without the optional reduction which is allowed to be elected by us if the threshold revenue levels are not achieved. To date, our revenues have been below the contractual threshold amount each quarter such that each payment reflects the calculated optional reduction amount as opposed to the contractual threshold payments for each quarterly period.

(3) Interest income for the three months ended March 31, 2017 and 2016 was $0.03 million and $0.02 million, respectively. Interest income represents income earned on cash balances.

Other Expense, net. Other expense, net, for the three months ended March 31, 2017 and 2016 was $5 thousand and $0.1 million, respectively. Other expense, net, primarily consists of losses and gains on foreign exchange transactions.

Benefit from Income Taxes. Benefit from income taxes for the three months ended March 31, 2017 and 2016 was nil and $0.3 million, respectively. 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 first quarter of 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 months ended March 31, 2017 is zero. The benefit recognized during the three months ended March 31, 2016 related entirely to the U.S. subsidiary operations. We are profitable in the United States as a result of intercompany transactions between our U.S. subsidiary and our other companies.

Liquidity and Capital Resources

Our sources of liquidity as of March 31, 2017 include cash and cash equivalents of $96.1 million. Our projected uses of cash include commercialization of Vascepa, the continued funding of the REDUCE-IT cardiovascular outcomes study, working capital and other general corporate activities. Our cash flows from operating, investing and financing activities, as reflected in the condensed consolidated statements of cash flows, are summarized in the following table:

	Three Months Ended March 31,	
In millions	2017	2016
Cash (used in) provided by:		
Operating activities (1)	$(13.9)	$(24.9)
Investing activities	—	—
Financing activities (1)	11.7	(0.7)
Decrease in cash and cash equivalents	$(2.2)	$(25.6)

(1) Due to the adoption of ASU No. 2016-09, Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting, and retrospective application of the aspects of the standard that affect cash flow presentation, $0.1 million of excess tax provision has been reclassified from cash flows provided by financing activities to cash flows used in operating activities for the three months ended March 31, 2016.

Net cash used in operating activities during the three months ended March 31, 2017 compared to the same period in 2016 decreased primarily as a result of increased collections due to higher revenues, which resulted in decreased net loss. Increased sales and marketing spending in the first quarter of 2017 in support of expanded Vascepa promotion was more than 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. We have agreed to repay BioPharma up to $150.0 million of future revenue and receivables. As of March 31, 2017, the net remaining amount to be repaid to BioPharma is $121.7 million. To date, our revenues have been below the contractual threshold amount such that each payment made has reflected the calculated optional reduction amount as opposed to the contractual threshold payments for each quarterly period. For example, based on our Vascepa net product revenue for the three months ended March 31, 2017 of $34.3 million, the amount to be repaid to BioPharma is $3.4 million compared to the maximum contractual threshold for the first quarter of 2017 of $13.0 million. The maximum amount payable under the contractual threshold for the first half of 2017 is $7.2 million, after which the maximum amount payable is subject to the calculated threshold limitation based on quarterly Vascepa revenues. In accordance with the agreement with BioPharma, quarterly differences between the

calculated optional reduction amounts and the repayment schedule amounts are rescheduled for payment beginning in 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 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 2012, we, through our wholly-owned subsidiary Corsicanto Designated Activity Company (formerly Corsicanto Limited), or Corsicanto, completed a private placement of $150.0 million in aggregate principal amount of 3.5% exchangeable senior notes due 2032, or the 2012 Notes. The proceeds we received from the January 2012 debt offering were approximately $144.3 million, net of fees and transaction costs. 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 with terms unchanged. In September 2016, we exercised our optional exchange rights upon satisfaction of specified equity conditions set forth in the 2014 Notes and 2015 Notes and mandatorily exchanged the entirety of the 2014 Notes and 2015 Notes into 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. As of March 31, 2017, no 2012 Notes, 2014 Notes or 2015 Notes remained outstanding.

In January 2017, we, through our wholly-owned subsidiary Corsicanto II Designated Activity Company, 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.

As of March 31, 2017, we had cash and cash equivalents of $96.1 million, a decrease of $2.2 million from December 31, 2016. The decrease is primarily due to net cash used in operating activities in support of the commercialization of Vascepa and funding of REDUCE-IT, substantially offset by accounts receivable collections and the net effect of financing activities related to the repayment of the 2012 Notes and issuance of the 2017 Notes.

We have incurred annual operating losses since our inception and, as a result, we had an accumulated deficit of $1.2 billion as of March 31, 2017. We believe that our net cash flow from operations in 2017, excluding interest, royalties and R&D costs, the majority of which are associated with REDUCE-IT, will be positive for 2017. We anticipate that quarterly net cash outflows in future periods will be variable as a result of the timing of certain items, including our intention in early 2017 to increase purchases of API. In addition, certain customers have negotiated extended payment terms with us, which will result in slower collections of receivables. We believe that our cash and cash equivalents will be sufficient to fund our projected operations through the results of the REDUCE-IT study, which we anticipate will be available mid-2018. Depending on the level of cash generated from operations, additional capital may be required to sustain operations, fund debt obligations or expand promotion of Vascepa as contemplated based on anticipated successful results of the REDUCE-IT study.

Contractual Obligations

We have Vascepa API supply agreements with three independent companies from which we purchase qualified API supply: Nisshin, Chemport, and Finorga SAS, or Novasep. We also have encapsulation agreements with three FDA-approved commercial API encapsulators for Vascepa manufacturing: Patheon, Inc. (formerly Banner Pharmacaps), Catalent Pharma Solutions, and Capsugel Plöermel SAS, LLC, or Capsugel. Our agreements with Chemport, Novasep, and Capsugel contain minimum annual purchase levels

to enable us to maintain certain supply exclusivity and also contain a provision that any shortfall in the minimum purchase commitments is payable in cash. Each supplier is required to meet certain performance obligations and the agreements may be terminated by us in the event of non-performance.

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

Under the terms of the agreement with BioPharma, we agreed to repay up to $150.0 million of future revenue and receivables. As of March 31, 2017, the net remaining amount to be repaid to BioPharma is $121.7 million. To date, our revenues have been below the contractual threshold amount such that each payment made has reflected the calculated optional reduction amount as opposed to the contractual threshold payments for each quarterly period. The maximum amount payable under the contractual threshold for the first half of 2017 is $7.2 million, after which the maximum amount payable is subject to the calculated threshold limitation based on quarterly Vascepa revenues. For example, based on our Vascepa net product revenue for the three months ended March 31, 2017 of $34.3 million, the amount to be repaid to BioPharma is $3.4 million compared to the maximum contractual threshold for the first quarter of 2017 of $13.0 million. The maximum amount payable under the contractual threshold for the first half of 2017 is $7.2 million, after which the maximum amount payable is subject to the calculated threshold limitation based on quarterly Vascepa revenues. In accordance with the agreement with BioPharma, quarterly differences between the calculated optional reduction amounts and the repayment schedule amounts are rescheduled for payment beginning in the second quarter of 2017 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 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. We currently estimate that Vascepa revenue levels will not be high enough in each quarter to support repayment to BioPharma in accordance with threshold amounts in the repayment schedule and that such payments will remain subject to the continued application of the calculated threshold for royalty based on quarterly Vascepa revenues.

We have scheduled interest payments due under the terms of the 2017 Notes, assuming that they remain outstanding through January 19, 2022 and have not been exchanged for ADSs.

Under the 2004 share repurchase agreement with Laxdale Limited, or Laxdale, upon approval of Vascepa by the FDA on July 26, 2012, we were required to make a milestone payment to Laxdale of £7.5 million. We made this payment in 2012 and capitalized this Laxdale milestone payment of $11.6 million as a component of other long-term assets. This long-term asset is being amortized over the estimated useful life of the intellectual property we acquired from Laxdale and we recognized amortization expense of $0.2 million in each of the three months ended March 31, 2017 and 2016. 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 $9.4 million as of March 31, 2017). 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 $6.2 million as of March 31, 2017) for each of the two potential market approvals (i.e. £10 million maximum, or approximately $12.5 million as of March 31, 2017).

We do not enter into financial instruments for trading or speculative purposes. As of March 31, 2017, we had no outstanding forward exchange contracts.

Off-Balance Sheet Arrangements

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

Item 3. Quantitative and Qualitative Disclosures about Market Risk

There have been no material changes with respect to the information appearing in PART II, Item 7A “Quantitative and Qualitative Disclosures about Market Risk” of our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 1, 2017.

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 March 31, 2017 (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 March 31, 2017, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

During the quarter ended March 31, 2017, there have been no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15(d)-15(f) promulgated under the Exchange Act, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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, 2016 includes a discussion 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, 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, 2016 filed with the SEC on March 1, 2017.

Risks Related to the Commercialization and Development of Vascepa

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

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

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

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

In January 2013, we launched Vascepa based on 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 > 500 mg/dL) hypertriglyceridemia. Approximately 4.0 million people in the United States have severely high triglyceride levels (TG > 500 mg/dL), commonly known as very high triglyceride levels. Guidelines for the management of very high triglyceride levels suggest that reducing triglyceride levels is the primary goal in patients to reduce the risk of acute pancreatitis. A secondary goal for this patient population is to reduce cardiovascular risk. The effect of Vascepa on cardiovascular mortality and morbidity, or the risk for pancreatitis, in patients with hypertriglyceridemia has not been determined and our FDA-approved labeling and promotional efforts state these facts.

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

both triglyceride reduction and the active pharmaceutical ingredient, or API, in Vascepa, EPA, as each relate to the potential of Vascepa to reduce cardiovascular risk.

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

- the perceived efficacy, safety and potential advantages of Vascepa, as compared to alternative treatments;
- our ability to offer Vascepa for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the scope, effectiveness and strength of product education, marketing and distribution support, including our sales and marketing team;
- publicity concerning Vascepa or competing products;
- our ability to continually promote Vascepa in the United States outside of FDA-approved labeling and the related perception thereof;
- sufficient third-party coverage or reimbursement for on-label use, and for permitted off-label use, the third-party coverage or reimbursement for which was not addressed in the scope of the August 2015 court declaration; and
- the actual efficacy of the product and the prevalence and severity of any side effects, including any limitations or warnings contained in Vascepa's approved labeling.

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

Since late 2013, our sales team has consisted of approximately 150 sales professionals, including sales representatives and their managers. This sales team promotes Vascepa to a limited group of physicians and other healthcare professionals in select geographies in the United States. This sales team is not large enough to call upon all physicians. In January 2013, when we initially began selling Vascepa in the United States through our own then newly established sales and marketing teams and through a newly established third-party commercial distribution infrastructure, our sales team was larger. In October 2013, following an FDA advisory committee recommendation against approval for the ANCHOR indication, we implemented a plan to reduce our workforce and our team of sales professionals by half.

In May 2014 we began co-promoting Vascepa in the United States with Kowa Pharmaceuticals America, Inc. under a co-promotion agreement we entered into in March 2014. Under the agreement, no less than 250 Kowa Pharmaceuticals America, Inc. sales representatives devote a substantial portion of their time to promoting Vascepa with our approximately 150 sales professionals, including sales representatives and their managers, based on a plan designed to focus on select sales territories that we believe have demonstrated the greatest potential for Vascepa sales growth and increase both the number of sales targets reached and the frequency of sales calls on existing sales targets. However, the commercialization of pharmaceutical products is a complex undertaking, and we have very limited experience as a company operating in this area and co-promoting a pharmaceutical product with a partner. In addition, if the results of the REDUCE-IT outcomes study are successful, we plan to expand our promotion of Vascepa, including increasing the size of our team. We will need to overcome challenges associated with rapidly hiring and training personnel and managing larger teams of people. Furthermore, our agreement with Kowa Pharmaceuticals America, Inc. is designed such that their co-promotion of Vascepa ceases after 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 by the end of co-promotion under this agreement.

Outside of the United States, we have expanded our commercialization activities through partnering arrangements in certain territories. In February 2015, we entered into a Development, Commercialization and Supply Agreement (the "DCS Agreement") with Eddingpharm (Asia) Macao Commercial Offshore Limited ("Eddingpharm") related to the development and commercialization of Vascepa in Mainland China, Hong Kong, Macau and Taiwan, or the China

Territory. Under the DCS Agreement, Eddingpharm is solely 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. 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.

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

In March 2016, we entered into an agreement with Biologix FZCo ("Biologix"), a company incorporated under the laws of United Arab Emirates, 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 region, as in China, is several years away in most jurisdictions and subject to similar risks. We continue to assess other partnership opportunities for licensing Vascepa to partners outside of the United States.

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

- our inability to attract and retain adequate numbers of effective sales and marketing personnel;
- our inability to adequately train our sales and marketing personnel, in particular as it relates to various healthcare regulatory requirements applicable to the marketing and sale of pharmaceutical products and the court declaration that we believe enables us to expand marketing efforts for Vascepa, and our inability to adequately monitor compliance with these requirements;
- the inability of our new sales personnel, working for us as a new market entrant, to obtain access to or persuade adequate numbers of physicians to prescribe Vascepa;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- an inability by us or our partners to obtain regulatory and marketing approval or establish marketing channels in foreign jurisdictions; and
- unforeseen costs and expenses associated with operating a new independent sales and marketing organization.

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

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

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

In April 2015, we received a Complete Response Letter, or CRL, from the FDA on our supplemental new drug application, or sNDA, that sought approval for the use of Vascepa in patients with high triglyceride levels (TG > 200 mg/dL and <500 mg/dL) who are also on statin therapy, which we refer to as the ANCHOR indication. In regulatory communications, the FDA acknowledged that the results of the ANCHOR trial as we presented them to FDA were valid and truthful in that, for example, Vascepa reduced triglyceride levels compared to placebo in patients treated in the ANCHOR study. The clinical rationale for reducing serum triglycerides with Vascepa and modifying other lipid/lipoprotein parameters shown in ANCHOR among statin-treated patients with triglycerides 200-499 mg/dL is to reduce cardiovascular risk. In not approving our ANCHOR sNDA, the FDA concluded that, for regulatory approval purposes, there were insufficient data to support a drug-induced change in serum triglycerides as a surrogate for

reducing cardiovascular risk in the ANCHOR population. The FDA did not determine that the drug-induced effects of Vascepa, which go beyond triglyceride-lowering, would not actually reduce cardiovascular risk in this population.

In August 2015, based on a federal court order, we began communicating promotional information beyond the MARINE indication to healthcare professionals in the United States through use of a set of qualified statements that reflect the state of research related to the use of Vascepa in the ANCHOR population and the supportive but not conclusive research on the use of Vascepa to reduce cardiovascular risk in this population. In March 2016, we settled the litigation related to this court order under terms by which the FDA and the U.S. government agreed to be bound by the conclusions from the federal court order that we may engage in truthful and non-misleading speech promoting the off-label use of Vascepa and that certain statements and disclosures that we proposed to

make to healthcare professionals were truthful and non-misleading. An FDA-approved indication for this patient population has not been granted. If new clinical information is demonstrated which changes what we understand today to be truthful and non-misleading, our promotion of Vascepa will need to be modified to ensure that our promotion remains truthful and non-misleading. Our ability to reach full potential in the commercialization of Vascepa in the United States is dependent upon marketing claims associated with Vascepa that are granted with the approval of an indication statement by the FDA.

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

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

The Federal Food, Drug, and Cosmetic Act, or FDCA, has been interpreted by the FDA to make it illegal for pharmaceutical companies to promote their 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.

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

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

In August 2015, we were granted preliminary relief in this lawsuit through the court's declaratory judgment that confirmed we may engage in truthful and non-misleading speech promoting the off-label use of Vascepa to healthcare professionals, i.e., to treat patients with persistently high triglycerides, and that such speech may not form the basis of a misbranding action under the FDCA. In August 2015, we began to 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.

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

communications with the FDA, we expect that final positive results from the REDUCE-IT outcomes study will be required for label expansion for Vascepa.

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

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

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

Our competitors both in the United States and Europe include large, well-established pharmaceutical companies, specialty pharmaceutical sales and marketing companies, and specialized cardiovascular treatment companies. GlaxoSmithKline plc, which currently sells Lovaza®, a prescription-only omega-3 fatty acid indicated for patients with severe hypertriglyceridemia was approved by FDA in 2004 and has been on the market in the United States since 2005. As described below, multiple generic versions of Lovaza are now available in the United States. Other large companies with competitive products include AbbVie, Inc., which currently sells Tricor® and Trilipix® for the treatment of severe hypertriglyceridemia and Niaspan®, which is primarily used to raise HDL-C but is also used to lower triglycerides. Generic versions of Tricor, Trilipix, and Niaspan are also now available in the United States. In addition, in May 2014, Epanova® (omega-3-carboxylic acids) capsules, a free fatty acid form of omega-3 (comprised of 55% EPA and 20% DHA), was approved by the FDA for patients with severe hypertriglyceridemia. Epanova was developed by Omthera Pharmaceuticals, Inc., and is now owned by AstraZeneca Pharmaceuticals LP (AstraZeneca). Also, in April 2014, Omtryg, another omega-3-acid fatty acid composition developed by Trygg Pharma AS, received FDA approval for severe hypertriglyceridemia. Neither Epanova nor Omtryg have been commercially launched, but could launch at any time. Each of these competitors, other than potentially Trygg, has greater resources than we do, including financial, product development, marketing, personnel and other resources.

Currently, seven manufacturers have launched generic versions of Lovaza. In April 2014, Teva Pharmaceuticals USA Inc., or Teva, launched a generic version of Lovaza after winning its patent litigation against Pronova BioPharma Norge AS, now owned by BASF, which owns such patent rights. In June 2014 and September 2014, Par Pharmaceutical Inc., or Par, and Apotex Inc., or Apotex, respectively, received FDA approval of their respective versions of generic Lovaza. Par launched a generic version of Lovaza in July 2014. In March 2011, Pronova/BASF entered into an agreement with Apotex to settle its patent litigation in the United States related to Lovaza. Pursuant to

the terms of the settlement agreement, Apotex launched a generic version of Lovaza in January 2015. Prasco Labs launched a generic version of Lovaza in March 2015 and AvKARE, Inc., or AvKARE, launched its version in May 2015. AvKARE supplies government agencies and does not participate in the commercial marketplace. Amneal Pharmaceuticals launched a generic version of Lovaza in January 2016. In December 2016, Golden State Medical Supply launched a generic version of Lovaza. Like AvKARE, Golden State Medical Supply only supplies products to government agencies and does not participate in the commercial marketplace.

In addition, we are aware of other pharmaceutical companies that are developing products that, if approved and marketed, would compete with Vascepa. We understand that Acasti Pharma, or Acasti, a subsidiary of Neptune Technologies & Bioresources Inc., announced in December 2015 that it intends to pursue a regulatory pathway under section 505(b)(2) of the FDCA for its omega-3 prescription drug candidate, CaPre®, derived from krill oil, for the treatment of hypertriglyceridemia. In September 2016, Acasti announced positive results from its pivotal bioavailability bridging study comparing CaPre to Lovaza, establishing a scientific bridge between the two that is expected to support the feasibility of a 505(b)(2) regulatory pathway. Acasti intends to complete long-term

toxicity studies in the next 6-9 months and follow these with a Phase 3 clinical program to assess the safety and efficacy of CaPre in patients with very high (³500 mg/dL) triglycerides. We believe Sancilio & Company, or Sancilio, is also developing potential treatments for hypertriglyceridemia based on omega-3 fatty acids. To our knowledge, Sancilio is pursuing a regulatory pathway under section 505(b)(2) of the FDCA for its product and submitted an Investigational New Drug Application, or IND, in July 2015. Sancilio completed two pharmacokinetic studies and Phase 2 bioavailability studies (FASTR I&II), with one comparing SC401 to Lovaza. We expect the company to initiate a pivotal clinical Phase 3 study as the next step in development.

In addition, we are aware that Matinas BioPharma, Inc. is developing an omega-3-based therapeutic for the treatment of severe hypertriglyceridemia and mixed dyslipidemia. Matinas BioPharma, Inc. has filed an IND with the FDA to conduct a human study in the treatment of severe hypertriglyceridemia. Akcea Therapeutics/Ionis Pharmaceuticals (formerly Isis Pharmaceuticals), or Akcea/Ionis, announced favorable Phase 3 results of volanesorsen (formerly ISIS-APOCIII$_{Rx}$), a drug candidate administered through weekly subcutaneous injections, in patients with severe hypertriglyceridemia (COMPASS trial). Phase 2 trials are currently ongoing studying volanesorsen in patients with familial chylomicronemia syndrome (FCS) and familial partial lipodystrophy (FPL) with data expected in 2017 and 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 volanesorsen. Madrigal Pharmaceuticals has completed Phase 1 clinical testing of MGL-3196 for the treatment of high triglycerides and various lipid parameters in patients. Finally, Gemfire Therapeutics announced favorable results from a Phase 2 trial to evaluate the safety and efficacy of gemcabene, an oral, once-daily pill, in the treatment of patients with homozygous familial hypercholesterolemia (HoFH) on stable lipid-lowering therapy. The novel mechanism of action of gemcabene may support multiple indications including a potential severe triglyceride reduction. Three Phase 2b trials of gemcabene are ongoing in patients with HoFH on stable lipid-lowering therapy, in patients with severe hypertriglyceridemia, and in patients with hypercholesterolemia on a high-intensity stable statin therapy with or without ezetimibe.

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

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

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

The paragraph IV notice is required to contain a detailed factual and legal statement explaining the basis for the applicant’s opinion that the proposed product does not infringe our patents, that our patents are invalid, or both. After receipt of a valid notice, we would have the option of bringing a patent infringement suit in federal district court against any generic company seeking approval for its product within 45 days from the date of receipt of each notice. If such a suit is commenced within this 45 day period, we will be entitled to receive a 30 month stay on FDA’s ability to give final approval to any of the proposed products that reference Vascepa that begins on the date we receive the paragraph IV notice. The stay may be shortened or lengthened if either party fails to cooperate in the litigation and it

may be terminated if the court decides the case in less than 30 months. If the litigation is resolved in favor of the applicant before the expiration of the 30 month period, the stay will be immediately lifted and the FDA's review of the application may be completed. Such litigation is often time-consuming and costly, and may result in generic competition if such patents are not upheld or if the generic competitor is found not to infringe such patents.

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

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

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

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

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

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

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

We filed 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.). 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 (collectively, "Teva") in the U.S. District Court for the District of Nevada. The case against Teva is 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 Vascepa before the last to expire of the asserted patents in 2030. The three lawsuits have been consolidated for pretrial proceedings, and are in their early stages. As a result of the statutory stay associated with the filing of these lawsuits under the Hatch-Waxman Act, the FDA cannot grant final approval to Roxane, DRL, or Teva's respective ANDA before January 2020, unless there is an earlier court decision holding that the subject patents are not infringed and/or are invalid.

The fourth ANDA applicant referenced above is Apotex Inc. ("Apotex"), which sent Amarin 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 Act.

We intend to vigorously enforce our intellectual property rights relating to Vascepa, but we cannot predict the outcome of the Roxane, DRL or Teva lawsuits or any subsequently filed lawsuits.

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

Vascepa's five-year, new chemical entity, or NCE, regulatory exclusivity from the FDA and related 30-month stay that is scheduled to expire in January 2020 could be challenged by companies seeking to make generic versions of Vascepa.

The timelines and conditions under the abbreviated new drug application, or ANDA, process that permit the start of patent litigation and allow the FDA to approve generic versions of brand name drugs like Vascepa differ based on whether a drug receives three-year, or five-year, new chemical entity, or NCE, marketing exclusivity. In May 2016, after significant litigation, FDA determined that Vascepa is eligible for NCE marketing exclusivity. Accordingly, a related 30-month stay is currently in place and 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 also help protect Vascepa against generic competition.

We applied to the FDA for five-year, NCE marketing exclusivity for Vascepa in connection with the NDA for our MARINE indication, which NDA was approved by the FDA on July 26, 2012. On February 21, 2014, in connection with the July 26, 2012 approval of the MARINE indication, the FDA denied a grant of five-year NCE marketing exclusivity to Vascepa and granted three-year marketing exclusivity. Under applicable regulations, such three-year exclusivity would have extended through July 25, 2015 and would have been supplemented by a 30-month stay triggered by patent litigation that would have extended into September 2016, unless such patent litigation was resolved against us sooner.

NCE marketing exclusivity precludes approval during the five-year exclusivity period of certain 505(b)(2) applications and ANDAs submitted by another company for another version of the drug. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. In this case, Amarin, as a 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. This determination provides Vascepa with the benefits of NCE exclusivity afforded by statute. NCE exclusivity for Vascepa runs from its date of FDA approval on July 26, 2012 and extends until July 26, 2017. The statutory 30-month stay triggered by patent litigation following generic application submissions permitted on July 26, 2016 would continue until January 26, 2020, seven-and-a-half years from FDA approval, unless such patent litigation was resolved against us sooner.

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

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 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 also marketed by others as non-prescription dietary supplements. We cannot be sure physicians will view the pharmaceutical grade purity and tested efficacy and safety of Vascepa as having a superior therapeutic profile to untested and largely unregulated omega-3 fatty acid dietary supplements. In addition, the FDA has not yet enforced what we view as illegal drug claims made by certain omega-3 fatty acid supplement manufacturers to the extent we believe appropriate under applicable law and regulations, for example, claims that such supplements reduce triglyceride levels. Also, for more than a decade now, the FDA has expressly permitted dietary supplement manufacturers that sell supplements containing the omega-3 fatty acids EPA and/or DHA to make the following qualified health claim directly to consumers: Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease. As a result of our First Amendment litigation and settlement, we may now make this claim to healthcare professionals subject to certain qualifications. These factors enable dietary supplements to effectively compete with Vascepa. In addition, to the extent the net price of Vascepa after insurance and offered discounts is significantly higher than the prices of commercially available omega-3 fatty acids marketed by other companies as dietary supplements (through that lack of coverage by insurers or otherwise), physicians and pharmacists may recommend these commercial alternatives instead of writing or filling prescriptions for Vascepa or patients may elect on their own to take commercially available omega-3 fatty acids. While Vascepa is highly price-competitive for patients generally, and in particular when covered by insurance—cheaper in many cases—either of these outcomes may adversely impact our results of operations by limiting how we price our product and limiting the revenue we receive from the sale of Vascepa due to reduced market acceptance.

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

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

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

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

Our special protocol assessment, or SPA, agreement for ANCHOR was rescinded and our SPA agreement for REDUCE-IT is not a guarantee of FDA approval of Vascepa for the proposed REDUCE-IT indication.

A SPA is an evaluation by the FDA of a protocol with the goal of reaching an agreement that the Phase 3 trial protocol design, clinical endpoints, and statistical analyses are acceptable to support regulatory approval of the drug product candidate with respect to effectiveness for the indication studied. The ANCHOR trial was, and the REDUCE-IT trial is, being conducted under a SPA agreement with the FDA. In each case, the FDA agreed that, based on the information we submitted to the agency, the design and planned analysis of the trial is adequate to support use of the conducted study as the primary basis for approval with respect to effectiveness. A SPA agreement is not a guarantee of approval. A SPA agreement is generally binding upon the FDA except in limited circumstances, such as if the FDA identifies a substantial scientific issue essential to determining safety or efficacy after the study begins, or if the study sponsor fails to follow the protocol that was agreed upon with the FDA. The FDA reserves the right of final determinations for approval based on its review of the entire data presented in a marketing application.

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

Thus, even though we have received regulatory approval of Vascepa for the MARINE indication under a SPA agreement, our ANCHOR SPA agreement was rescinded. There is no assurance that the FDA will not rescind our REDUCE-IT SPA agreement.

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

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

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

In accordance with the SPA agreements for our MARINE and ANCHOR trials, efficacy was evaluated in these trials compared to placebo at twelve weeks. No placebo-controlled studies have been conducted regarding the long-term effect of Vascepa on lipids, and no outcomes study has been conducted evaluating Vascepa. The REDUCE-IT study, which commenced in 2011 and completed patient enrollment and randomization of 8,175 individual patients in 2016, is designed to evaluate the efficacy of Vascepa in reducing major cardiovascular events in an at-risk patient population with high triglyceride levels despite being on statin therapy.

Outcomes studies of certain other lipid-modifying therapies have failed to achieve the endpoints of such studies, even though they reduced triglyceride levels and showed other favorable effects on parameters relevant to cardiovascular health in studied patients. For example, in 2010, the results of the ACCORD-Lipid trial were published. This trial studied the effect of adding fenofibrate onto open-label simvastatin therapy on cardiovascular outcomes. The addition of fenofibrate did not show any treatment benefit on cardiovascular outcomes over simvastatin monotherapy in this study. In 2011, the results of the AIM-HIGH trial were published. This trial studied the effect of adding a second lipid-altering agent, extended-release niacin, to simvastatin therapy on cardiovascular outcomes in people at high risk for cardiovascular events. No significant incremental treatment benefit with extended-release niacin was observed.

Outcomes studies of certain other lipid-modifying therapies included results which, after review of information not fully available to the sponsors during the conduct of the trials, modified initial reports of the trial results. Two examples are the AIM-HIGH trial and the IMPROVE-IT trial. When the AIM-HIGH trial was stopped, there were initial reports of certain safety concerns which, upon further and more detailed subsequent review, were concluded to not be associated with the study therapy. After the IMPROVE-IT trial was completed, initial reports on the effect of adding ezetimibe to statin therapy in subjects with acute coronary syndrome suggested greater benefit on cardiovascular outcomes than was considered to be the case after later reassessment and further evaluation of study data. In 2015, the results of the IMPROVE-IT trial were published. Based on the published results, the addition of ezetimibe showed incremental lowering of LDL-C levels and improved cardiovascular outcomes. This result was statistically significant but less than ten percent. Further evaluation of the IMPROVE-IT results suggested that the outcomes benefit may have been lower after factoring in and making certain assumptions regarding complicating factors such as a high number of patients who discontinued the study drug, withdrew consent, or were lost to follow-up. FDA approval of a new indication for ezetimibe based on the IMPROVE-IT results was denied after a negative FDA advisory committee recommendation that followed examination of the study results.

In addition, in September 2012, researchers published in the Journal of the American Medical Association, or JAMA, the results of a retrospective meta-analysis of twenty previously conducted studies regarding the use of omega-3 supplements across various patient populations. This meta-analysis suggested that the use of such supplements was not associated with a lower risk of all-cause death, cardiac death, sudden death, heart attack, or stroke. These facts illustrate categories of challenges faced in demonstrating favorable results in complex clinical studies like REDUCE-IT and in seeking to apply those results in support of regulatory approvals.

Data from clinical trials are invariably complex. It is also not typically possible to reliably extrapolate results from one trial to predict results from another as many factors differ between trials. For instance, unlike REDUCE-IT, the outcomes studies for fenofibrates and niacin were conducted in patient populations in which the majority of patients studied had triglycerides below 200 mg/dL and fenofibrates and niacin are believed to work differently than Vascepa in the body and do not have as favorable a side-effect profile. Of the twenty studies included in the JAMA meta-analysis, nineteen involved the use of omega-3 supplements containing a mixture of EPA and DHA, and most were evaluated at relatively lower doses. In addition, in May 2013, The New England Journal of Medicine published the results of an outcomes study of 1 gram per day of an omega-3 acid ethyl ester composition containing both EPA and DHA. In that study, the composition failed to show a benefit in reducing the rate of death from cardiovascular causes or hospitalization for cardiovascular causes when administered to patients with cardiovascular risk factors under different study conditions than in the REDUCE-IT study. Vascepa is comprised of highly-pure ethyl-EPA, and has been approved by the FDA for use in adult patients with severe hypertriglyceridemia at a dose of 4 grams per day and is being studied in REDUCE-IT at 4 grams per day.

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

Further, FDA determined that JELIS results could not be used as support for or against the use of triglyceride levels as a surrogate for cardiovascular risk reduction. Patients treated with EPA and statin in JELIS achieved triglyceride levels that were only 5% lower, on average, than those achieved among patients treated with statin alone; however, the

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

There can be no assurance that the REDUCE-IT study will be completed successfully, that the endpoints of the REDUCE-IT cardiovascular outcomes study will be achieved, that, like the IMPROVE-IT trial, patients who discontinue the study drug, withdrew consent, or were lost to follow-up will not negatively affect REDUCE-IT results, that the results will support regulatory approvals, or that the lipid-modifying effects of Vascepa in REDUCE-IT or any other study of Vascepa will not be subject to variation beyond twelve weeks. If the REDUCE-IT trial is not successful or if the results of this long-term study are not consistent with the 12-week clinical results, it could prevent us from expanding the labeled approval of Vascepa or even call into question the currently understood efficacy and safety profile of Vascepa. In any such case, the market potential for Vascepa would suffer and our business would be materially affected.

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

There can be no assurance as to the adequacy for commercial success of Vascepa outside the United States. For example, even if we and Eddingpharm obtain marketing approval in countries within the China Territory, applicable regulatory agencies may impose restrictions on the product's conditions for use, distribution or marketing and in some cases may impose ongoing requirements for post-market surveillance, post-approval studies or clinical trials. Also, 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 potentially subject to U.S. federal and state consumer protection and unfair competition laws. Similar requirements exist in many of these areas in other countries.

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

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; and
- A new formula that increases the rebates a manufacturer must pay under the Medicaid Drug Rebate Program.

We expect further federal and state proposals and 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, and appear likely in the 115th United States Congress and 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. It will be time consuming and expensive for us to go through the process of seeking coverage and reimbursement from Medicare and private payors. Our products may not be considered cost effective, and government and third-party private health insurance coverage and reimbursement may not be available to patients for any of our future products or sufficient to allow us to sell our products on a competitive and profitable basis. Our results of operations could be adversely affected by PPACA and by other healthcare reforms that may be enacted or adopted in the future. In addition, increasing emphasis on managed care in the United States will continue to put pressure on the pricing of pharmaceutical products. Cost control initiatives could

decrease the price that we or any potential collaborators could receive for any of our future products and could adversely affect our profitability.

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

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

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products. In particular, in general, the U.S. government's position has been that a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. Even though we received FDA marketing approval for Vascepa for the MARINE indication and we believe the First Amendment court ruling and litigation settlement affords us a degree of protection for other promotional efforts, physicians may still prescribe Vascepa to their patients for use in the treatment of conditions that are not included as part of the indication statement in our FDA-approved Vascepa label or our settlement. If we are found to have promoted Vascepa outside the terms of the litigation settlement or in violation of what federal or state government may determine to be acceptable, we may become subject to significant government fines and other related liability, such as under the 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 partner outside the United States, Eddingpharm. For example, the Federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

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

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

The prospective 80% interim efficacy and safety analysis of the REDUCE-IT cardiovascular outcomes trial may not be completed in the contemplated timeframe and may not demonstrate to the independent committee monitoring the study a sufficient benefit risk result to warrant the independent committee recommending stopping the study early for overwhelming efficacy. The independent monitoring committee may, at its discretion, also recommend that the study be stopped for safety or related concerns.

In September 2016, we announced that the DMC completed its review of the first pre-specified interim efficacy analysis upon reaching approximately 60% of the target aggregate number of cardiovascular events in accordance with the SPA agreement for our REDUCE-IT cardiovascular outcomes trial and, consistent with previously stated expectations, recommended that the trial continue as planned without modification. In March 2017, we announced that the onset of approximately 80% of the target aggregate number of primary cardiovascular events has triggered preparation for a pre-specified interim efficacy and safety analysis by the study's independent DMC. We currently expect the independent interim analysis to be conducted before the end of the third calendar quarter of 2017. It may actually take longer than anticipated for the DMC assessment of data for the interim analysis.

Further, as is typical of interim analyses, the statistical threshold for defining overwhelming efficacy on the primary endpoint that would call for stopping the study early in connection with such analysis is considerably higher than the threshold for defining statistical significance after the expected completion of the study near the end of 2017. We do not expect the study to be stopped due to overwhelming efficacy at the next interim look. We have requested the DMC to not recommend stopping the study early based only upon the achievement of statistical significance for the primary endpoint, but to ensure that supportive trends of benefit are also consistently observed in certain secondary endpoints and subpopulations before recommending that the study be stopped early for overwhelming efficacy. For example, even if the appropriate studied cardiovascular events in the trial occur at sufficiently low rates in the active, Vascepa, group as compared to the placebo group such that the study would be a success at completion, the more rigorous statistical analysis applied by the DMC at the interim analysis may not warrant stoppage of the study for overwhelming efficacy in connection with the interim analysis. The study may also be stopped pursuant to recommendation by the DMC at this interim analysis due to low likelihood of obtaining a favorable result at completion. Despite no formal futility analysis or boundary being pre-specified in the protocol, it is within the purview of the DMC to weigh all available information and recommend study stoppage or continuation.

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

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

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

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

Even if we obtain positive results from early stage preclinical studies or clinical trials, we may not achieve the same success in future trials. Clinical trials that we or potential partners conduct may not provide sufficient safety and efficacy data to obtain the requisite regulatory approvals for product candidates. The failure of clinical trials to demonstrate safety and efficacy for our desired indications could harm the development of that product candidate as well as other product candidates, and our business and results of operations would suffer. For example, the efficacy results of our Vascepa Phase 3 clinical trials for the treatment of Huntington’s disease were negative. As a result, we stopped development of that product candidate, revised our clinical strategy and shifted our focus to develop Vascepa for use in the treatment of cardiovascular disease. 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 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 has recommended to continue the REDUCE-IT study as planned. Each of these DMC recommendations has been shared with FDA. Amarin and FDA remain blinded to such study data. Despite the currently positive disposition of this matter, it 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.

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. We have a relatively small sales organization consisting of approximately 150 sales professionals, including sales representatives and their managers. 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 beyond Nisshin 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 difficult and subject to numerous regulations and other operational challenges. The resources of our suppliers vary and are limited; costs associated with projected expansion and qualification can be significant. For example, Chemport, which was approved as one of our API suppliers in April 2013, is a privately-held company and their commitment to Vascepa supply has required them to seek additional resources. There can be no assurance that the expansion plans of any of our suppliers will be successful. Our aggregate capacity to produce API is dependent upon the qualification of our API suppliers. Each of our API suppliers has outlined plans for potential further capacity expansion. If no additional API supplier is approved by the FDA as part of an sNDA, our API supply will be limited to the API we purchase from previously approved suppliers. If our third-party manufacturing capacity is not expanded and/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), Catalent Pharma Solutions, and Capsugel Plöermel SAS. 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.

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

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

We are dependent upon our collaboration with Eddingpharm and others to commercialize Vascepa in certain regions outside of the United States, and if such third parties fail to successfully fulfill their obligations, or are ineffective in their commercialization of Vascepa, or if our collaborations are terminated, our plans to commercialize Vascepa outside of the United States may be adversely affected.

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

In addition, Eddingpharm has the right to terminate the agreement under certain conditions. If Eddingpharm terminates the DCS Agreement, we would be required to either enter into alternative arrangements with third parties to commercialize Vascepa in the China Territory, which we may be unable to do, or to increase our internal

infrastructure, both of which would likely result in significant additional expense and delay or termination of our Vascepa clinical development programs outside of the United States.

We also have an agreement with Biologix, entered into in March 2016, to register and commercialize Vascepa in countries within the Middle East and North Africa. Commercialization across the region, as in China, is subject to similar third party risk.

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