AMARIN CORP PLC\UK
Form 10-Q
May 01, 2019

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, 2019

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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). YES NO

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

Large accelerated filer	Accelerated filer
Non-accelerated filer	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

330,686,553 common shares were outstanding as of April 26, 2019, including 330,480,979 shares held as American Depositary Shares (ADSs), each representing one Ordinary Share, 50 pence par value per share and 205,574 Ordinary Shares. In addition, 28,931,746 ordinary share equivalents were issuable in exchange for outstanding preferred shares as of April 26, 2019, for a total of 359,618,299 ordinary shares and ordinary share equivalents outstanding as of April 26, 2019.

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PART I

AMARIN CORPORATION PLC

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited, in thousands, except share amounts)

	March 31, 2019	December 31, 2018
ASSETS		
Current Assets:		
Cash and cash equivalents	$211,089	$249,227
Restricted cash	1,502	1,500
Accounts receivable, net	79,485	66,523
Inventory	57,909	57,802
Prepaid and other current assets	5,334	2,945
Total current assets	355,319	377,997
Property, plant and equipment, net	57	63
Operating lease right-of-use asset	8,900	—
Other long-term assets	643	174
Intangible asset, net	7,319	7,480
TOTAL ASSETS	$372,238	$385,714
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$26,776	$37,632
Accrued expenses and other current liabilities	94,170	84,171
Current portion of long-term debt from royalty-bearing instrument	38,960	34,240
Deferred revenue, current	1,898	1,220
Total current liabilities	161,804	157,263
Long-Term Liabilities:		
Long-term debt from royalty-bearing instrument	35,338	46,108
Deferred revenue, long-term	18,265	19,490
Long-term operating lease liability	7,930	—
Other long-term liabilities	8,030	10,523
Total liabilities	231,367	233,384
Commitments and contingencies (Note 6)		
Stockholders' Equity:		
Series A Convertible Preferred Stock, £0.05 par, unlimited authorized; 289,317,460 shares issued and outstanding as of March 31, 2019 and December 31, 2018 (equivalent to 28,931,746 ordinary shares upon future consolidation and redesignation at a 10:1 ratio)	21,850	21,850
Common stock, £0.50 par, unlimited authorized; 334,365,726 issued, 330,578,168 outstanding as of March 31, 2019; 329,110,863 issued, 325,850,013 outstanding as of December 31, 2018	250,088	246,663
Additional paid-in capital	1,301,389	1,282,762
Treasury stock; 3,787,558 shares as of March 31, 2019; 3,260,850 shares as of December 31, 2018	(19,493)	(10,413)
Accumulated deficit	(1,412,963)	(1,388,532)

Total stockholders' equity	140,871	152,330
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$372,238	$385,714

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,	
	2019	2018
Product revenue, net	$72,731	$43,777
Licensing revenue	547	142
Total revenue, net	73,278	43,919
Less: Cost of goods sold	17,140	10,648
Gross margin	56,138	33,271
Operating expenses:		
Selling, general and administrative	71,633	43,407
Research and development	7,242	11,762
Total operating expenses	78,875	55,169
Operating loss	(22,737)	(21,898)
Interest expense, net	(1,697)	(2,252)
Other income, net	3	55
Loss from operations before taxes	(24,431)	(24,095)
(Provision for) benefit from income taxes	—	—
Net loss	$(24,431)	$(24,095)
Loss per share:		
Basic	$(0.07)	$(0.08)
Diluted	$(0.07)	$(0.08)
Weighted average shares:		
Basic	328,712	285,207
Diluted	328,712	285,207

See notes to condensed consolidated financial statements.

AMARIN CORPORATION PLC

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

(Unaudited, in thousands, except share amounts)

	Preferred Shares	Common Shares	Treasury Shares	Preferred Stock	Common Stock	Additional Paid-in Capital	Treasury Stock	Accumulated Deficit	Total
December 31, 2018	289,317,460	329,110,863	(3,260,850)	$21,850	$246,663	$1,282,762	$(10,413)	$(1,388,532)	$152,330
Exercise of stock options	—	3,838,739	—	—	2,496	12,960	—	—	15,456
Vesting of restricted stock units	—	1,416,124	(526,708)	—	929	(929)	(9,080)	—	(9,080)
Stock-based compensation	—	—	—	—	—	6,596	—	—	6,596
Loss for the period	—	—	—	—	—	—	—	(24,431)	(24,431)
March 31, 2019	289,317,460	334,365,726	(3,787,558)	$21,850	$250,088	$1,301,389	$(19,493)	$(1,412,963)	$140,871

	Preferred Shares	Common Shares	Treasury Shares	Preferred Stock	Common Stock	Additional Paid-in Capital	Treasury Stock	Accumulated Deficit	Total
December 31, 2017	328,184,640	272,719,044	(1,697,033)	$24,364	$208,768	$977,866	$(4,229)	$(1,271,869)	$(65,100)
Cumulative-effect adjustment	—	—	—	—	—	—	—	(218)	(218)
January 1, 2018	328,184,640	272,719,044	(1,697,033)	$24,364	$208,768	$977,866	$(4,229)	$(1,272,087)	$(65,318)
Issuance of common stock, net of transaction costs	—	20,616,438	—	—	14,635	55,372	—	—	70,007
Exercise of stock options	—	782,553	—	—	541	1,007	—	—	1,548
Vesting of restricted stock units	—	1,838,380	(675,242)	—	1,302	(1,302)	(2,553)	—	(2,553)
Stock-based compensation	—	—	—	—	—	3,754	—	—	3,754

Loss for the period	—	—	—	—	—	—	—	(24,095)	(24,095)
March 31, 2018	328,184,640	295,956,415	(2,372,275)	$24,364	$225,246	$1,036,697	$(6,782)	$(1,296,182)	$(16,657)

See notes to condensed consolidated financial statements.

AMARIN CORPORATION PLC

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited, in thousands)

	Three months ended March 31,	
	2019	2018
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$(24,431)	$(24,095)
Adjustments to reconcile loss to net cash used in operating activities:		
Depreciation and amortization	6	8
Stock-based compensation	6,883	3,762
Amortization of debt discount and debt issuance costs	446	573
Amortization of intangible asset	161	162
Changes in assets and liabilities:		
Accounts receivable, net	(12,962)	6,138
Inventory	(107)	(4,844)
Prepaid and other current assets	(2,389)	(163)
Other long-term assets	(469)	—
Accrued interest payable	(73)	(327)
Deferred revenue	(547)	(142)
Accounts payable and other current liabilities	(2,238)	9,123
Other long-term liabilities	(2,369)	—
Net cash used in operating activities	(38,089)	(9,805)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Net cash used in investing activities	—	—
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock, net of transaction costs	—	70,007
Proceeds from exercise of stock options, net of transaction costs	15,456	1,548
Payment on long-term debt from royalty-bearing instrument	(6,423)	(3,785)
Taxes paid related to stock-based awards	(9,080)	(2,553)
Net cash (used in) provided by financing activities	(47)	65,217
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS AND RESTRICTED CASH	(38,136)	55,412
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH, BEGINNING OF PERIOD	250,727	74,237
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH, END OF PERIOD	$212,591	$129,649
Supplemental disclosure of cash flow information:		
Cash paid during the year for:		
Interest	$7,709	$5,873
Income taxes	$—	$23
Supplemental disclosure of non-cash transactions:		
Initial recognition of operating lease right-of-use asset	$8,995	$—

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, ordinary shares may also be referred to as "common shares" or "common stock."

(1) Nature of Business and Basis of Presentation

Nature of Business

Amarin Corporation plc ("Amarin" or the "Company") is a pharmaceutical company with expertise in omega-3 fatty acids and lipid science focused on the commercialization and development of therapeutics to improve cardiovascular health and reduce cardiovascular risk. Since its inception, the Company has devoted substantial resources to research and development.

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 (the "U.S.") by prescription only. In January 2013, the Company began selling and marketing 1-gram size Vascepa capsules in the United States, and in October 2016, introduced a smaller 0.5-gram capsule size. In August 2015, in addition to marketing Vascepa for severe hypertriglyceridemia, the Company commenced marketing Vascepa for use in adult patients with mixed dyslipidemia, as an adjunct to diet and an add-on to statin therapy in patients who despite statin therapy have high triglycerides (TGs >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 also developed Vascepa for FDA approval of potential additional indications for use. In particular, the Company conducted a cardiovascular outcomes study of Vascepa, titled REDUCE-IT™ (Reduction of Cardiovascular Events with EPA—Intervention Trial). The REDUCE-IT study, which commenced in 2011 and completed patient enrollment and randomization of 8,179 individual patients in 2016, was designed to evaluate the efficacy of Vascepa in reducing major cardiovascular events in a high-risk patient population on statin therapy. The REDUCE-IT study topline results were made public in September 2018, and the primary results of the REDUCE-IT study were presented at the 2018 Scientific Sessions of the American Heart Association (AHA) in November 2018 with such results concurrently published in The New England Journal of Medicine. The total (first and subsequent) cardiovascular events results of the REDUCE-IT study were presented at the American College of Cardiology's (ACC) 68th Annual Scientific Session in March 2019 and concurrently published in the Journal of the American College of Cardiology. The Company submitted a supplemental new drug application (sNDA) in March 2019 to the FDA seeking revised labeling for Vascepa based on results of the REDUCE-IT study and, upon such expanded labeling, subject to FDA approval of such label, to further expand its promotion of Vascepa in the United States.

In the United States, 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 in the United States through its direct sales force, which prior to the REDUCE-IT results topline announcement in September 2018 consisted of approximately 170 sales professionals, including sales representatives and their managers, and to begin 2019 increased to approximately 440 sales professionals, including approximately 400 sales representatives and remained at approximately this level as of March 31, 2019. Prior to 2019, the Company also engaged a co-promotion partner to help promote Vascepa in the United States which co-promotion by mutual agreement was not extended beyond December 31, 2018. Outside of the United States, the Company has entered into agreements with third party companies in select geographies for purposes of pursuing regulatory approval and commercialization of Vascepa. The Company operates in one business segment.

Basis of Presentation

The condensed consolidated financial statements included herein have been prepared by the Company, without audit, in accordance with accounting principles generally accepted in the United States 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, 2018, or the 2018 Form 10-K, filed with the SEC. The balance sheet amounts at December 31, 2018 in this report were derived from the Company's audited 2018 consolidated financial statements included in the 2018 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, 2019 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. 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.

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

As of March 31, 2019, the Company had current assets of $355.3 million, including cash and cash equivalents of $211.1 million, accounts receivable, net, of $79.5 million and inventory of $57.9 million. The Company's condensed consolidated balance sheets also include long-term debt from a royalty-bearing instrument which is anticipated to be repaid quarterly calculated as a percentage of Vascepa net revenues until fully satisfied. As of March 31, 2019, the Company had no other debt outstanding.

(2) Significant Accounting Policies

Accounts Receivable, net

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

The following table summarizes the impact of accounts receivable reserves on the gross trade accounts receivable balances as of March 31, 2019 and December 31, 2018:

In thousands	March 31, 2019	December 31, 2018
Gross trade accounts receivable	$ 104,011	$ 86,133
Trade allowances	(23,992)	(19,495)
Chargebacks	(534)	(115)
Accounts receivable, net	$ 79,485	$ 66,523

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.

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

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

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

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

The Company's and its subsidiaries' income tax returns are periodically examined by various tax authorities, including the Internal Revenue Service (IRS) and states. The Company recently completed the audit by the IRS for the years 2013 to 2014 with no material changes to the filed income tax returns. Although the outcome of tax audits is always uncertain and could result in significant cash tax payments, the Company does not believe the outcome of these audits will have a material adverse effect on its consolidated financial position or results of operations.

Loss per Share

Basic net loss per share is determined by dividing net loss by the weighted average shares of common stock outstanding during the period. Diluted net loss per share is determined by dividing net loss by diluted weighted average shares outstanding. Diluted weighted average shares reflects the dilutive effect, if any, of potentially dilutive common shares, such as common stock options calculated using the treasury stock method and convertible notes using the "if-converted" method. In periods with reported net operating losses, all common stock options are deemed anti-dilutive such that basic net loss per share and diluted net loss per share are equal.

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

The calculation of net loss and the number of shares used to compute basic and diluted net loss per share for the three months ended March 31, 2019 and 2018 are as follows:

	Three months ended March 31,	
In thousands	2019	2018
Net loss—basic and diluted	$(24,431)	$(24,095)
Weighted average shares outstanding—basic and diluted	328,712	285,207
Net loss per share—basic and diluted	$(0.07)	$(0.08)

For the three months ended March 31, 2019 and 2018, the following potentially dilutive securities were not included in the computation of net loss per share because the effect would be anti-dilutive:

	Three months ended March 31,	
In thousands	2019	2018
Stock options	16,837	25,703
Restricted stock and restricted stock units	9,341	12,420
Exchangeable senior notes (if converted)	—	7,716
Preferred stock (if converted)	28,932	32,818

Concentration of Credit Risk

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

A significant portion of the Company's sales are to wholesalers in the pharmaceutical industry. The Company monitors the creditworthiness of customers to whom it grants credit terms and has not experienced any credit losses. The Company does not require collateral or any other security to support credit sales. Three customers individually accounted for 10% or more of the Company's gross product sales, Customers A, B, and C accounted for 21%, 39%, and 29%, respectively, of gross product sales for the three months ended March 31, 2019, and represented 32%, 37%, and 21%, respectively, of the gross accounts receivable balance as of March 31, 2019. Customers A, B, and C accounted for 26%, 31%, and 31%, respectively, of gross product sales for the three months ended March 31, 2018 and represented 37%, 30%, and 24%, respectively, of the gross accounts receivable balance as of March 31, 2018. The Company has not experienced any significant write-offs of its accounts receivable.

Concentration of Suppliers

The Company has contractual freedom to source the API for Vascepa and to procure other services supporting its supply chain 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 suppliers.

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

The Company currently has manufacturing agreements with multiple independent FDA-approved API manufacturers and several independent FDA-approved API encapsulators and packagers for Vascepa manufacturing. Each of these companies has qualified and validated 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 manufacture Vascepa or Vascepa API will remain qualified to do so to its specifications or that these and any future suppliers will have the manufacturing capacity to meet anticipated demand for Vascepa.

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, 2019 and December 31, 2018 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, 2019			
In thousands	Total	Level 1	Level 2	Level 3
Asset:				
Cash equivalents—money market	$9,945	$9,945	$ —	$ —

	December 31, 2018			
In thousands	Total	Level 1	Level 2	Level 3
Asset:				
Cash equivalents—money market	$9,880	$9,880	$ —	$ —

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, 2019 and December 31, 2018 are as follows:

	March 31, 2019		December 31, 2018	
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	$38,394		$33,602	
Long-term debt from royalty-bearing instrument	35,338		46,108	
Total long-term debt from royalty-bearing instrument	$73,732	$ 72,600	$79,710	$ 78,600

The estimated fair value of the long-term debt from royalty-bearing instrument is calculated utilizing the same Level 3 inputs utilized in valuing the related derivative liability (see Derivative Liabilities below). The carrying value of the long-term debt from royalty-bearing instrument as of both March 31, 2019 and December 31, 2018 did not include a debt discount as it had been fully amortized.

Derivative Liabilities

Derivative financial liabilities are recorded at fair value, with gains and losses arising for changes in fair value recognized in the condensed consolidated statement of operations at each period end while such instruments are outstanding. If the Company issues shares to discharge the liability, the derivative financial liability is derecognized and common stock and additional paid-in capital are recognized on the issuance of those shares.

Long-Term Debt Redemption Feature

The Company’s December 2012 royalty-bearing instrument financing arrangement (discussed in Note 5—Debt) contains a redemption feature whereby, upon a change of control, the Company would be required to repay $150.0 million, less any previously repaid amount. The Company determined this redemption feature to be an embedded derivative, which is carried at fair value and is classified as Level 3 in the fair value hierarchy due to the use of significant unobservable inputs. The fair value of the embedded derivative was calculated using a probability-weighted model incorporating management estimates of future revenues and for a potential change in control, and by determining the fair value of the debt with and without the change in control provision included. The difference between the two was determined to be the fair value of the embedded derivative. The fair value of this derivative liability is remeasured at each reporting period, with changes in fair value recognized in the condensed consolidated statement of operations. As of March 31, 2019, the fair value of the derivative was determined to be nil, and the debt was valued by comparing debt issues of similar companies with (i) remaining terms of between 1.3 and 7.6 years, (ii) coupon rates of between 5.4% and 11.6% and (iii) market yields of between 8.1% and 14.9%. As of December 31, 2018, 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 1.3 and 4.0 years, (ii) coupon rates of between 5.4% and 10.8% and (iii) market yields of between 6.7% and 15.8%. As such, the Company recognized no gain or loss on change in fair value of derivative liability for the three months ended March 31, 2019. The Company recognized no gain or loss on change in fair value of derivative liability for the three months ended March 31, 2018.

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

Segment and Geographical Information

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

Recent Accounting Pronouncements

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

In February 2016, the FASB issued Accounting Standard Update ("ASU") 2016-02, Leases (ASC 842), which supersedes the existing guidance for lease accounting, Leases (Topic 840). ASU 2016-02 requires lessees to recognize a lease liability and a right-of-use asset

for virtually all of their leases (other than leases that meet the definition of a short-term lease). Lessor accounting remains largely unchanged except for changes in the definition and classification of leases. ASU 2016-02 requires a modified retrospective approach for all leases existing at, or entered into after the date of initial adoption, with an option to elect to use certain transition relief. The FASB also proposed a transition method to allow entities to not apply the new leases standard in the comparative periods they present in their financial statements in the year of adoption.

On January 1, 2019, the Company adopted ASC 842 using the modified retrospective method for all leases that existed at or commenced after January 1, 2019. The adoption of ASC 842 did not have a material impact on the Company's condensed consolidated financial statements as of the effective date. See Note 11 – Leases for further details. The Company elected to apply the practical expedients in ASC 842-10-65-1 (f) and therefore:

1) Did not reassess expired contracts for the presence of lease components therein and if it was already concluded that such contracts had lease components then the classification of the respective lease components therein was not re-assessed.
2) Did not re-assess initial direct costs for any existing leases.
3) Will not separate the lease and non-lease components.

In June 2018, the FASB issued ASU No. 2018-07, Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting, which is intended to simplify the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. The Company adopted this standard effective January 1, 2019, which did not have a material impact on the Company's condensed consolidated financial statements.

The Company also considered the following recent accounting pronouncements which were not yet adopted as of March 31, 2019:

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

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

(3) Intangible Asset

Intangible asset consists of the historical acquisition cost of certain technology rights for Vascepa and has an estimated weighted-average remaining useful life of 11.3 years. The carrying value as of March 31, 2019 and December 31, 2018 is as follows:

In thousands	March 31, 2019	December 31, 2018

Technology rights	$ 11,624	$ 11,624
Accumulated amortization	(4,305)	(4,144)
Intangible assets, net	$ 7,319	$ 7,480

(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, 2019 and December 31, 2018 consist of the following:

In thousands	March 31, 2019	December 31, 2018
Raw materials	$ 7,941	$ 14,142
Work in process	8,653	8,590
Finished goods	41,473	35,357
Total inventory, gross	58,067	58,089
Inventory cost adjustment	(158)	(287)
Inventory	$ 57,909	$ 57,802

(5) Debt

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

On December 6, 2012, the Company entered into a Purchase and Sale Agreement with BioPharma Secured Debt Fund II Holdings Cayman LP, or BioPharma. Under this agreement, the Company granted to BioPharma a security interest in future receivables associated with the Vascepa patent rights, in exchange for $100.0 million received at the closing of the agreement which occurred in December 2012. Under these terms, the Company continues to own all Vascepa intellectual property rights, however, such rights, as described below, could be used as collateral for repayment of the remaining unpaid balance under this agreement if the Company defaults on making required payments. In the agreement, the Company agreed to repay BioPharma up to $150.0 million with such repayment based on a portion of net revenues and receivables generated from Vascepa. On December 20, 2017, BioPharma assigned all rights under this agreement to CPPIB Credit Europe S.à r.l., or CPPIB.

As of March 31, 2019, the remaining amount to be repaid to CPPIB is $80.9 million. During the three months ended March 31, 2019, the Company made repayments under the agreement of $7.7 million to CPPIB and an additional $7.3 million is scheduled to be paid in May 2019 for the first quarter of 2019. These payments, as well as additional quarterly repayments scheduled in the future, are calculated as 10% of Vascepa net revenues. All such payments reduce the remainder of the $150.0 million in aggregate payments to CPPIB. Except upon a change of control in Amarin, the agreement does not expire until $150.0 million in aggregate has been repaid. The Company can prepay the net remaining amount at any time.

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, 2019 and 2018.

As of March 31, 2019 and December 31, 2018, the carrying value of the royalty-bearing instrument, net of the unamortized debt discount and issuance costs, was $73.7 million and $79.7 million, respectively. During the three months ended March 31, 2019, the Company recorded cash and non-cash interest expense of $1.2 million and $0.4

million, respectively, in connection with the royalty-bearing instrument. During the three months ended March 31, 2018, the Company recorded $1.5 million and $0.5 million of cash and non-cash interest expense, respectively, in connection with the royalty-bearing instrument. The Company will periodically evaluate the remaining term of the agreement and the effective interest rate is recalculated each period based on the Company's most current estimate of repayment.

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

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

(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. Refer to Item 1 - Legal Proceedings of this Quarterly Report on Form 10-Q below for a discussion of the Company's current legal proceedings. There have been no material changes to the matters described in those disclosures as of the date of this filing.

Milestone and Supply Purchase Obligations

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

These agreements include 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.

Pursuant to supply agreements, there is a total of approximately $90.0 million that is potentially payable over the term of such agreements based on minimum purchase obligations. The Company continues to meet its contractual purchase obligations.

Under the 2004 share repurchase agreement with Laxdale Limited ("Laxdale"), upon receipt of marketing approval in Europe for the first indication for Vascepa (or first indication of any product containing Amarin Neuroscience Limited intellectual property acquired from Laxdale in 2004), the Company must make an aggregate stock or cash payment to the former shareholders of Laxdale (at the sole option of each of the sellers) of £7.5 million (approximately $9.8 million as of March 31, 2019). Also under the Laxdale agreement, upon receipt of a marketing approval in the United States or Europe for a further indication of Vascepa (or further indication of any other product using Amarin Neuroscience Limited intellectual property), the Company must make an aggregate stock or cash payment (at the sole option of each of the sellers) of £5 million (approximately $6.5 million as of March 31, 2019) for each of the two potential market approvals (i.e. £10 million maximum, or approximately $13.0 million as of March 31, 2019).

The Company has no provision for any of the obligations above since the amounts are either not probable or able to be estimated as of March 31, 2019.

(7) Equity

Preferred Stock

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

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

preferred stock in the accompanying condensed consolidated balance sheets.

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

ADSs representing the ordinary shares pursuant to Rule 144 under the Securities Act, or if such ADSs representing the ordinary shares are eligible for sale under Rule 144, following the expiration of the one-year holding requirement under Rule 144. During the year ended December 31, 2015, at the request of the holders, a portion of the Series A Preference Shares were consolidated and redesignated, resulting in the issuance of 6,283,333 ADSs.

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

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

The restricted American Depositary Shares and Series A Preference Shares were sold in a transaction exempt from the registration requirements under the Securities Act of 1933, as amended (the “Securities Act”). The Company filed a registration statement with the SEC covering the resale of the restricted American Depositary Shares and the ADSs representing ordinary shares created by the consolidation and redesignation of the Series A Preference Shares (the “Registrable Securities”) on April 9, 2015, which was declared effective by the SEC on May 1, 2015. In addition, the Company agreed to use its commercially reasonable best efforts to keep the registration, and any qualification, exemption or compliance under state securities laws which the Company determines to obtain, continuously effective, and to keep the Registration Statement free of any material misstatements or omissions, until the earlier of (a) March 11, 2017 or (b) the date on which all Registrable Securities held by Purchasers may be sold or transferred in compliance with Rule 144 under the Securities Act, without any volume or manner of sale restrictions.

The Series A Preference Shares contain a contingent beneficial conversion feature (“BCF”) because they contain a conversion feature at a fixed rate that was in-the-money when issued. The BCF was recorded in the three months ended June 30, 2015 as a result of the related Form S-3 Registration Statement being declared effective, which represents the resolution of the contingency to convert the Series A Preference Shares. The BCF was recognized in stockholders’ deficit and was measured by allocating a portion of the proceeds equal to the intrinsic value of that feature to additional paid-in capital. The effective purchase price of the ordinary shares into which the preferred shares are convertible was $1.50, which was used to compute the intrinsic value. The intrinsic value was calculated as the difference between the effective purchase price of the ordinary shares and the market value ($2.39 per share) on the date the preferred shares were issued, multiplied by the number of shares into which the preferred shares are convertible. The BCF resulting from the issuance of the Series A Preference Shares was determined to be $31.3 million. The BCF was recorded as a non-cash dividend to preferred shareholders through accumulated deficit, and was therefore reflected as an adjustment to net loss applicable to common shareholders for earnings per common share purposes in accordance with GAAP for the year ended December 31, 2015.

During the year ended December 31, 2018, the Company issued 3,886,718 ADSs upon consolidation and redesignation of Series A Preference Shares at the request of the holder, such that a maximum of 28,931,746 ordinary shares remain issuable upon future consolidation and redesignation of the remaining Series A Preference Shares as of March 31, 2019, subject to certain adjustments for dilutive events.

Common Stock

On November 29, 2018, the Company completed a public offering of 11,111,112 ADSs, with each ADS representing one ordinary share of the Company. The underwriters purchased the ADSs from the Company at a price of $17.575

per ADS after commission, resulting in net proceeds to the Company of approximately $194.8 million, after deducting customary commissions and offering expenses.

On February 1, 2018, the Company completed a public offering of 19,178,082 ADSs, with each ADS representing one ordinary share of the Company. The Company also granted the underwriters a 30-day option to purchase an additional 2,876,712 ADSs, which was partially exercised on March 5, 2018 for issuance of 1,438,356 ADSs. The underwriters purchased the ADSs from the Company at a price of $3.41 per ADS after commission, resulting in net proceeds to the Company of approximately $70.0 million, after deducting customary commissions and offering expenses.

Incentive Equity Awards

As of March 31, 2019, there were an aggregate of 16,837,051 stock options and 9,341,393 restricted stock units (“RSUs”) outstanding, representing approximately 4% and 2%, respectively, of outstanding shares (including common and preferred shares) on a fully diluted basis.

During the three months ended March 31, 2019 and 2018, the Company issued 3,838,739 and 782,553 shares, respectively, as a result of the exercise of stock options, resulting in gross and net proceeds of $15.5 million during the three months ended March 31, 2019 and $1.5 million during the three months ended March 31, 2018.

On February 1, 2019, the Company granted a total of 757,800 RSUs and 1,193,400 stock options to employees under the Amarin Corporation plc Stock Incentive Plan (the "2011 Plan"). The RSUs vest annually over a three-year period and the stock options vest quarterly over a four-year period. Also on February 1, 2019, the Company granted a total of 580,000 RSUs to employees under the 2011 Plan that vest upon the achievement of a specified sales performance condition.

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

On May 14, 2018, the Company granted a total of 190,034 RSUs and 286,536 stock options to members of the Company's Board of Directors under the Amarin Corporation plc Stock Incentive Plan (the "2011 Plan"). The RSUs vest in equal installments over a three-year period upon the earlier of the anniversary of the grant date or the Company's annual general meeting of shareholders in such anniversary year. The stock options vest in full upon the earlier of the one-year anniversary of the grant date or the Company's annual general meeting of shareholders in such anniversary year. Upon termination of service to the Company or upon a change of control, each Director shall be entitled to a payment equal to the fair market value of one share of Amarin common stock per award vested or granted, respectively, which is required to be made in shares.

On March 12, 2018 and November 1, 2018, the Company granted a total of 970,000 RSUs and 90,000 RSUs, respectively, to employees under the 2011 Plan that vest over three years commencing after REDUCE-IT results upon the achievement of certain regulatory and sales performance conditions associated with the REDUCE-IT clinical trial and subsequent revenue growth.

On February 1, 2018, the Company granted a total of 1,305,575 RSUs and 2,205,075 stock options to employees under the 2011 Plan. The RSUs vest annually over a three-year period and the stock options vest monthly over a four-year period. During the three months ended March 31, 2019, the Company issued 387,715 common shares related to the vesting of these RSUs, of which 139,928 shares were retained as treasury shares as settlement of employee tax obligations. three months ended March 31, 2019

(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 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 Agreement was amended on July 25, 2017 to reflect evolving promotional needs, including refinement of target lists. Amarin and Kowa Pharmaceuticals America, Inc. intentionally designed the co-promotion to naturally end as of December 31, 2018 and mutually agreed not to renew the agreement.

During 2018, which was the last year of the Agreement, as amended, the Company incurred expense for both the annual co-promotion fee, which in 2018 was calculated as eighteen-and-a-half percent (18.5%) of Vascepa gross margin, plus accrual for co-promotion tail payments which are calculated as a percentage of the 2018 co-promotion fee. The accrued tail payments are paid over three years with declining amounts each year. Kowa Pharmaceuticals America, Inc. is eligible to receive $17.8 million in co-promotion tail payments, the present value of which of $16.6 million was fully accrued as of December 31, 2018. No tail payments were made during the three months ended

March 31, 2019. As of March 31, 2019, of the $16.9 million the Company had accrued for tail payments under the Agreement, $9.5 million was classified as current on the condensed consolidated balance sheet.

(9)Revenue Recognition

The Company sells Vascepa principally to a limited number of major wholesalers, as well as selected regional wholesalers and specialty pharmacy providers in the United States, or collectively, its Distributors or its Customers, that in turn resell Vascepa to retail pharmacies for subsequent resale to patients and healthcare providers. Patients are required to have a prescription in order to purchase Vascepa. In addition to distribution agreements with Distributors, the Company enters into arrangements with health care providers and payors that provide for government-mandated and/or privately-negotiated rebates, chargebacks and discounts with respect to the purchase of the Company’s product.

Revenues from product sales are recognized when the Distributor obtains control of the Company’s product, which occurs at a point in time, typically upon delivery to the Distributor. Payments from Distributors are generally received 30-60 days from date of sale. The Company evaluates the creditworthiness of each of its Distributors to determine whether revenues can be recognized upon delivery, subject to satisfaction of the other requirements, or whether recognition is required to be delayed until receipt of payment. The

Company calculates gross product revenues generally based on the wholesale acquisition cost that the Company charges its Distributors for Vascepa.

Reserves for Variable Consideration

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

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

Rebates, Chargebacks and Discounts: The Company contracts with Medicaid, Medicare, other government agencies and various private organizations, or collectively, Third-party Payors, so that Vascepa will be eligible for purchase by, or partial or full reimbursement from, such Third-party Payors. The Company estimates the rebates, chargebacks and discounts it will provide to Third-party Payors and deducts these estimated amounts from its gross product revenues at the time the revenues are recognized. The Company estimates these reserves based upon a range of possible outcomes that are probability-weighted for the estimated payor mix. These reserves are recorded in the same period the revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability, which is included in accrued expenses and other current liabilities on the condensed consolidated balance sheets. For Medicare, the Company also estimates the number of patients in the prescription drug coverage gap for whom the Company will owe an additional liability under the Medicare Part D program. The Company estimates the rebates, chargebacks and discounts that it will provide to Third-party Payors based upon (i) the Company's contracts with these Third-party Payors, (ii) the government-mandated discounts applicable to government-funded programs, (iii) information obtained from the Company's Distributors and (iv) information obtained from other third parties regarding the payor mix for Vascepa. The Company's liability for these rebates consists of invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet been received, estimates of claims for the current quarter, and estimated future claims that will be made for product that has been recognized as revenue, but remains in the distribution channel inventories at the end of each reporting period.

Product Returns: The Company's Distributors have the right to return unopened 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 1-gram and 0.5-gram size capsules is currently four years and three years, respectively, after being converted into capsule form, which is the last step in the manufacturing process for Vascepa and generally occurs within a few months before Vascepa is delivered to Distributors. The Company estimates future product returns on sales of Vascepa based on: (i) data provided to the Company by its Distributors (including weekly reporting of Distributors' sales and inventory held by Distributors that provided the Company with visibility into the distribution channel in order to determine what quantities were sold to retail pharmacies and other providers), (ii) information provided to the Company from retail pharmacies, (iii) data provided to the Company by a third-party data provider which collects and publishes prescription data, and other third parties, (iv) historical industry information regarding return rates for similar pharmaceutical products, (v) the estimated remaining shelf life of Vascepa previously shipped and currently being shipped to Distributors and (vi) contractual agreements intended to limit the amount of inventory maintained by the Company's Distributors. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses and other current liabilities on the condensed consolidated balance sheets.

Other Incentives: Other incentives that the Company offers to indirect customers include co-pay mitigation rebates provided by the Company to commercially insured patients who have coverage for Vascepa and who reside in states that permit co-pay mitigation programs. The Company's co-pay mitigation program is intended to reduce each participating patient's portion of the financial responsibility for Vascepa's purchase price to a specified dollar amount. Based upon the terms of the program and information regarding programs provided for similar specialty pharmaceutical products, the Company estimates the average co-pay mitigation amounts and the percentage of patients that it expects to participate in the program in order to establish its accruals for co-pay mitigation rebates. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses and other current liabilities on the condensed consolidated balance sheets. The Company adjusts its accruals for co-pay mitigation rebates based on actual redemption activity and estimates regarding the portion of issued co-pay mitigation rebates that it estimates will be redeemed.

The following tables summarize activity in each of the net product revenue allowance and reserve categories described above for the three months ended March 31, 2019 and 2018:

In thousands	Trade Allowances	Rebates, Chargebacks and Discounts	Product Returns	Other Incentives	Total
Balance as of December 31, 2018	$ 19,495	$ 41,634	$ 2,948	$ 1,167	$ 65,244
Provision related to current period sales	15,881	70,410	418	8,286	94,995
Provision related to prior period sales	—	—	—	—	—
Credits/payments made for current period sales	(2,624)	(18,494)	—	(6,891)	(28,009)
Credits/payments made for prior period sales	(8,760)	(37,521)	(179)	(1,199)	(47,659)
Balance as of March 31, 2019	$ 23,992	$ 56,029	$ 3,187	$ 1,363	$ 84,571

In thousands	Trade Allowances	Rebates, Chargebacks and Discounts	Product Returns	Other Incentives	Total
Balance as of December 31, 2017	$ 12,035	$ 32,064	$ 1,887	$ 2,107	$ 48,093
Provision related to current period sales	8,506	32,947	222	4,185	45,860
Provision related to prior period sales	(200)	(435)	—	(69)	(704)
Credits/payments made for current period sales	(875)	(10,487)	—	(1,799)	(13,161)
Credits/payments made for prior period sales	(1,336)	(20,994)	(25)	(2,296)	(24,651)
Balance as of March 31, 2018	$ 18,130	$ 33,095	$ 2,084	$ 2,128	$ 55,437

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

Licensing Revenue

The Company enters into licensing agreements which are within the scope of Topic 606, Revenue from Contracts with Customers, under which it licenses certain rights to Vascepa for uses that are currently commercialized and under development by the Company. The terms of these arrangements typically include payment to the Company of one or more of the following: non-refundable, up-front license fees; development, regulatory and commercial milestone payments; payments for manufacturing supply services the Company provides through its contract manufacturers; and royalties on net sales of licensed products. Each of these payments results in licensing revenues.

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

In determining performance obligations, management evaluates whether the license is distinct from the other performance obligations with the collaborative partner based on the consideration of the relevant facts and circumstances for each arrangement. Factors considered in the determination of include the stage of development of the license delivered, research and development capabilities of the partner and the ability of partners to develop and commercialize Vascepa independent of the Company.

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

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

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

(10) Development, Commercialization and Supply Agreements
In-licenses

Mochida Pharmaceutical Co., Ltd.

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

Upon closing of the collaboration agreement, the Company made a non-refundable, non-creditable upfront payment of approximately $2.7 million, which was recorded in research and development expense in the condensed consolidated

statement of operations for the year ended December 31, 2018. In addition, the agreement provides for the Company to pay milestone payments upon the achievement of certain product development milestones and royalties on net sales of future products arising from the collaboration, if any.

Out-licenses

Eddingpharm (Asia) Macao Commercial Offshore Limited

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

Under the DCS Agreement, Eddingpharm is solely responsible for development and commercialization activities in the China Territory and associated expenses. The Company provides development assistance and is responsible for supplying finished and later bulk drug product at defined prices under negotiated terms. The Company retains all Vascepa manufacturing rights. Eddingpharm

agreed to certain restrictions regarding the commercialization of competitive products globally and the Company agreed to certain restrictions regarding the commercialization of competitive products in the China Territory.

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

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

Upon closing of the DCS Agreement, the Company received a non-refundable $15.0 million up-front payment. In March 2016, Eddingpharm submitted its clinical trial application ("CTA") with respect to the MARINE indication for Vascepa to the Chinese regulatory authority. Following the CTA submission, the Company received a non-refundable $1.0 million milestone payment. In March 2017, the CTA was approved by the Chinese regulatory authority, and, in December 2017, Eddingpharm commenced a pivotal clinical trial aimed to support the regulatory approval of the first indication of Vascepa in a patient population with severe hypertriglyceridemia in Mainland China.

In addition to the non-refundable, up-front and regulatory milestone payments described above, the Company is entitled to receive certain regulatory and sales-based milestone payments of up to an additional $153.0 million as well as tiered double-digit percentage royalties on net sales of Vascepa in the China Territory escalating to the high teens. The regulatory milestone events relate to the submission and approval of certain applications to the applicable regulatory authority, such as a clinical trial application, clinical trial exemption, or import drug license application. The amounts to be received upon achievement of the regulatory milestone events relate to the submission and approval for three indications, and range from $2.0 million to $15.0 million for a total of $33.0 million. The sales-based milestone events occur when annual aggregate net sales of Vascepa in the territory equals or exceeds certain specified thresholds, and range from $5.0 million to $50.0 million for a total of $120.0 million. Each such milestone payment shall be payable only once regardless of how many times the sales milestone event is achieved. Each such milestone payment is non-refundable and non-creditable against any other milestone payments.

The Company assessed this arrangement in accordance with Topic 606 and concluded that the contract counterparty, Eddingpharm, is a customer. The Company identified the following performance obligations at the inception of the DCS Agreement: (1) the exclusive license to develop and commercialize Vascepa in the China Territory for uses that are currently commercialized and under development by the Company, (2) the obligation to participate in various steering committees, (3) ongoing development and regulatory assistance, and (4) manufacture and supply of commercial product. Based on the analysis performed, the Company concluded that the identified performance obligations are not distinct and therefore a combined performance obligation.

The transaction price includes the $15.0 million up-front consideration received and the $1.0 million milestone payment received related to the successful submission of the CTA for the MARINE indication. None of the other

clinical or regulatory milestones have been included in the transaction price, as all milestone amounts were fully constrained. As part of its evaluation of the constraint, the Company considered numerous factors, including that receipt of the milestones is outside the control of the Company and contingent upon success in future clinical trials and the licensee's efforts. Any consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur as they were determined to relate predominantly to the license granted to Eddingpharm and therefore have also been excluded from the transaction price. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

During the three months ended March 31, 2019 and 2018, the Company recognized less than $0.1 million and less than $0.1 million, respectively, as licensing revenue related to the up-front and milestone payments received in connection with the Eddingpharm agreement. Through March 31, 2019 and December 31, 2018, the Company recognized $2.9 million and $2.8 million, respectively, as licensing revenue under the DCS Agreement concurrent with the support provided by Amarin to Eddingpharm in achieving the combined performance obligation, which in the Company's judgment is the best measure of progress towards satisfying the performance obligation. The remaining transaction price of $13.1 million and $13.2 million is recorded in deferred revenue as of

March 31, 2019 and December 31, 2018, respectively, on the condensed consolidated balance sheets and will be recognized as revenue over the remaining period of 15 years.

Biologix FZCo

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

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

HLS Therapeutics, Inc.

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

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

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

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

During the three months ended March 31, 2019 and 2018, the Company recognized $0.4 million and $0.1 million, respectively, as licensing revenue related to up-front and milestone payments received in connection with the HLS agreement. Through March 31, 2019 and December 31, 2018, the Company recognized $1.3 million and $0.9 million, respectively, as licensing revenue is recognized under the agreement concurrent with the support provided by Amarin to HLS in achieving the performance obligation, which in the Company's judgment is the best measure of progress towards satisfying the combined performance obligation. The remaining transaction price of $6.2 million and $6.6 million is recorded in deferred revenue as of March 31, 2019 and December 31, 2018, respectively, on the condensed consolidated balance sheets and will be recognized as revenue over the remaining period of 11 years.

The following table presents changes in the balances of the Company's contract assets and liabilities during the three months ended March 31, 2019:

In thousands	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
Three months ended March 31, 2019:				
Contract assets	$—	$—	$—	$—
Contract liabilities:				
Deferred revenue	$20,710	$—	$(547)	$20,163

During the three months ended March 31, 2019, the Company recognized the following revenues as a result of changes in the contract asset and contract liability balances in the respective periods:

In thousands	Three Months Ended March 31, 2019
Revenue recognized in the period from:	
Amounts included in contract liability at the beginning of the period	$ 547
Performance obligations satisfied in previous periods	$ —

(11)Leases

The Company leases office space under operating leases. The lease liability is initially measured at the present value of the lease payments to be made over the lease term. Lease payments are comprised of the fixed and variable payments to be made by the Company to the lessor during the lease term minus any incentives or rebates or abatements receivable by the Company from the lessor or the owner. Payments for non-lease components do not form part of lease payments. The lease term includes renewal options only if these options are specified in the lease agreement and if failure to exercise the renewal option imposes a significant economic penalty for the Company. As there are no significant economic penalties, renewal cannot be reasonably assured and the lease terms for the office space do not include any renewal options. The Company has not entered into any leases with related parties. The Company accounts for short-term leases (i.e., lease term of 12 months or less) by making the short-term lease policy election and will not apply the recognition and measurement requirements of ASC 842.

The Company has determined that the rate implicit in the lease is not determinable and the Company does not have borrowings with similar terms and collateral. Therefore, the Company considered a variety of factors, including the Company's credit rating, observable debt yields from comparable companies with a similar credit profile and the volatility in the debt market for securities with similar terms, in determining that 11.5% was reasonable to use as the incremental borrowing rate for purposes of the calculation of lease liabilities and a change of 1% would not result in a material change to the Company's condensed consolidated financial statements.

On September 30, 2011, the Company entered into an agreement for office space in Dublin, Ireland which terminates on October 31, 2019 and can be extended automatically for successive on year periods. On July 1, 2011, the Company leased office space in Bedminster, New Jersey. The lease, as amended, terminates on September 15, 2019, to coincide

with the start of the new Bridgewater, New Jersey lease, as described below. On January 26, 2019, the Company leased additional space in another building in Bedminster, New Jersey, effective February 1, 2019 and terminating June 30, 2019.

These leases have been determined to be short-term leases and the Company is committed to making aggregate payments of approximately $0.3 million during the next twelve months.

On February 5, 2019, the Company entered into a lease agreement for new office space in Bridgewater, New Jersey (the “Lease”). The Lease will commence upon delivery of the premises after certain improvements are made, which is anticipated to be on or about August 15, 2019 (the “Commencement Date”) for an 11-year period, with two five-year renewal options. Subject to the terms of the Lease, Amarin will have a one-time option to terminate the agreement effective on the first day of the ninety-seventh month after the Commencement Date upon advance written notice and a termination payment specified in the Lease. Under the Lease, the Company will pay monthly rent of approximately $0.1 million for the first year following the Commencement Date, and such rent will increase by a nominal percentage every year following the first anniversary of the Commencement Date. In addition, Amarin will receive certain abatements subject to the limitations in the Lease. The operating lease liability is $9.0 million, of which the current operating lease liability of $1.1 million is recorded in accrued expenses and other current liabilities on the condensed consolidated balance sheet, and the operating lease right-of-use asset is $8.9 million, as of March 31, 2019. The lease expense for the three months ended March 31, 2019 is approximately $0.3 million.

The table below depicts a maturity analysis of the Company's undiscounted payments for its operating lease liabilities and their reconciliation with the carrying amount of lease liability presented in the statement of financial position as of March 31, 2019:

	Undiscounted lease payments ($000s)
2020	$ —
2021	738
2022	1,587
2023	1,784
2024	1,818
2025 and thereafter	12,297
Total undiscounted payments	$ 18,224
Discount Adjustments	$ (9,199)
Current operating lease liability	$ 1,095
Long-term operating lease liability	$ 7,930

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, 2018 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 pharmaceutical company with expertise in omega-3 fatty acids and lipid science focused on the commercialization and development of therapeutics to improve cardiovascular, or CV, health and reduce CV risk.

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, or TG, levels in adult patients with severe (TG ≥500 mg/dL) hypertriglyceridemia. In January 2013, we began selling and marketing Vascepa in the United States by prescription only based on the FDA-approved MARINE indication for use in patients with severe (TG ≥500 mg/dL) triglyceride levels. We sell 1-gram and 0.5-gram capsule sizes of 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.

Since our inception, we have devoted substantial resources to our research and development efforts, most significantly our Vascepa cardiovascular outcomes trial, REDUCE-IT™. We announced topline results from the REDUCE-IT study on September 24, 2018. On November 10, 2018, we publicly presented primary results of the REDUCE-IT study at the 2018 Scientific Sessions of the American Heart Association, or AHA, and the results were concurrently published in The New England Journal of Medicine. REDUCE-IT met its primary endpoint demonstrating a 25% relative risk reduction, or RRR, to a high degree of statistical significance ($p<0.001$), in first occurrence of major adverse cardiovascular events, or MACE, in the intent-to-treat patient population with use of Vascepa 4 grams/day as compared to placebo. REDUCE-IT also showed a 26% RRR in its key secondary composite endpoint of cardiovascular death, heart attacks and stroke ($p<0.001$). On March 18, 2019, we publicly presented the total cardiovascular events results, and the method of calculating such events, of the REDUCE-IT study at the American College of Cardiology's (ACC) 68th Annual Scientific Session in March 2019 and the total events results and methods were concurrently published in the Journal of the American College of Cardiology. Included in such results were that Vascepa reduced total events, first and subsequent events, by 30% compared to placebo, reflecting that for every 1000 patients treated for 5 years with Vascepa versus placebo approximately 159 MACE could be prevented with Vascepa.

On March 28, 2019, we submitted a supplemental new drug application (sNDA) to the FDA seeking an expanded indication for Vascepa in the United States based on the positive results of the REDUCE-IT study. The indication we

are seeking pertains to use of Vascepa to reduce cardiovascular events in at-risk patients. Based on the final positive results of REDUCE-IT, we plan to continue to develop Vascepa commercially in major markets around the world. On March 28, 2019 the American Diabetes Association, or ADA, issued important updates to the Standard of Medical Care in Diabetes for 2019, including a recommendation for the use of icosapent ethyl in treating at-risk patients based on the results of the REDUCE-IT cardiovascular outcomes study.

We promote Vascepa directly in the United States. Such promotion, prior to results of the REDUCE-IT study, was based on demonstrated changes in biomarkers based on the MARINE study and, as to healthcare professionals with respect to cardiovascular risk reduction potential, the ANCHOR study of Vascepa in patients with persistent high (200-499 mg/dL) triglycerides after statin therapy. In considering drug treatment for cardiovascular risk reduction, most healthcare professionals express that they prefer outcomes data to biomarker data. Because prior to results of the REDUCE-IT study we did not have outcomes data regarding the clinical effect of Vascepa and because a substantial portion of our resources were being spent on the REDUCE-IT study, prior to REDUCE-IT results our commercialization of Vascepa was somewhat limited. Subsequent to learning the positive cardiovascular outcomes results of the REDUCE-IT study, we have begun increasing our promotion of Vascepa.

Commercialization

We commenced the commercial launch of 1-gram size Vascepa capsules in the United States in January 2013. We commenced sales and shipments of Vascepa at that time to our network of U.S.-based wholesalers. Prior to the REDUCE-IT results topline announcement in September 2018, our direct sales force consisted of approximately 170 sales professionals, including sales representatives and their managers. Pursuant to the positive REDUCE-IT results, to begin 2019, we increased the size of our sales force to approximately 440 sales professionals, including approximately 400 sales representatives and commenced other actions to expand our promotion of Vascepa. From May 2014 to December 2018, in addition to Vascepa promotion by our sales representatives, Kowa Pharmaceuticals America, Inc. co-promoted Vascepa in conjunction with its promotion of its primary product, a branded statin for patients with high cholesterol. Amarin and Kowa Pharmaceuticals America, Inc. intentionally designed the co-promotion to naturally end as of December 31, 2018 and mutually agreed not to renew the agreement. During 2018, as a result of not renewing the agreement, we incurred expense for the accrual of co-promotion tail payments, which were calculated as a percentage of the 2018 co-promotion fee. Kowa Pharmaceuticals America, Inc. will receive $17.8 million in co-promotion tail payments, the present value of which of $16.6 million was fully accrued as of December 31, 2018 and will be paid over three years with declining amounts each year. No tail payment was made during the three months ended March 31, 2019. We also employ various medical affairs and marketing personnel to support our commercialization of Vascepa. We expanded certain medical education and market awareness initiatives following the reporting of positive REDUCE-IT results in 2018. We intend to further expand promotion of Vascepa following label expansion of Vascepa, subject to FDA approval of such expanded label.

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

Based on monthly compilations of data provided by a third party, Symphony Health, the estimated number of normalized total Vascepa prescriptions for the three months ended March 31, 2019 and 2018 was approximately 618,000 and 391,000, respectively. According to data from another third party, IQVIA, the estimated number of normalized total Vascepa prescriptions for the three months ended March 31, 2019 and 2018 was approximately 553,000 and 356,000, respectively. Normalized total prescriptions represent the estimated total number of Vascepa prescriptions dispensed to patients, calculated on a normalized basis (i.e., one month’s supply, or total capsules dispensed multiplied by the number of grams per capsule divided by 120 grams). Inventory levels at wholesalers tend to fluctuate based on seasonal factors, prescription trends and other factors. In each of the three months ended March 31, 2019 and 2018, it appears that Symphony Health and IQVIA may have understated the rate of growth in Vascepa prescription levels.

Symphony Health and IQVIA collect and report estimates of prescription information. There is a limited amount of information available to such companies to determine the actual number of total prescriptions for prescription products like Vascepa during such periods. Data reported by Symphony Health and IQVIA is rarely identical. Their estimates are based on a combination of data received from pharmacies and other distributors, and historical data when actual data is unavailable. Their calculations of changes in prescription levels between periods can be significantly affected by lags in data reporting from various sources or by changes in pharmacies and other distributors providing data. Such methods can from time to time result in significant inaccuracies in information when ultimately compared with actual results. These inaccuracies have historically been most prevalent and pronounced during periods of time of inflections upward or downward in rates of use and less prevalent and pronounced over longer periods of time such as annually. As such, the resulting conclusions from such sources should be viewed with caution. Amarin cites such third-party information as a courtesy to its investors and because Amarin does not have direct access to prescription information. The prescription levels and changes in prescription levels reported above are based on information made available to us from third-party resources and may be subject to adjustment and may overstate or

understate actual prescriptions. For example, it is Amarin's understanding that in March and April 2019 Symphony Health has been working to fill gaps in data sources and that they may issue "corrected" data at some point in the near future. Amarin is not directly aware of the details related to such source issues, or the precise timeline for corrective data or the degree to which estimated Vascepa prescriptions, as reported by Symphony Health, may change upward or downward if such corrections are implemented. 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.

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. In March 2016, we entered into an agreement with Biologix FZCo, or Biologix, to register and commercialize Vascepa in several Middle Eastern and North African countries. In September 2017, we entered into an agreement with HLS to register, commercialize and distribute Vascepa in Canada. In March 2019, HLS received formal confirmation from Health Canada that the Canadian regulatory authority has granted priority review status for the upcoming New Drug Submission, which was filed in April 2019, for Vascepa.

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

Research and Development

Since its inception in 2011, conduct of the REDUCE-IT cardiovascular outcomes study of Vascepa has been the centerpiece of our research and development. Most of our other research and development during this period also pertained to Vascepa, including study of the mechanism of action of the single active ingredient in Vascepa, icosapent ethyl. The REDUCE-IT study was conducted based on a special protocol assessment, or SPA, agreement with the FDA. Based on the final positive results of REDUCE-IT, we are seeking additional indicated uses for Vascepa in the United States and to pursue approval for Vascepa around the world. We also anticipate continuing to publish additional details of the REDUCE-IT study to address scientific interest beyond the primary results of this study derived from the over 35,000 patient years of study experience which were accumulated in the REDUCE-IT study. The REDUCE-IT study topline results were made public in September 2018, and the primary results of the REDUCE-IT study were presented at the 2018 Scientific Sessions of the American Heart Association (AHA) on November 10, 2018 with such results concurrently published in The New England Journal of Medicine. Potential additional research and development opportunities beyond REDUCE-IT will be prioritized after giving priority to securing regulatory approval for Vascepa based on the REDUCE-IT results in the United States and in various geographies internationally, including pursuit of approval for Vascepa in Europe and in countries where we have commercialization partners for Vascepa.

On March 28, 2019, we submitted a supplemental new drug application (sNDA) to the FDA seeking an expanded indication for Vascepa in the United States based on the positive results of the REDUCE-IT study. The indication we are seeking pertains to use of Vascepa to reduce cardiovascular events in at-risk patients. While the current FDA-approved indication for Vascepa is biomarker based (i.e., lowering triglyceride levels), the indication we are seeking based on REDUCE-IT results is outcomes based (i.e., lowering cardiovascular events).

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

Commercial and Clinical Supply

We manage the manufacturing and supply of Vascepa internally and have done so since we began clinical development of Vascepa prior to the drug’s marketing approval by FDA in 2012. We rely on contract manufacturers in

each step of our commercial and clinical product supply chain. These steps include active pharmaceutical ingredient, or API, manufacturing, encapsulation of the API, product packaging and supply-related logistics. Our approach to product supply procurement is designed to mitigate risk of supply interruption and maintain an environment of cost competition through diversification of contract manufacturers at each stage of the supply chain and lack of reliance on any single supplier. We have multiple FDA-approved international API suppliers, encapsulators and packagers to support the Vascepa commercial franchise. 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 Operations Overview

Product Revenue, net. All of our product revenue is derived from product sales of 1-gram and 0.5-gram size capsules of Vascepa, net of allowances, discounts, incentives, rebates, chargebacks and returns. We sell product to a limited number of major wholesalers, as well as selected regional wholesalers and specialty pharmacy providers, or collectively, our Distributors or our customers, who resell the product to retail pharmacies for purposes of their reselling the product to fill patient prescriptions. We commenced our commercial launch of 1-gram size Vascepa capsules in the United States in January 2013, and introduced a smaller 0.5-gram capsule size in October 2016. Revenues from product sales are recognized when the Distributor obtains control of our product, which occurs at a point in time, typically upon delivery to the Distributor.

Licensing revenue. Licensing revenue currently consists of revenue attributable to receipt of up-front, non-refundable payments and milestone payments related to license and distribution agreements for Vascepa outside the United States. We recognize revenue from licensing arrangements as we fulfill the performance obligations under each of the agreements.

Cost of Goods Sold. Cost of goods sold includes the cost of API for Vascepa on which revenue was recognized during the period, as well as the associated costs for encapsulation, packaging, shipment, supply management, quality assurance, insurance, and other indirect manufacturing, logistics and product support costs. The cost of the API included in cost of goods sold reflects the average cost method of inventory valuation and relief. This average cost reflects the actual purchase price of Vascepa API.

Selling, General and Administrative Expense. Selling, general and administrative expense consists primarily of salaries and other related costs, including stock-based compensation expense, for personnel in our sales, marketing, executive, business development, finance and information technology functions, as well as co-promotion fees payable to Kowa Pharmaceuticals America, Inc. and, in 2018, the final year of the co-promotion agreement, accrual for the co-promotion tail payments. Other costs primarily include facility costs and professional fees for accounting, consulting and legal services.

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

Interest and Other Income, Net. Interest expense consists of interest incurred under our December 2012 royalty-bearing instrument financing arrangement, and interest incurred under our previously outstanding 3.5% exchangeable notes. Interest expense under our royalty-bearing instrument financing arrangement is calculated based on an estimated repayment schedule. Interest expense under our exchangeable notes includes the amortization of the conversion option related to our exchangeable debt, the amortization of the related debt discounts and debt obligation coupon interest. Interest income consists of interest earned on our cash and cash equivalents. Other income, net, consists primarily of foreign exchange losses and gains.

(Provision for) benefits from Income Taxes. Provision for income taxes, deferred tax assets and liabilities, and reserves for unrecognized tax benefits reflect management’s best assessment of estimated future taxes to be paid. We are subject to income taxes in both the United States and foreign jurisdictions. In applying the estimated annual effective tax rate approach prescribed under ASC 740-270 and based on present evidence and conclusions around the

realizability of deferred tax assets, we determined that any tax benefit related to the pretax losses generated during the first quarters of 2019 and 2018 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, 2019 and 2018 is zero.

Critical Accounting Policies and Significant Judgments and Estimates

Our discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements and notes, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expenses. On an ongoing basis, we evaluate our estimates and judgments, including those related to derivative financial liabilities. We base our estimates on historical experience and on various market-specific and other relevant assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. Estimates are assessed each period and updated to reflect current information. A summary of our critical accounting policies, significant judgments and estimates is presented in Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2018. There were no material changes to our critical accounting policies, significant judgments and estimates during the three months ended March 31, 2019.

Recent Accounting Pronouncements

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

Effects of Inflation

We believe the impact of inflation on operations has been minimal during the past three years.

Results of Operations

Comparison of Three Months Ended March 31, 2019 and March 31, 2018

Product Revenue, net. We recorded net product revenue of $72.7 million and $43.8 million during the three months ended March 31, 2019 and 2018, respectively, an increase of $29.0 million, or 66%. This increase in revenue was driven primarily by increased volume of Vascepa sold to independent wholesalers and other customers with increased volumes appearing to result from an increase in estimated normalized total Vascepa prescriptions in the United States. Based on data provided by Symphony Health and IQVIA, estimated normalized total Vascepa prescriptions in the United States increased by approximately 227,000 and 197,000, respectively, over the three months ended March 31, 2018, representing growth of 58% and 55%, respectively.

All of our product revenue in the three months ended March 31, 2019 and 2018 was derived from product sales of 1-gram and 0.5-gram size capsules of Vascepa, net of allowances, discounts, incentives, rebates, chargebacks and returns. The FDA-approved dosing for Vascepa continues to be 4 grams per day and, as expected, the majority of new and existing patients taking Vascepa continue to be prescribed the 1-gram size Vascepa capsules. Timing of shipments to wholesalers, as used for revenue recognition, and timing of prescriptions as estimated by third-party sources such as Symphony Health and IQVIA may differ from period to period. Inventory of Vascepa held by independent commercial wholesalers, calculated on a day’s sales outstanding basis, appeared to decline modestly both at March 31, 2019 and 2018 compared to the start of such respective quarterly periods.

During the quarters ended March 31, 2019 and 2018, 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, 2019 and 2018 was up to $110 and $70, respectively, per 30-day prescription filled and up to $330 and $140, respectively per 90-day prescription filled. Since launch, certain third-party payors have added Vascepa to their Tier 2 coverage, which results in lower co-payments for patients covered by these third-party payors. In connection with such Tier 2 coverage, we have agreed to pay customary rebates to these third-party payors on the resale of Vascepa to patients covered by these third-party payors.

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

Licensing Revenue. Licensing revenue during the three months ended March 31, 2019 and 2018 was $0.5 million and $0.1 million, respectively, an increase of $0.4 million, or 285%. Licensing revenue relates to the recognition of amounts received in connection with a Vascepa licensing agreement for the China Territory, specifically a $15.0 million up-front payment received in February 2015 and a $1.0 million milestone payment achieved in March 2016, as well as recognition of amounts received in connection with a Vascepa licensing agreement for Canada, specifically a $5.0 million up-front payment which was received upon closing of the agreement in September 2017 and a $2.5 million milestone payment that was received following achievement of the REDUCE-IT trial primary endpoint in September 2018. The up-front and milestone payments are being recognized over the estimated period in which we are required to provide regulatory and development support pursuant to the agreements. The amount of licensing

revenue is expected to vary from period to period based on timing of milestones achieved and changes in estimates of the timing and level of support required. We do not anticipate significant revenues from international sources in 2019.

Cost of Goods Sold. Cost of goods sold during the three months ended March 31, 2019 and 2018 was $17.1 million and $10.6 million, respectively, an increase of $6.5 million, or 61%. 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, 2019 and 2018 was sourced from multiple API suppliers. These suppliers compete with each other based on cost, consistent quality, capacity, timely delivery and other factors. In the future, we may see the average cost of supply change based on numerous potential factors including increased volume purchases, continued improvement in manufacturing efficiency, the mix of purchases made among suppliers, currency exchange rates and other factors. We currently anticipate API average cost in 2019 to be similar to or modestly lower than 2018. The average cost may be variable from period to period depending upon the timing and quantity of API purchased from each supplier.

Our gross margin on product sales for each of the three months ended March 31, 2019 and 2018 was 76%.

Selling, General and Administrative Expense. Selling, general and administrative expense for the three months ended March 31, 2019 and 2018 was $71.6 million and $43.4 million, respectively, an increase of $28.2 million, or 65%. Selling, general and administrative expenses for the three months ended March 31, 2019 and 2018 are summarized in the table below:

	Three months ended March 31,	
In thousands	2019	2018
Selling, general and administrative expense (1)	$66,027	$31,134
Co-promotion fees (2)	—	9,071
Non-cash stock-based compensation expense (3)	5,606	3,202
Total selling, general and administrative expense	$71,633	$43,407

(1) Selling, general and administrative expense, excluding co-promotion fees and non-cash compensation charges for stock compensation, for the three months ended March 31, 2019 and 2018 was $66.0 million and $31.1 million, respectively, an increase of $34.9 million, or 112%. This increase is due primarily to increased commercial and other promotional spend for expansion following successful REDUCE-IT results (announced on September 24, 2018), as well as costs for sales force expansion.

(2) Co-promotion fees payable to Kowa Pharmaceuticals America, Inc. for the three months ended March 31, 2019 and 2018 were nil and $9.1 million, respectively, a decrease of $9.1 million, or 100%. Amarin and Kowa Pharmaceuticals America, Inc. intentionally designed the co-promotion agreement to naturally end as of December 31, 2018 and mutually agreed not to renew the agreement.

(3) Non-cash stock-based compensation expense for the three months ended March 31, 2019 and 2018 was $5.6 million and $3.2 million, respectively, an increase of $2.4 million, or 75%. Non-cash stock-based compensation expense represents the estimated costs associated with equity awards issued to internal staff supporting our selling, general and administrative functions. The increase is due primarily to the determination that certain performance awards are probable to be achieved following positive REDUCE-IT results in September 2018, as well as an increase in the number of employees receiving equity awards as a result of the growth of our sales force and an

increase in the underlying fair value of the equity awards resulting from the increase in the price of our stock.

Research and Development Expense. Research and development expense for the three months ended March 31, 2019 and 2018 was $7.2 million and $11.8 million, respectively, a decrease of $4.5 million, or 38%. Research and development expenses for the three months ended March 31, 2019 and 2018 are summarized in the table below:

	Three months ended March 31,	
In thousands	2019	2018
REDUCE-IT study (1)	$1,652	$8,736
Regulatory filing fees and expenses (2)	435	243
Internal staffing, overhead and other (3)	3,877	2,223
Research and development expense, excluding non-cash expense	5,964	11,202
Non-cash stock-based compensation expense (4)	1,278	560
Total research and development expense	$7,242	$11,762

The decrease in research and development expenses for the quarter ended March 31, 2019, as compared to the prior year period, is primarily due to timing of REDUCE-IT and related costs.

(1) In September 2018, we announced landmark positive topline results of the REDUCE-IT cardiovascular outcomes trial. The REDUCE-IT study met its primary endpoint demonstrating an approximately 25% relative risk reduction in composite of major adverse cardiovascular events with high statistical significance. This result was supported by robust demonstrations of efficacy across multiple secondary endpoints. The REDUCE-IT study results were further presented at the 2018 Scientific Sessions of the American Heart Association (AHA) on November 10, 2018 and concurrently published in The New England Journal of Medicine. The total (first and subsequent) cardiovascular events results of the REDUCE-IT study were presented at the American College of Cardiology's (ACC) 68th Annual Scientific Session in March 2019 and concurrently published in the Journal of the American College of Cardiology. We managed the study through a contract research organization (CRO) through which all costs for the conduct of this outcomes study were incurred with the exception of costs for clinical trial material (CTM) and costs for internal management. The decrease in expenses in 2019 as compared to 2018 is primarily driven by a decline in REDUCE-IT related costs after the successful REDUCE-IT results. Following the completion of the REDUCE-IT trial, costs consisted primarily of the clinical study's wrap-up activities, regulatory support and publications.

(2) The regulatory filing fees in each of the quarters ended March 31, 2019 and 2018 included annual FDA fees for maintaining manufacturing sites. Such fees primarily represent fees for qualification of new suppliers, including increasing capacity capabilities, and fees for sites used for the manufacture of product used in the REDUCE-IT clinical outcomes study.

(3) Internal staffing, overhead and other research and development expenses primarily relate to the costs of our personnel employed to manage research, development and regulatory affairs activities and related overhead costs including consulting and other professional fees that are not allocated to specific projects. Also included are costs related to qualifying suppliers. These costs increased in 2019 compared to 2018 in support of publishing results of the REDUCE-IT study and preparing for sNDA submission based on the results of the study, which occurred in March 2019.

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

Interest Expense, net. Net interest expense for the three months ended March 31, 2019 and 2018 was $1.7 million and $2.3 million, respectively, a decrease of $0.6 million, or 25%. Net interest expense for the three months ended March 31, 2019 and 2018 is summarized in the table below:

	Three months ended March 31,	
In thousands	2019	2018
Exchangeable senior notes (1):		
Amortization of debt discounts	$—	$55
Contractual coupon interest	—	262
Total exchangeable senior notes interest expense	—	317
Long-term debt from royalty-bearing instrument (2):		
Cash interest	1,212	1,499
Non-cash interest	446	518
Total long-term debt from royalty-bearing instrument interest expense	1,658	2,017
Other interest expense	174	—
Total interest expense	1,832	2,334
Interest income (3)	(135)	(82)
Total interest expense, net	$1,697	$2,252

(1) Cash and non-cash interest expense related to the exchangeable senior notes, which were fully exchanged and retired for equity in November 2018, for the three months ended March 31, 2019 and 2018 was nil and $0.3 million, respectively.

(2) Cash and non-cash interest expense related to the December 2012 royalty-bearing instrument for the three months ended March 31, 2019 and 2018 was $1.7 million and $2.0 million, respectively. These amounts reflect the fact that our Vascepa net revenue levels have not been, and during these years were not assumed to be, high enough to support repayment in accordance with the contractual repayment schedule without the optional reduction which is allowed to be elected by us if the threshold revenue levels are not achieved. To date, our revenues have been below the contractual threshold amount each quarter such that each payment reflects the calculated optional reduction amount as opposed to the contractual threshold payments for each quarterly period.

(3) Interest income for the three months ended March 31, 2019 and 2018 was $135 thousand and $82 thousand, respectively. Interest income represents income earned on cash balances.

Other Income, net. Other income, net, for the three months ended March 31, 2019 and 2018 was income of $3 thousand and $55 thousand, respectively. Other income, net, primarily consists of gains and losses on foreign exchange transactions.

Liquidity and Capital Resources

Our sources of liquidity as of March 31, 2019 include cash and cash equivalents and restricted cash of $212.6 million. 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	2019	2018
Cash (used in) provided by:		
Operating activities	$(38.1)	$(9.8)
Investing activities	—	—
Financing activities	—	65.2
(Decrease) increase in cash and cash equivalents and restricted cash	$(38.1)	$55.4

Net cash used in operating activities during the three months ended March 31, 2019 compared to the same period in 2018 increased primarily as a result of commercial and promotional activities following the successful REDUCE-IT study results, including costs associated with expanding the sales force, publications of the REDUCE-IT results, and timing of collections and increased receivables driven by higher product sales.

No cash was generated from financing activities during the three months ended March 31, 2019. In February 2018, we completed a public offering of 19,178,082 ADSs and, in March 2018, we issued an additional 1,438,356 ADSs upon the underwriter’s partial exercise of a 30-day option to purchase additional shares. The underwriter purchased the ADSs from us at a price of $3.41 per ADS after commission, resulting in net proceeds to us of approximately $70.0 million, after deducting customary commissions and offering expenses.

In December 2012, we entered into a financing agreement with BioPharma. Under this agreement, we granted to BioPharma a security interest in future receivables and all related rights to Vascepa, in exchange for $100.0 million received at the closing of the agreement which closing occurred in December 2012. In December 2017, BioPharma assigned all rights under this agreement to CPPIB. We have agreed to repay up to $150.0 million of future revenue and receivables. As of March 31, 2019, the net remaining amount to be repaid to CPPIB is $80.9 million, which will be repaid in quarterly installments calculated as 10% of quarterly Vascepa net revenues. We can prepay the net remaining amount at any time.

As of March 31, 2019, we have no exchangeable notes or term debt outstanding since, in October 2018, we exercised our optional exchange rights upon satisfaction of specified equity conditions set forth in the 3.5% exchangeable senior notes due 2047, or the 2017 Notes, to mandatorily exchange the entirety of the $30.0 million in aggregate principal amount outstanding into ADSs. This resulted in elimination of the debt and issuance of 7,716,046 ADSs. The 2017 Notes were issued and sold in January 2017 when we, through our wholly-owned subsidiary Corsicanto II DAC, or Corsicanto II, a private designated activity company incorporated under the laws of Ireland, entered into separate, privately negotiated purchase agreements with certain unrelated investors. The net proceeds we received from the January 2017 offering were approximately $28.8 million, after deducting placement agent fees and estimated offering expenses. See Note 5—Debt in the Notes to the Condensed Consolidated Financial Statements for further discussion.

As of March 31, 2019, we had cash and cash equivalents and restricted cash of $212.6 million, a decrease of $38.1 million from December 31, 2018. The decrease is primarily due to net cash used in operating activities in support of the commercialization and promotion of Vascepa and expansion of the sales force following the successful results of REDUCE-IT. As of March 31, 2019, we had accounts receivable, net, of $79.5 million and inventory, net, of $57.9 million. We have incurred annual operating losses since our inception and, as a result, we had an accumulated deficit

of $1.4 billion as of March 31, 2019. We anticipate that quarterly net cash outflows in future periods will continue to be variable as a result of the timing of certain items, including our purchases of API and expanded Vascepa promotional activities resulting from positive REDUCE-IT results both before and after label change for Vascepa based on REDUCE-IT results both before and after REDUCE-IT results, which label change is subject to FDA review and approval of our sNDA. Because levels of Vascepa revenues are difficult to predict, as is the timing of label expansion, we intend to purchase API during 2019 at a rate which, based on current levels of revenue growth, is higher than is required for 2019. We estimate the incremental cost of this anticipated inventory build to be between $50 million and $75 million in 2019. We believe that there is limited financial risk of over-purchasing Vascepa inventory as the product has demonstrated stability supporting approved commercial expiry dating through four years.

Contractual Obligations

Our contractual obligations consist mainly of payments related to purchase obligations with certain supply chain contracting parties, operating leases related to real estate used as office space and long-term debt and related interest. As a result of entering into a new operating lease during the three months ended March 31, 2019 as described in Note 11 – Leases, we have provided updated

operating lease obligations information. The following table summarizes our contractual obligations associated with our operating leases as of March 31, 2019.

	Payments Due By Period				
In millions	Total	Remainder of 2019	2020 to 2021	2022 to 2023	After 2023
Contractual obligations:					
Operating lease obligations (1)	$18.5	$ 0.3	$ 1.9	$ 3.6	$12.8

(1) Represents operating lease costs, primarily consisting of leases for facilities in Bridgewater, NJ, Dublin, Ireland and Bedminster, NJ.

Off-Balance Sheet Arrangements

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

Item 3. Quantitative and Qualitative Disclosures about Market Risk

There have been no material changes with respect to the information appearing in PART II, Item 7A “Quantitative and Qualitative Disclosures about Market Risk” of our Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 27, 2019.

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, 2019 (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, 2019, 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, 2019, we implemented certain internal controls in connection with our adoption of ASC Topic 842. There were no other changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15(d)-15(f) promulgated under the Exchange Act, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II

Item 1. Legal Proceedings

In the ordinary course of business, we are from time to time involved in lawsuits, claims, investigations, proceedings, and threats of litigation relating to intellectual property, commercial arrangements and other matters. “Item 3. Legal Proceedings” of our Annual Report on Form 10-K for the fiscal year ended December 31, 2018 includes a discussion of our current legal proceedings. There have been no material changes to the matters described in those disclosures during the three months ended March 31, 2019, other than as set forth below.

On February 22, 2019, a purported investor in our publicly traded securities filed a putative class action lawsuit against Amarin Corporation plc, our chief executive officer and chief scientific officer in the U.S. District Court for the District of New Jersey, Debendra Sharma v. Amarin Corporation plc, John F. Thero and Steven Ketchum, No. 2:19-cv-06601 (D.N.J. Feb. 22, 2019). On March 12, 2019, another purported investor filed a substantially similar lawsuit captioned Richard Borghesi v. Amarin Corporation plc, John F. Thero and Steven Ketchum, No. 3:19-cv-08423 (D.N.J. March 12, 2019). Both lawsuits allege that, during the period September 24, 2018 to November 9, 2018, we misled investors by purportedly not disclosing that the placebo given to patients in the REDUCE-IT study, mineral oil, may have caused cardiovascular problems in the patients taking it, thereby misleading investors on the outcome of the REDUCE-IT study and artificially inflating the price of our securities. Based on these allegations, the suits assert claims under the Securities Exchange Act of 1934 and seeks unspecified monetary damages and attorneys’ fees and costs. We believe that we have valid defenses and we will vigorously defend against the claims, but cannot predict the outcome. We are unable to reasonably estimate the loss exposure, if any, associated with these claims. We have insurance coverage that is anticipated to cover any significant loss exposure that may arise from this action after payment by us of the associated deductible obligation.

Item 1A. Risk Factors

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

Except those denoted below with a “*”, these risk factors have not been materially updated from our Annual Report on 10-K for the year ended December 31, 2018 filed with the SEC on February 27, 2019.

Risks Related to the Commercialization and Development of Vascepa

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

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

Even if we are able to successfully develop Vascepa outside the United States or develop additional products from our research and development efforts, the development time cycle for products typically takes several years. If we seek to diversify our development programs or product offerings through licensing or acquisitions, such transactions are also time-consuming, dilutive to existing shareholdings, and can be disruptive to operations. These dynamics can restrict our ability to respond rapidly to adverse business conditions for Vascepa. If demand for Vascepa does not meet

expectations and we are not successful with development, we may not have the ability to effectively shift our resources to the development of alternative products or do so in a timely manner without suffering material adverse effects on our business. As a result, the lack of alternative markets and products we develop could constrain our ability to generate revenues and achieve profitability.

Factors out of our control make it more difficult for Vascepa to achieve a level of market acceptance by physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

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

In August 2015, based on a federal court order, we began communicating promotional information beyond the MARINE indication to healthcare professionals in the United States for the treatment of patients with high (TG >200 mg/dL and <500 mg/dL) triglyceride levels who are also on statin therapy for elevated low-density lipoprotein cholesterol, or LDL-C, levels, based on results from the ANCHOR study of Vascepa. Many patients with high triglycerides also have other lipid level abnormalities such as high cholesterol and are on statin therapy. FDA did not approve Vascepa for use in this population due to the uncertain effect of pharmaceutically induced triglyceride reduction in this patient population on cardiovascular risk reduction, the ultimate targeted clinical 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.

In September 2018, we announced topline results from the REDUCE-IT™ (Reduction of Cardiovascular Events with EPA—Intervention Trial) cardiovascular (CV) outcomes study of Vascepa. In November 2018, we announced the primary results of our REDUCE-IT cardiovascular outcomes study confirming 25% relative risk reduction for the topline primary endpoint result with multiple robust demonstrations of efficacy, including 20% reduction in cardiovascular death. REDUCE-IT was a multinational, prospective, randomized, double-blind, placebo-controlled study, enrollment for which started in November 2011. REDUCE-IT investigated the effects of Vascepa on CV risk in statin-treated adults with well-controlled LDL-C 41-100 mg/dL (median baseline LDL-C: 75 mg/dL) and other CV risk factors, including persistent elevated TG 150-499 mg/dL (median baseline TG: 216 mg/dL). REDUCE-IT topline results showed the trial met its primary endpoint demonstrating an approximately 25% relative risk reduction, to a high degree of statistical significance ($p<0.001$), in major adverse cardiovascular events (MACE) in the intent-to-treat patient population with use of Vascepa 4 grams/day as compared to placebo. MACE events were defined as a composite of cardiovascular death, nonfatal myocardial infarction (MI), nonfatal stroke, coronary revascularization, or unstable angina requiring hospitalization. This result was supported by robust demonstrations of efficacy across multiple secondary endpoints. Vascepa was well tolerated in REDUCE-IT with a safety profile generally consistent with clinical experience associated with omega-3 fatty acids and current FDA-approved labeling. The proportions of patients experiencing adverse events and serious adverse events in REDUCE-IT were similar between the active and placebo treatment groups. Based on the final positive results of REDUCE-IT, we plan to seek additional indicated uses for Vascepa in the United States and to continue to develop Vascepa commercially in major markets around the world.

Even though we have released positive results from the REDUCE-IT trial, our approved label for Vascepa in the United States currently remains unchanged pending additional interactions and review by the FDA. A failure to obtain an expanded label may make it more difficult for Vascepa to gain market acceptance by physicians, patients, healthcare payors and others in the medical community. If Vascepa does not achieve an adequate level of acceptance, we may not generate product revenues sufficient to become profitable. The degree of market acceptance of Vascepa for the MARINE indication and in ANCHOR patients and in any future indications and uses based on the REDUCE-IT trial or otherwise will depend on a number of factors, including:

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the perceived efficacy and safety of Vascepa by prescribing healthcare professionals, as compared to no treatment and as compared to alternative treatments in various at-risk patient populations, both as studied in clinical trials of Vascepa such as MARINE, ANCHOR and REDUCE-IT and not studied but for which the benefit/risk profile may be viewed as positive;

- peer review of REDUCE-IT results and publication of results in one or more medical journals over time;
- the FDA's review and analysis of the results of REDUCE-IT;
- our ability to offer Vascepa for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the scope, effectiveness and strength of product education, marketing and distribution support, including our sales and marketing team;
- publicity concerning Vascepa or competing products;

- our ability to continually promote Vascepa in the United States outside of FDA-approved labeling and the related perception thereof;
- sufficient third-party coverage or reimbursement for on-label use, and for permitted off-label use, the third-party coverage or reimbursement which was not addressed in the scope of the August 2015 court declaration or related settlement;
- natural disasters that can inhibit our ability to promote Vascepa regionally and can negatively affect product demand by creating obstacles for patients to seek treatment and fill prescriptions;
- new policies or laws affecting Vascepa sales, such as state and federal efforts to affect drug pricing and provide or remove healthcare coverage that includes reimbursement for prescription drugs; and
- the actual efficacy of the product and the prevalence and severity of any side effects, including any limitations or warnings contained in Vascepa's approved labeling.

As with any cardiovascular outcomes trial, over time further REDUCE-IT data assessment and data release will yield additional useful information to inform greater understanding of study outcome. That additional data and related interpretations by us, regulatory authorities such as FDA or third parties may exceed, meet or not meet investor expectations. If the additional data or related interpretations do not meet expectations, the perception of REDUCE-IT results and Vascepa may suffer and our stock price may decline.

In September 2018, we announced topline results from the REDUCE-IT trial showing that the trial met its primary endpoint demonstrating an approximately 25% relative risk reduction, to a high degree of statistical significance ($p<0.001$), in MACE in the intent-to-treat patient population with use of Vascepa 4 grams/day as compared to placebo. More detailed presentation of REDUCE-IT results was first made at the 2018 Scientific Sessions of the American Heart Association (AHA) on November 10, 2018 with such results concurrently published in The New England Journal of Medicine. Additional data assessment and data release will yield additional useful information to inform greater understanding of study outcome. Generally, trial data assessment sufficient to convey a complete picture of trial data typically takes several months and can take years to complete and publish. When new data are assessed and released it could exceed, match or may not meet investor expectations. For example, in March 2019, the American Diabetes Association issued updates to the Standards of Medical Care in Diabetes for 2019, including updates related to the results of the REDUCE-IT study. This type of updates and any future presentation and additional data may exceed, match or may not meet investors expectations.

In addition, the same set of data can sometime be interpreted to reach conclusions that conflict with our conclusions, as was the case when FDA reviewed earlier cardiovascular outcomes trials of other drugs in the context of the effects of triglyceride lowering agents on cardiovascular risk reduction. For example, we recently filed a sNDA seeking an expanded indication based on REDUCE-IT study results. FDA review of that application in connection with its final determination or with any public advisory committee meeting, or otherwise, could bring public attention to data interpretations that conflict with our own or the public's. Conflicting interpretations of data, or new data, could impact public and medical community perception of the totality of the efficacy and safety data from REDUCE-IT.

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

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

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

*Ongoing clinical trials involving Vascepa and similar moderate-to-high doses of icosapent ethyl ester could influence public perception of Vascepa's clinical profile and the commercial and regulatory prospects of Vascepa.

Ongoing trials of moderate-to-high doses of Vascepa and icosapent ethyl could provide further information on the effects of Vascepa and its commercial prospects. The Randomized Trial for Evaluation in Secondary Prevention Efficacy of Combination Therapy–Statin and EPA (RESPECT-EPA; UMIN Clinical Trials Registry number, UMIN000012069), is a study examining Japanese patients with chronic coronary artery disease receiving LDL-C lowering treatment by statin therapy. Patients will be randomized to either a control group (standard treatment) or EPA group (standard treatment plus 1.8 grams/day of icosapent ethyl), to examine the effects of a different formulation of icosapent ethyl than Vascepa on the incidence of cardiovascular events. The relationship between the ratio of EPA to aracadonic acid and incidence of event will be also examined. Results from this study are expected in the second half of 2021, but could be announced sooner. In addition, the Effect of Vascepa on Improving Coronary Atherosclerosis in People with High Triglycerides Taking Statin Therapy (EVAPORATE; ClinicalTrials.gov number, NCT02926027), is examining changes in patients' coronary plaque over 9 to 18 months. The goal of this study is to evaluate whether treatment with Vascepa (4 grams/day) results in a greater change from baseline in low attenuation plaque than placebo in subjects with elevated triglycerides (200-499 mg/dL). Entry criteria for EVAPORATE include elevated triglycerides (fasting value between 200-499 mg/dl) at qualifying or baseline visit; LDL-C ≤115 mg/dL on appropriate statin therapy; LDL-C >40 mg/dL; stable diet and exercise, as defined as the same pattern for the previous 4 weeks; and stable treatment with a statin with or without ezetimibe for at least 4 weeks. Results from EVAPORATE are expected in 2020, but could be announced sooner. If the outcome of these studies do not meet expectations, the perception of REDUCE-IT results and the perceived value of Vascepa and its regulatory status may suffer. If this occurs our business could suffer and our stock price could significantly decline.

Clinical trials that we or potential partners conduct, including the REDUCE-IT trial, may not provide sufficient safety and efficacy data to obtain the requisite regulatory approvals for product candidates or to achieve a level of market acceptance by physicians, patients, healthcare payors and others in the medical community necessary for commercial success if we obtain regulatory approval.

On November 10, 2018, we announced the primary results of our REDUCE-IT cardiovascular outcomes study confirming 25% relative risk reduction for the topline primary endpoint result with multiple robust demonstrations of efficacy, including 20% reduction in cardiovascular death. Major cardiovascular outcomes studies like REDUCE-IT typically motivate the medical community to search for ways to fit the results into the mosaic of prior studies considered as successful, like JELIS, and CANTOS, and their associated mechanisms of action, and to also distinguish results from prior failed studies, like what the authors of The New England Journal of Medicine editorial on REDUCE-IT referred to as the "parade of failed cardiovascular outcome trials of fish oils." It is important for the medical community to understand related science on the unique active pharmaceutical ingredient in Vascepa, icosapent ethyl, and REDUCE-IT. As with any clinical study, as the medical community and regulators such as the FDA review and analyze REDUCE-IT study data, dialogue is expected to continue with respect to the reliability of REDUCE-IT data and the study quality that could adversely affect our product development, regulatory review, market or medical community acceptance, and level of payor reimbursement in the event of an expansion of the Vascepa label. Likewise, public perception of the REDUCE-IT results and Vascepa may be affected.

For example, in the REDUCE-IT trial, cardiovascular benefits appeared not to be influenced significantly by TG levels at baseline (above or below 150 mg/dL baseline range) or as achieved at one year, potentially suggesting mechanisms at work with use of Vascepa that are independent of baseline TG levels or therapy-driven reduction in TG levels. Determination of the mechanisms responsible for the benefit shown in REDUCE-IT was not the focus or purpose of the study. As summarized from the primary results of REDUCE-IT in The New England Journal of

Medicine, potential Vascepa mechanisms of action at work in REDUCE-IT may include TG reduction, antithrombotic effects, antiplatelet or anticoagulant effects, membrane-stabilizing effects, effects on stabilization and/or regression of coronary plaque and inflammation reduction, each as supported by earlier stage mechanistic studies.

In addition, the median change in LDL cholesterol level from baseline was 6.6% (5.0 mg/dL; $p < 0.001$) on a placebo-corrected basis reflecting an increase of 3.1% (+2.0 mg/dL) in the Vascepa group and an increase of 10.2% (+7.0 mg/dL) in the placebo group. Increases in the placebo group relative to the Vascepa group were also observed in other parameters classically measured in such studies but with uncertain relevance to cardiovascular outcomes. An upward drift in LDL cholesterol and such other parameters has been commonly, although not always, observed in statin-stabilized patients across numerous studies within varying patient populations, and many have estimated LDL cholesterol increases of at least 6% and ranging up to more than 30%. Factors cited as potentially contributing to this circumstance include decreased drug and lifestyle regimen compliance, physiological compensation for drug-induced lipid changes, regression to the mean, intraindividual variability, lab variability, genetics, metabolic state, disease state, age, and season. If light liquid paraffin oil, or mineral oil, used as the placebo in REDUCE-IT adversely affected statin absorption or other parameters in some patients as is asserted by certain critics of the study, this could be theorized to have contributed to differences in outcomes between the groups and leave open the possibility that the placebo used in the trial was not biologically inert. These and other observations, whether scientifically reliable or not, may negatively impact how these trial results

are interpreted by regulators, the medical community and third-party payors. This is the case notwithstanding that a post hoc analysis of REDUCE-IT data published in The New England Journal of Medicine showed no material differences in the primary and key secondary endpoint event rates for placebo patients with an increase in LDL-C at one year versus those with no change or a decrease, and also suggested a similar relative risk reduction regardless of whether there was an increase in LDL cholesterol level among the patients in the placebo group. Data generated by Amarin after, but supporting, this analysis reflect that patient-by-patient differences in LDL cholesterol levels from baseline to Year 1 included some patients with increases, some patients with decreases and others with no change in both the Vascepa arm and the placebo arm of the REDUCE-IT study. If mineral oil affected statin absorption significantly, it is reasonable to expect that such effect might be evident in all patients on placebo (i.e., if mineral oil had a definitive effect one would expect LDL cholesterol increases would be consistently observed among patients in the placebo arm) rather than the observed mixed results that include many patients with LDL cholesterol decreases or lack of change in LDL cholesterol. Moreover, as the authors of the primary results publication on REDUCE-IT in The New England Journal of Medicine noted, the relatively small differences in LDL cholesterol levels between the groups would not be likely to explain the 25% lower MACE risk observed with Vascepa and JELIS, an over 18,000 patient cardiovascular outcomes study in Japan of a highly-pure EPA product similar to Vascepa, that, previously demonstrated a 19% risk reduction without a mineral oil placebo.

Consistent with our SPA for REDUCE-IT agreed to with the FDA, the trial subjects in the placebo arm of REDUCE-IT were given light liquid paraffin oil, or mineral oil, to mimic the color and consistency of Vascepa. We also used mineral oil in the placebo arms of our MARINE and ANCHOR trials. 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, led to further discussion 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. The FDA, early in the course of the REDUCE-IT trial, directed the independent data monitoring committee, or 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, the DMC recommended to continue the REDUCE-IT study as planned. Each of these DMC recommendations has been shared with FDA. In addition, following discussions on this topic in October 2013 in connection with the FDA's review of our supplemental new drug application for our ANCHOR study, the FDA did not seek to require that we include any qualification related to the use of mineral oil as a placebo in REDUCE-IT at the time of our March 2016 amendment to the REDUCE-IT SPA. As noted, importantly and consistently, JELIS, an over 18,000 patient cardiovascular outcomes study in Japan of a highly-pure EPA product similar to Vascepa previously demonstrated a 19% risk reduction without a mineral oil placebo.

As with any cardiovascular outcomes trial, further REDUCE-IT data assessment and data release could yield additional useful information to inform a greater understanding of the trial outcome. Further detailed data assessment by Amarin and regulatory authorities will continue and take several months or more to complete and record. The final evaluation of the totality of the efficacy and safety data from REDUCE-IT may include some or all of the following, as well as other considerations: new information affecting the degree of treatment benefit on studied endpoints; study conduct and data robustness, quality, integrity and consistency; additional safety data considerations and risk/benefit considerations; consideration of the cumulative effect of Vascepa in studied patients; and consideration of REDUCE-IT results in the context of other clinical studies. That additional data may exceed, meet or not meet the expectations of regulators, the medical community and third-party payors.

If Vascepa's specific mechanism of action shown in the REDUCE-IT study or the potential effects of the mineral oil used in the placebo arm of REDUCE-IT remains uncertain, or any additional data from the REDUCE-IT study do not meet expectations, the perception of REDUCE-IT results and Vascepa may suffer and could adversely affect our

product development, regulatory review, market or medical community acceptance, level of payor reimbursement in the event of an expansion of the Vascepa label, or the public perception of the REDUCE-IT results and Vascepa, any of which could have a material adverse effect on our business and financial condition and our stock price may decline.

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

Prior to REDUCE-IT topline results announcement in September 2018, our sales team consisted of approximately 170 sales professionals, including sales representatives and their managers. We have recently increased the size of our sales force to approximately 440 sales professionals, including approximately 400 sales representatives, pursuant to positive REDUCE-IT results and are expanding our promotion of Vascepa. This sales team promotes Vascepa to a limited group of physicians and other healthcare professionals in select geographies in the United States. Even after planned expansion, this sales team is not large enough to call upon all physicians. We intend to further expand the promotion of Vascepa following our assumed label expansion for Vascepa, subject to FDA review and approval of our sNDA.

In May 2014, we began co-promoting Vascepa in the United States with Kowa Pharmaceuticals America, Inc. under a co-promotion agreement we entered into in March 2014, which we amended in July 2017. Under the agreement, Kowa Pharmaceuticals America, Inc. co-promoted Vascepa in conjunction with its promotion of its primary product, a branded statin for patients with high cholesterol, along with our sales professionals based on a plan designed to focus on select sales territories that we believed had demonstrated the greatest potential for Vascepa sales growth, increasing both the number of sales targets reached and the frequency of sales calls on existing sales targets. However, the commercialization of pharmaceutical products is a complex undertaking, and we had very limited experience as a company operating in this area and co-promoting a pharmaceutical product with a partner.

Furthermore, our agreement with Kowa Pharmaceuticals America, Inc. was designed such that Kowa's co-promotion of Vascepa ceased at the end of 2018. The parties mutually agreed not to renew the agreement. If over time our newly expanded sales team are not at least equally capable, our sales may be negatively impacted.

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

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

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

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

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

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

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

In August 2015, we were granted preliminary relief in this lawsuit through the court’s declaratory judgment that confirmed we may engage in truthful and non-misleading speech promoting the off-label use of Vascepa to healthcare professionals, i.e., to treat patients with persistently high triglycerides, and that such speech may not form the basis of a misbranding action under the FDCA. In August 2015, we began to communicate promotional information beyond the MARINE indication to healthcare professionals in the United States as permitted by this court declaration. The FDA did not appeal the court’s ruling. In March 2016, we settled this litigation under terms by which the FDA and the U.S. government agreed to be bound by the conclusions from the federal court order that we may engage in truthful and non-misleading speech promoting the off-label use of Vascepa and that certain statements and disclosures that we proposed to make to healthcare professionals were truthful and non-misleading. As part of the settlement, given, as expressed in the court’s opinion, that the dynamic nature of science and medicine is that knowledge is ever-advancing and that a statement that is fair and balanced one day may become incomplete or otherwise misleading in the future as new studies are done and new data is acquired, we agreed that we bear the responsibility to ensure that our communications regarding off-label use of Vascepa remain truthful and non-misleading, consistent with the federal court ruling.

While we believe we are now permitted under applicable law to more broadly promote Vascepa, the FDA-approved labeling for Vascepa did not change as a result of this litigation and settlement, and neither government nor other third-party coverage or reimbursement to pay for the off-label use of Vascepa promoted under the court declaration was required. Based on our communications with the FDA, we expect that the FDA’s review of our recently submitted sNDA containing the final positive results from the REDUCE-IT outcomes study will be required for FDA-approved label expansion for Vascepa. However, we proactively communicate results from the REDUCE-IT trial in a manner we believe is truthful and non-misleading and thus protected under the freedom of speech clause of the First Amendment to the United States Constitution.

Even though we have the benefit of a final settlement in this litigation, our promotion is still subject to a high, perhaps abnormally high, degree of scrutiny to ensure that our promotion remains within the scope covered by the settlement. For example, under the settlement, we remain responsible for ensuring our speech is truthful and non-misleading. Data arising from studies of drug products are complex, such as the many studies that we believe show supportive but not conclusive research on the potential connection between the effects of EPA, the active ingredient in Vascepa, and cardiovascular risk reduction (e.g., the JELIS trial of a highly-pure EPA product in Japan by Mochida Pharmaceutical Co., Ltd., or Mochida, and other data using a variety of levels of evidence that connect EPA to favorable effects toward reduced cardiovascular risk). We, the FDA, the U.S. government, our competitors and other interested parties may not agree on the truthfulness and non-misleading nature of our promotional materials with respect to the outcome of these trials or other direct or indirect claims we make about Vascepa. Likewise, the FDA, the U.S. government, our competitors and other interested parties may not agree on the truthfulness and non-misleading nature of our promotional materials related to the REDUCE-IT results. Federal and state governments or agencies may also seek to find other means to prevent our promotion of unapproved truthful and non-misleading information about Vascepa. If our promotional activities or other operations are found to be in violation of any law or governmental regulation through existing or new interpretations, we may be subject to prolonged litigation, penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of

our operations. Also, if governmental parties or our competitors view our claims as misleading or false, we could also be subject to liability based on fair competition-based statutes, such as the Lanham Act. Any of such negative circumstances could adversely affect our ability to operate our business and our results of operations.

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

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

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

In addition, in May 2014, Epanova® (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.

AstraZeneca is currently conducting a long-term outcomes study to assess Statin Residual Risk Reduction With EpaNova in HiGh Cardiovascular Risk PatienTs With Hypertriglyceridemia (STRENGTH). The study is a randomized, double-blind, placebo-controlled (corn oil), parallel group design that is believed to have enrolled approximately 13,000 patients with hypertriglyceridemia and low HDL and high risk for cardiovascular disease randomized 1:1 to either corn oil plus statin or Epanova plus statin, once daily, for approximately 3-5 years as determined when the number of major adverse cardiovascular event outcomes is reached. The STRENGTH study is estimated to be completed in 2020, but it could be stopped earlier if, for example, it generates an overwhelming efficacy result. In addition, in March 2017, Kowa Research Institute (a subsidiary of the Japanese company Kowa Co., Ltd) initiated a phase III cardiovascular outcomes trial titled PROMINENT examining the effect of pemafibrate (experimental name K-877) in reducing cardiovascular events in Type II diabetic patients with hypertriglyceridemia. Kowa Research Institute has publicly estimated study completion in May 2022, and if successful, U.S. regulatory approval is estimated in mid-2023.

During 2018, two outcomes studies were completed of omega-3 mixtures which both failed to achieve their primary endpoints of cardiovascular risk reduction and two meta-analyses were published showing that omega-3 mixtures are not effective in lowering cardiovascular risk. Results of these failed outcomes studies and analysis, while not done with Vascepa, may negatively affect sales of Vascepa. For example, results of VITamin D and OmegA-3 TriaL (VITAL), as announced immediately before the presentation of REDUCE-IT results at the 2018 Scientific Sessions of the American Heart Association (AHA) on November 10, 2018, failed to achieve its primary endpoint of lowering cardiovascular events. VITAL was an NIH funded randomized double-blind, placebo-controlled, 2x2 factorial trial of 2000 IU per day of vitamin D3 and 1 gram per day of omega-3 fatty acid supplementation (Lovaza) for the primary prevention of cancer and cardiovascular disease in a nationwide USA cohort of 25,874 adults not selected for elevated cardiovascular or cancer risk.

Likewise, in 2018, results from A Study of Cardiovascular Events iN Diabetes (ASCEND) trial were released and showed negligible results for omega-3 fatty acids 1 gram daily. ASCEND was a British Heart Foundation funded 2x2 factorial design, randomized study to assess whether aspirin 100 mg daily versus placebo and separately, omega-3 fatty acids 1 gram daily versus placebo, reduce the risk of cardiovascular events in a nationwide UK cohort of over 15,000 individuals with diabetes who do not have atherosclerotic cardiovascular disease. In addition, VITAL showed that supplementation with either omega-3 fatty acid at a dose of 1

gram per day or vitamin D3 at a dose of 2000 IU per day was not effective for primary prevention of CV or cancer events among healthy middle-aged men and women across 5 years of follow up.

In meta-analysis, presented in 2018 by the Cochran Foundation and separately as published in JAMA, additional omega-3 studies were evaluated. Similar to the VITAL and ASCEND studies, most of the studies in these omega-3 meta-analyses were of omega-3 mixtures, including DHA, and most were studies of relatively low doses of omega-3 as is associated with dietary supplementation and/or they studied relatively low risk patient populations. The exception was the JELIS study, conducted in Japan, of highly pure EPA which demonstrated a positive outcome benefit. The negative results from such omega-3 mixture studies could create misleading impressions about the use of omega-3s generally, including Vascepa, despite REDUCE-IT positive results and the highly-pure and stable EPA active ingredient in Vascepa and its higher dose regimen.

We are also aware of other pharmaceutical companies that are developing products that, if successfully developed, approved and marketed, would compete with Vascepa. Acasti Pharma, or Acasti, a subsidiary of Neptune Technologies & Bioresources Inc., announced in December 2015 that it intends to pursue a regulatory pathway under section 505(b)(2) of the FDCA for its omega-3 prescription drug candidate, CaPre® (omega-3 phospholipid), derived from krill oil, for the treatment of hypertriglyceridemia. In September 2016, Acasti announced positive results from its pivotal bioavailability bridging study comparing CaPre to Lovaza, establishing a scientific bridge between the two that is expected to support the feasibility of a 505(b)(2) regulatory pathway. Acasti initiated a Phase 3 clinical program (TRILOGY) to assess the safety and efficacy of CaPre in patients with very high (≥500 mg/dL) triglycerides in the first quarter of 2018. Acasti completed enrollment in Q4 2018 and study completion is expected by the end of 2019. We believe Micelle BioPharma Inc., or Micelle, is also developing potential treatments for hypertriglyceridemia based on omega-3 fatty acids. To our knowledge, Micelle, after acquiring SC401 from Sancilio & Company, or Sancilio, is pursuing a regulatory pathway under section 505(b)(2) of the FDCA for its product and submitted an Investigational New Drug Application, or IND, in July 2015. Micelle (Sancilio) completed two pharmacokinetic studies and Phase 2 bioavailability studies (FASTR I&II), with one comparing SC401 to Lovaza. We expect the company or a potential partner to initiate a pivotal clinical Phase 3 study as the next step in development.

Matinas BioPharma, Inc. is developing an omega-3-based therapeutic (MAT9001) for the treatment of severe hypertriglyceridemia and mixed dyslipidemia. In the fourth quarter of 2014 Matinas BioPharma, Inc. filed an IND with the FDA to conduct a human study in the treatment of severe hypertriglyceridemia and, in June 2015, the company announced topline results for its head-to-head comparative pharmacokinetic and pharmacodynamic study of MAT9001 versus Vascepa in patients under conditions inconsistent with the FDA-approved label for Vascepa and presented results based on biomarker modification without outcomes data. In September 2017, Matinas announced that it will be seeking a partner company to develop and commercialize MAT9001. In March 2019, Matinas announced that net proceeds from a public offering of common stock would be used for development activities for MAT9001.

In June 2018, Gemphire Therapeutics announced positive topline results from a Phase 2b trial (INDIGO-1) of its drug candidate, gemcabene, in patients with severe hypertriglyceridemia. Gemcabene is an oral, once-daily pill for a number of hypercholesterolemic populations and severe hypertriglyceridemia. In August 2018, the FDA requested that Gemphire conduct an additional long-term toxicity study before commencing any further clinical testing, thereby effectively placing gemcabene on clinical hold. Gemcabene expects to submit a request to the FDA to lift the clinical hold in Q4 2019. In December 2018, Gemphire announced that top-line clinical results from a Phase II trial in Familial Partial Lipodystrophy (FPL)/NASH is expected in Q2 2019. Phase III studies for homozygous familial hypercholesterolemia (HoFH), heterozygous familial hypercholesterolemia (HeFH) and non-familial hypercholesterolemia in ASCVD patients are planned. Zydus Cadila has a Phase 2 development program for its lead molecule, Saroglitazar, in various indications, including severe hypertriglyceridemia in the United States. In August 2018, the company announced that it had suspended the Phase 2 trial in the severe hypertriglyceridemia indication due to study enrollment issues, while it continues development activities in other indications. The product is approved in India under the name Lipaglyn® for the treatment of hypertriglyceridemia and diabetic dyslipidemia.

Based on prior communications from the FDA, including communications in connection with its review of the ANCHOR indication for Vascepa, it is our understanding that the FDA is not prepared to approve any therapy for treatment of cardiovascular risk based on biomarker modification without outcomes study data, with the potential exception of therapies which lower LDL-cholesterol. In particular, it is our understanding that the FDA is not prepared to approve any therapy based on data demonstrating lowering of triglyceride levels. In our view, this position from the FDA is unlikely to change based on the REDUCE-IT study particularly in light of the independence of the positive benefit demonstrated in the REDUCE-IT study from triglyceride levels and benefit from the REDUCE-IT study supporting that the positive effects of Vascepa are unique to Vascepa and extend beyond triglyceride reduction. If the FDA were to change this position, it could potentially have a negative impact on Amarin by making it easier for other products to achieve a cardiovascular risk reduction indication without the need in advance to conduct a long and expensive cardiovascular outcomes study.

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

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

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

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

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

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

The paragraph IV notice is required to contain a detailed factual and legal statement explaining the basis for the applicant's opinion that the proposed product does not infringe our patents, that the relevant patents are invalid, or both. After receipt of a valid notice, the branded product manufacturer has the option of bringing a patent infringement suit in federal district court against any generic company seeking approval for its product within 45 days from the date of receipt of each notice. If such a suit is commenced within this 45-day period, the Hatch-Waxman Amendments provide for a 30-month stay on FDA's ability to give final approval to the proposed generic product, which period begins on the date the paragraph IV notice is received. Generally, during a period of time in which generic applications may be submitted for a branded product based on a product's regulatory exclusivity status, if no patents are listed in the Orange Book before the date on which a complete ANDA application for a product (excluding an amendment or supplement to the application) is submitted, an ANDA application could be approved by FDA

without regard to a stay. For products entitled to five-year exclusivity status, the Hatch-Waxman Amendments provide that an ANDA application may be submitted after four years following FDA approval of the branded product if it contains a certification of patent invalidity or non-infringement to a patent listed in the Orange Book. In such a case, the 30-month stay runs from the end of the five-year exclusivity period. Statutory stays may be shortened or lengthened if either party fails to cooperate in the litigation and it may be terminated if the court decides the case in less than 30 months. If the litigation is resolved in favor of the ANDA applicant before the expiration of the 30-month period, the stay will be immediately lifted and the FDA's review of the application may be completed. Such litigation is often time-consuming and costly, and may result in generic competition if such patents are not upheld or if the generic competitor is found not to infringe such patents.

In the first half of 2014, we received six paragraph IV notices notifying us of accepted ANDAs to the Vascepa 1-gram dose strength under the Hatch-Waxman Amendments. These ANDAs were submitted and accepted by FDA under the regulatory scheme

adopted under the Hatch-Waxman Amendments based on the FDA's determination that we were entitled to three, and not five-year exclusivity. As a result, from the first half of 2014 until June 2015, we were engaged in costly litigation with the ANDA applicants to protect our patent rights.

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

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

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

On May 31, 2016, in a reversal that FDA and we view as consistent with the court's May 28, 2015 summary judgment motion, FDA determined that Vascepa is eligible for five-year, NCE marketing exclusivity. This determination provides Vascepa with the benefits of NCE exclusivity afforded by statute. NCE exclusivity for Vascepa ran from its date of FDA approval on July 26, 2012 and extended until July 26, 2017. We believe the statutory NCE-related 30-month stay triggered by the 1-gram dose patent litigation following generic application submissions permitted on July 26, 2016 is scheduled to continue until January 26, 2020, seven-and-a-half years from FDA approval, unless such patent litigation is resolved against us sooner.

In September and October 2016, we received paragraph IV certification notices from four companies contending to varying degrees that certain of our patents are invalid, unenforceable and/or will not be infringed by the manufacture, use, sale or offer for sale of a generic form of the 1-gram dose strength of Vascepa as described in those companies' ANDAs. These certifications were expected given the eligibility for submission of ANDAs under the NCE regulatory structure, after the expiration of four years from the July 2012 approval of Vascepa.

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

Vascepa before the last to expire of the asserted patents in 2030. The three lawsuits have been consolidated for pretrial proceedings.

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

In October 2016, we introduced to the market a 0.5-gram dose strength of Vascepa. In August 2017, as anticipated, we received a paragraph IV certification notice from Teva contending that certain of our patents are invalid, unenforceable and/or will not be infringed by the manufacture, use, sale or offer for sale of a generic form of the 0.5-gram dose strength of Vascepa, as described in the Teva ANDA. This Teva ANDA was filed as an amendment to the 1-gram Teva ANDA and is related to patents already at issue in the 1-gram Vascepa patent litigation. This certification followed the related listing in the Orange Book of patents associated with the 0.5-gram product in June 2017. This June 2017 listing was within the five-year, post NDA-approval period during which the Hatch-Waxman Amendments require a paragraph IV certification of patent invalidity or non-infringement under the Hatch-Waxman, five-year, NCE regulatory scheme. Accordingly, in October 2017, we filed a patent infringement lawsuit against Teva in the U.S. District Court for the District of Nevada. The case is captioned Amarin Pharma, Inc. et al. v. Teva Pharmaceuticals USA, Inc. et al., Civ. A. No. 2:17-cv-2641 (D. Nev.). In this lawsuit, we sought, among other remedies, an order enjoining Teva from marketing generic versions of the 0.5-gram dose strength of Vascepa before the last to expire of the asserted patents in 2030.

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

In July 2018, as anticipated, we received a paragraph IV certification notice from DRL contending that certain of our patents are invalid, unenforceable and/or will not be infringed by the manufacture, use, sale or offer for sale of a generic form of the 0.5-gram dose strength of Vascepa, as described in the DRL ANDA. This DRL ANDA was filed as an amendment to the 1-gram DRL ANDA and is related to patents already at issue in the 1-gram Vascepa patent litigation. This certification followed the related listing in the Orange Book of patents associated with the 0.5-gram product in June 2017. This June 2017 listing was within the five-year, post NDA-approval period during which the Hatch-Waxman Amendments require a paragraph IV certification of patent invalidity or non-infringement under the Hatch-Waxman, five-year, NCE regulatory scheme. Accordingly, in August 2018, we filed a patent infringement lawsuit against DRL in the U.S. District Court for the District of Nevada. The case is captioned Amarin Pharma, Inc. et al. v. Dr. Reddy's Laboratories, Inc. et al., Civ. A. No. 2:18-cv-01596 (D. Nev.). In this lawsuit, we are seeking, among other remedies, an order enjoining DRL from marketing generic versions of the 0.5-gram dose strength of Vascepa before the last to expire of the asserted patents in 2030. In light of the overlap between the cases, DRL and Amarin have stipulated that the final judgment on the merits of the parties' contentions in the consolidated 1-gram action shall also be binding in the 0.5-gram case.

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

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

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

to market the generic drug product and postpones the final ANDA approval until any exclusivity protections, such as a 30-month stay, have expired.

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

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

Any generic market entry would limit our U.S. sales, which would have a significant adverse impact on our business and results of operations. In addition, even if a competitor's effort to introduce a generic product is ultimately unsuccessful, the perception that

such development is in progress and/or news related to such progress could materially affect the perceived value of our company and our stock price.

Vascepa's five-year, NCE and related exclusivity benefits could be challenged by companies seeking to introduce generic versions of Vascepa.

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

The FDA typically makes a determination on marketing exclusivity in connection with an NDA approval of a drug for a new indication. FDA marketing exclusivity is separate from, and in addition to, patent protection, trade secrets and manufacturing barriers to entry which could also help protect Vascepa against generic competition.

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

NCE marketing exclusivity precludes approval during the five-year exclusivity period of certain 505(b)(2) applications and ANDAs submitted by another company for another version of the drug. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. In such case, the pioneer drug company is afforded the benefit of a 30-month stay against the launch of such a competitive product that extends from the end of the five-year exclusivity period. A pioneer company could also be afforded extensions to the stay under applicable regulations, including a six-month pediatric exclusivity extension or a judicial extension if applicable requirements are met. A drug sponsor could also gain a form of marketing exclusivity under the Hatch-Waxman Amendments if such company can, under certain circumstances, complete a human clinical trial process and obtain regulatory approval of its product.

In contrast, a three-year period of exclusivity under the Hatch-Waxman Amendments is generally granted for a drug product that contains an active moiety that has been previously approved, such as when the application contains reports of new clinical investigations (other than bioavailability studies) conducted by the sponsor that were essential to approval of the application. Accordingly, we expect to receive three-year exclusivity in connection with any future regulatory approvals of Vascepa, such as an approval sought based on positive REDUCE-IT outcomes study results. Such three-year exclusivity protection precludes the FDA from approving a marketing application for an ANDA, a product candidate that the FDA views as having the same conditions of approval as Vascepa (for example, the same indication and/or other conditions of use), or a 505(b)(2) NDA submitted to the FDA with Vascepa as the reference product, for a period of three years from the date of FDA approval. The FDA may accept and commence review of such applications during the three-year exclusivity period. Such three-year exclusivity grant does not prevent a company from challenging the validity of patents at any time, subject to any prior four-year period pending from a grant of five-year exclusivity. This three-year form of exclusivity may also not prevent the FDA from approving an NDA that relies only on its own data to support the change or innovation.

On February 27, 2014, we sued the FDA in the U.S. District Court for the District of Columbia to challenge the agency's denial of five-year NCE exclusivity for Vascepa, based on our reading of the relevant statute, our view of

FDA’s inconsistency with its past actions in this area and the retroactive effect of what we believe is a new policy at FDA as it relates to our situation. On May 28, 2015, the court granted our motion for summary judgment. The decision vacated the FDA’s denial of our claim for such exclusivity and remanded to the FDA for proceedings consistent with the decision. On July 22, 2015, Watson Laboratories Inc., the purported first Vascepa ANDA filer, sought to intervene and appeal the court’s decision. We and FDA opposed this intervention effort. The applicable courts denied Watson (now doing business as Hikma) the relief sought and appeal periods have expired.

On May 31, 2016, in a reversal that FDA and we view as consistent with the court’s May 28, 2015 summary judgment motion, FDA determined that Vascepa is eligible for five-year, NCE marketing exclusivity. We believe this determination provides Vascepa with the benefits of NCE exclusivity afforded by statute. NCE exclusivity for Vascepa ran from its date of FDA approval on July 26, 2012 and extended until July 26, 2017. We believe the statutory NCE-related 30-month stay triggered by the 1-gram dose patent litigation following generic application submissions permitted on July 26, 2016 is scheduled to continue until January 26, 2020, seven-and-a-half years from FDA approval, unless such patent litigation is resolved against us sooner.

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

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

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

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

Also, for more than a decade now, subject to certain limitations, the FDA has expressly permitted dietary supplement manufacturers that sell supplements containing the omega-3 fatty acids EPA and/or DHA to make the following qualified health claim directly to consumers: Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease. As a result of our First Amendment litigation and settlement, we may now make this claim to healthcare professionals subject to certain qualifications.

These factors enable dietary supplements to compete with Vascepa to a certain degree. Although we have taken steps to address these competitive issues, and plan to continue to do so vigorously, we may not be successful in such efforts. For example, on August 30, 2017, Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Limited, each a wholly-owned subsidiary of Amarin Corporation plc, filed a lawsuit with the United States International Trade Commission, or the ITC, against manufacturers, importers, and distributors of products containing synthetically produced omega-3 products in ethyl ester or re-esterified triglyceride form that contain more EPA than DHA or any other single component for use in or as dietary supplements. The lawsuit sought an investigation by the ITC regarding potentially unfair methods of competition and unfair acts involving the importation and sale of articles in the United States that injure or threaten injury to a domestic industry. On October 27, 2017, the ITC determined to not institute our requested investigation. We have appealed this determination in federal court and are awaiting a ruling. We have also recently sued several omega-3 dietary supplement manufacturers for making claims that we believe make them unfairly competitive to Vascepa.

In addition, to the extent the net price of Vascepa after insurance and offered discounts is significantly higher than the prices of commercially available omega-3 fatty acids marketed by other companies as dietary supplements (through that lack of coverage by insurers or otherwise), physicians and pharmacists may recommend these commercial alternatives instead of writing or filling prescriptions for Vascepa or patients may elect on their own to take commercially available omega-3 fatty acids. Also, insurance plans may increasingly impose policies that favor supplement use over Vascepa. While Vascepa is highly price-competitive for patients generally, and in particular when covered by insurance—cheaper in many cases—any of these outcomes may adversely impact our results of operations by limiting how we price our product and limiting the revenue we receive from the sale of Vascepa due to reduced market acceptance.

We may not be successful in replacing our Vascepa co-promotion effort with Kowa Pharmaceuticals America, Inc. after it expired at the end of 2018.

In March 2014, we entered into a co-promotion agreement with Kowa Pharmaceuticals America, Inc. to co-promote Vascepa in the United States under which Kowa Pharmaceuticals America, Inc. co-promoted Vascepa in conjunction with its promotion of its primary product, a branded statin for patients with high cholesterol. Co-promotion under the agreement commenced in May 2014 and ceased at the end of 2018. We could seek to search for another commercialization partner, though there is no guarantee we would be successful in doing so. If we do not enter into a co-promotion agreement with an equally capable company or if our newly hired sales representatives are not effective as planned, our sales may be negatively impacted. 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 proposed REDUCE-IT indications.

The REDUCE-IT trial was conducted pursuant to a SPA agreement with the FDA which means that the FDA agreed, based on the information we submitted to the agency, that the design and planned analysis of the trial was adequate to support use of the conducted study as the primary basis for approval with respect to effectiveness.

A SPA agreement does not cover every aspect of clinical trial conduct and assessment. For example 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.

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. The FDA previously rescinded our SPA agreement with the FDA for our ANCHOR trial 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. There can be no assurance that the FDA or the applicable regulatory authorities in other jurisdictions will not reach a similar conclusion with respect to the results of the REDUCE-IT trial or will not require additional studies by of Vascepa in additional patient populations.

* We cannot predict whether the FDA will approve our sNDA for Vascepa.

In March 2019, we submitted a supplemental new drug application, or sNDA, to the FDA seeking revised labeling for Vascepa based on results of the REDUCE-IT study and, upon such expanded labeling, subject to FDA approval of such label, to further expand its promotion of Vascepa in the United States. However, there can be no assurance as to the actual timetable for FDA action or whether the sNDA will be approved by the FDA. Additionally, even if the sNDA is approved, such approval could require various actions by us including modification of the existing Vascepa label or the adoption of FDA-mandated risk evaluation and mitigation strategies. Any adverse developments or results or perceived adverse developments or results with respect to our sNDA will significantly harm our business and could cause the market price of our securities to decline.

The commercial value to us of sales of Vascepa outside the United States may be smaller than we anticipate.

There can be no assurance as to the adequacy for commercial success of Vascepa outside the United States. For example, even if we and Eddingpharm (Asia) Macao Commercial Offshore Limited, or Eddingpharm, obtain marketing approval in Mainland China, Hong Kong, Macau and Taiwan, or the China Territory, applicable regulatory agencies may impose restrictions on the product's conditions for use, distribution or marketing and in some cases may impose ongoing requirements for post-market surveillance, post-approval studies or clinical trials. Also, there is a degree of unpredictability with regard to the eventual pricing and reimbursement levels of medications in markets outside the United States. If the pricing and reimbursement levels of Vascepa are lower than we anticipate, then affordability of, and market access to, Vascepa may be adversely affected and thus market potential in these territories would suffer. Furthermore, with regard to any indications for which we may gain approval in territories outside the United States, the number of actual patients with the condition included in such approved indication may be smaller than we anticipate. If any such approved indication is narrower than we anticipate, the market potential in these countries for our product would suffer.

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

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

With respect to sales and marketing activities including direct-to-healthcare provider and direct-to-consumer advertising and promotional activities involving the internet, advertising and promotional materials must comply with FDA rules in addition to other applicable federal and local laws in the United States and in other countries. The result of our First Amendment litigation and settlement may cause the government to scrutinize our promotional efforts or otherwise monitor our business more closely. Industry-sponsored scientific and educational activities also must comply with FDA and other requirements. In the United States, the distribution of product samples to physicians must comply with the requirements of the U.S. Prescription Drug Marketing Act. Manufacturing facilities remain subject to FDA inspection and must continue to adhere to the FDA's pharmaceutical current good manufacturing practice requirements, or cGMPs. Application holders must obtain FDA approval for product and manufacturing changes, depending on the nature of the change.

We also are subject to the federal transparency requirements under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, enacted in March 2010, which require manufacturers of certain drugs, devices, biologics, and medical supplies to report to the Centers for Medicare & Medicaid Services, or CMS, information related to payments and other transfers of value to physicians and teaching hospitals and physician ownership and investment interests. We may also be subject, directly or indirectly through our customers and partners, to various fraud and abuse laws, including, without limitation, the U.S. Anti-Kickback Statute, U.S. False Claims Act, and similar state laws, which impact, among other things, our proposed sales, marketing, and scientific/educational grant programs. If we participate in the U.S. Medicaid Drug Rebate Program, the Federal Supply Schedule of the U.S. Department of Veterans Affairs, or other government drug programs, we will be subject to complex laws and regulations regarding reporting and payment obligations. We must also comply with requirements to collect and report adverse events and product complaints associated with our products. For example, in September 2014, we participated in a routine inspection from the FDA in which the FDA made observations on perceived deficiencies related to our processes for collection and processing of adverse events. We have responded to FDA with respect to these observations and continue to work with FDA to show that we have improved related systems and, given we received communication from the FDA that it considers this matter to be closed, we believe that we have demonstrated to FDA that we have adequately responded to these observations. Our activities are also subject to U.S. federal and state consumer protection and unfair competition laws, non-compliance with which could subject us to significant liability. Similar requirements exist in many of these areas in other countries.

Depending on the circumstances, failure to meet these post-approval requirements can result in criminal prosecution, fines or other penalties, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, or refusal to allow us to enter into supply contracts, including government contracts. We may also be held responsible for the non-compliance of our partners, such as our former co-promotion partner 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. Newly discovered or developed safety or effectiveness data may require changes to a drug's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Adverse regulatory action, whether pre- or post-approval, can potentially lead to product liability claims and increase our product liability exposure. We must also compete against other products in qualifying for coverage and reimbursement under applicable third-party payment and insurance programs. In addition, all of the above factors may also apply to any regulatory approval for Vascepa obtained in

territories outside the United States. Given our inexperience with marketing and commercializing products outside the United States, we will need to rely on third parties, such as Eddingpharm in China, to assist us in dealing with any such issues.

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

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

Specifically, in both the United States and some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. For example, beginning April 1, 2013, Medicare payments for all items and services, including drugs and biologics, were reduced by 2% under the sequestration (i.e., automatic spending reductions) required by the Budget Control Act of 2011, as amended by the American Taxpayer Relief Act of 2012. Subsequent legislation extended the 2% reduction, on average, to 2027. These cuts reduce reimbursement payments related to our products, which could potentially negatively impact our revenue. Also for example, the ACA substantially changed the way healthcare is financed by both governmental and private insurers. Among other cost-containment measures, ACA establishes:

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

There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Additionally, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The U.S. Department of Health and Human Services, or HHS, has already started the process of soliciting feedback on some of these measures and, at the same time, is immediately implementing others under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2019, and in October 2018, CMS proposed a new rule that would require direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product. Although a number of these, and other proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. For example, the State of California enacted legislation that requires notice for exceeding specified limits on annual drug price increases and other legislation that seeks to limit the use of co-pay cards in certain situations.

In addition, it is time-consuming and expensive for us to go through the process of seeking coverage and reimbursement from Medicare and private payors. Our products may not be considered cost effective, and government and third-party private health insurance coverage and reimbursement may not be available to patients for any of our future products or sufficient to allow us to sell our products on a competitive and profitable basis. Our results of operations could be adversely affected by ACA and by other healthcare reforms that may be enacted or adopted in the future. In addition, increasing emphasis on managed care in the United States will continue to put pressure on the pricing of pharmaceutical products. For example, proposals are being considered to expand the use of dietary

supplements in addition to or in place of drugs in government and private payor plans. In addition, cost control initiatives could decrease the price that we or any potential collaborators could receive for any of our future products and could adversely affect our profitability.

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

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We participate in the Medicaid Drug Rebate program, the 340B drug pricing program, and the U.S. Department of Veterans Affairs, or VA, Federal Supply Schedule, or FSS, pricing program. Under the Medicaid Drug Rebate program, we are required to pay a rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid and Medicare Part B. Those rebates are based on pricing data reported by us on a monthly and quarterly basis to CMS, the federal agency that administers the Medicaid Drug Rebate program. These data include the average manufacturer price and, in the case of innovator products, the best price for each drug which, in general, represents the lowest price available from the manufacturer to any entity in the U.S. in any pricing structure, calculated to include all sales and associated rebates, discounts and other price concessions. Our failure to comply with these price reporting and rebate payment obligations could negatively impact our financial results.

The ACA made significant changes to the Medicaid Drug Rebate program. CMS issued a final regulation, which became effective on April 1, 2016, to implement the changes to the Medicaid Drug Rebate program under the ACA. The issuance of the final regulation has increased and will continue to increase our costs and the complexity of compliance, has been and will continue to be time-consuming to implement, and could have a material adverse effect on our results of operations, particularly if CMS challenges the approach we take in our implementation of the final regulation.

Federal law requires that any company that participates in the Medicaid Drug Rebate program also participate in the Public Health Service's 340B drug pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B program requires participating manufacturers to agree to charge statutorily defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The 340B ceiling price is calculated using a statutory formula based on the average manufacturer price and Medicaid rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate program, and in general, products subject to Medicaid price reporting and rebate liability are also subject to the 340B ceiling price calculation and discount requirement. Any additional future changes to the definition of average manufacturer price and the Medicaid rebate amount under the ACA, other legislation, or in regulation could affect our 340B ceiling price calculations and negatively impact our results of operations.

The Health Resources and Services Administration, or HRSA, which administers the 340B program, issued a final regulation regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities, which became effective on January 1, 2019. It is currently unclear how HRSA will apply its enforcement authority under the new regulation. HRSA also is implementing a ceiling price reporting requirement related to the 340B program during the first quarter of 2019, pursuant to which we are required to report our 340B ceiling prices to HRSA on a quarterly basis. Implementation of the civil monetary penalties regulation and the issuance of any other final regulations and guidance could affect our obligations under the 340B program in ways we cannot anticipate. In addition, legislation may be introduced that, if passed, would further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in the inpatient setting.

Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by us, governmental or regulatory agencies and the courts. In the case of our Medicaid pricing data, if we become aware that our reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing

data, we are obligated to resubmit the corrected data for up to three years after those data originally were due. Such restatements and recalculations increase our costs for complying with the laws and regulations governing the Medicaid Drug Rebate program and could result in an overage or underage in our rebate liability for past quarters. Price recalculations also may affect the ceiling price at which we are required to offer our products under the 340B program or could require us to issue refunds to 340B covered entities.

Significant civil monetary penalties can be applied if we are found to have knowingly submitted any false pricing information to CMS, or if we fail to submit the required price data on a timely basis. Such conduct also could be grounds for CMS to terminate our Medicaid drug rebate agreement, in which case federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs. Significant civil monetary penalties also can be applied if we are found to have knowingly and intentionally charged 340B covered entities more than the statutorily mandated ceiling price. We cannot assure you that our submissions will not be found by CMS or HRSA to be incomplete or incorrect.

In order to be eligible to have our products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies and grantees, we participate in the U.S. Department of Veterans Affairs, or VA, Federal Supply Schedule, or FSS, pricing program. As part of this program, we are obligated to make our products available for procurement on an FSS contract under which we must comply with standard government terms and conditions and charge a price that is no higher than the statutory Federal Ceiling Price, or FCP, to four federal agencies (VA, U.S. Department of Defense, or DOD, Public Health

Service, and U.S. Coast Guard). The FCP is based on the Non-Federal Average Manufacturer Price, or Non-FAMP, which we calculate and report to the VA on a quarterly and annual basis. Pursuant to applicable law, knowing provision of false information in connection with a Non-FAMP filing can subject a manufacturer to significant penalties for each item of false information. These obligations also contain extensive disclosure and certification requirements.

We also participate in the Tricare Retail Pharmacy program, under which we pay quarterly rebates on utilization of innovator products that are dispensed through the Tricare Retail Pharmacy network to Tricare beneficiaries. The rebates are calculated as the difference between the annual Non-FAMP and FCP. We are required to list our covered products on a Tricare Agreement in order for these products to be eligible for DOD formulary inclusion. If we overcharge the government in connection with our FSS contract or Tricare Agreement, whether due to a misstated FCP or otherwise, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the False Claims Act and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Changes in reimbursement procedures by government and other third-party payors may limit our ability to market and sell our approved drugs. These changes could have a material adverse effect on our business and financial condition.

In the U.S. and abroad, sales of pharmaceutical drugs are dependent, in part, on the availability of reimbursement to the consumer from third-party payors, such as government and private insurance plans. Third-party payors are increasingly challenging the prices charged for medical products and services. Some third-party payor benefit packages restrict reimbursement, charge copayments to patients, or do not provide coverage for specific drugs or drug classes.

In addition, certain healthcare providers are moving toward a managed care system in which such providers contract to provide comprehensive healthcare services, including prescription drugs, for a fixed cost per person. We are unable to predict the reimbursement policies employed by third-party healthcare payors.

We expect to experience pricing and reimbursement pressures in connection with the sale of our products due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals. In addition, we may confront limitations in insurance coverage for our products. If we fail to successfully secure and maintain reimbursement coverage for our approved drugs or are significantly delayed in doing so, we may have difficulty achieving market acceptance of our approved drugs and investigational drug candidates for which we obtain approval, and our business may be harmed. Congress has enacted healthcare reform and may enact further reform, which could adversely affect the pharmaceutical industry as a whole, and therefore could have a material adverse effect on our business.

Ongoing healthcare legislative and regulatory reform measures may have a material adverse effect on our business and results of operations.

Some of the provisions of the ACA have yet to be fully implemented, and certain provisions have been subject to judicial and Congressional challenges. In addition, there have been efforts by the Trump administration to repeal or replace certain aspects of the ACA and to alter the implementation of the ACA and related laws. Since January 2017, the Trump administration has signed two Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. One Executive Order directs federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. The second Executive Order terminates the cost-sharing subsidies that reimburse insurers under the ACA.

Nineteen state Attorneys General filed suit to stop the administration from terminating the subsidies, but on July 18, 2018, the U.S. District Court for the Northern District of California dismissed the case without prejudice. Further, on June 14, 2018, U.S. Court of Appeals for the Federal Circuit ruled that, due to Congressional appropriations riders that prohibited the Department of Health and Human Services (HHS) from paying out more in risk corridor payments than it collected, HHS was not required to pay more than $12 billion in ACA risk corridor payments owed to insurers under the risk corridor formula. On November 6, 2018, the Federal Circuit declined to rehear the case en banc. Insurers have appealed this ruling to the Supreme Court.

Moreover, the Tax Cuts and Jobs Act enacted on December 22, 2017, eliminated the tax-based shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code of 1986, commonly referred to as the “individual mandate,” effective January 1, 2019. On January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called “Cadillac” tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. The Bipartisan Budget Act of 2018, or the BBA, among other things, amends the ACA, effective January 1, 2019, to reduce the coverage gap in most Medicare drug plans, commonly referred to as the “donut hole” by raising the manufacturer discount under the Medicare Part D coverage gap discount program to 70%.

In July 2018, the Centers for Medicare and Medicaid Services, or CMS, published a final rule permitting certain further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. In addition, CMS has published a final rule that gives states greater flexibility, starting in 2020, in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or the Texas District Court Judge, ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Cuts and Jobs Act of 2017, the remaining provisions of the ACA are invalid as well. This ruling is under appeal and stayed pending appeal. While the Trump Administration and CMS have both stated that the ruling will have no effect while this appeal is pending, it is unclear how this decision, subsequent appeals, and other efforts to invalidate the ACA or portions thereof will impact the ACA, its implementation, and our business.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. In August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction, which triggered the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of, on average, 2% per fiscal year through 2025 unless Congress takes additional action. These reductions were extended through 2027 under the BBA. In January 2013, the American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

We expect that the healthcare reform measures that have been adopted and may be adopted in the future, may result in more rigorous coverage criteria, and new payment methodologies, and in additional downward pressure on coverage and payment and the price that we receive for any approved product, and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private third-party payors.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

Failure to comply with health and data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business.

We and any potential collaborators may be subject to federal, state, and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA. Although we are not directly subject to HIPAA – other than with respect to providing certain employee benefits – we could potentially be subject to criminal penalties if we, our

affiliates, or our agents knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. In addition, state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with these laws and regulations could result in government enforcement actions (which could include civil, criminal and administrative penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects, employees and other individuals about whom we or our potential collaborators obtain personal information, as well as the providers who share this information with us, may limit our ability to collect, use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

European data collection is governed by restrictive regulations governing the use, processing and cross-border transfer of personal information.

In the event we decide to conduct clinical trials in the European Union, or EU, we may be subject to additional privacy restrictions. The collection and use of personal health data in the EU is governed by the provisions of the General Data Protection Regulation, or GDPR. This directive imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, notification of data processing obligations to the competent national data protection authorities and the security and confidentiality of the personal data. The GDPR also imposes strict rules on the transfer of personal data out of the European Union to the United States. Failure to comply with the requirements of the Data Protection Directive, the GDPR, and the related national data protection laws of the European Union Member States may result in fines and other administrative penalties. The GDPR introduces new data protection requirements in the European Union and substantial fines for breaches of the data protection rules. The GDPR regulations may impose additional responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with these and/or new data protection rules. This may be onerous and adversely affect our business, financial condition, prospects and results of operations.

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

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

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

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

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

The success of our research and development efforts is dependent in part upon our ability, and the ability of our partners or potential partners, to meet regulatory requirements in the jurisdictions where we or our partners or potential partners ultimately intend to sell such products once approved. The development, manufacture and marketing of pharmaceutical products are subject to extensive regulation by governmental authorities in the United States and elsewhere. In the United States, the FDA generally requires preclinical testing and clinical trials of each drug to establish its safety and efficacy and extensive pharmaceutical development to ensure its quality before its introduction into the market. Regulatory authorities in other jurisdictions impose similar requirements. The process of obtaining regulatory approvals is lengthy and expensive and the issuance of such approvals is uncertain. The commencement and rate of completion of clinical trials and the timing of obtaining marketing approval from regulatory authorities may be delayed by many factors, including but not limited to:

- the lack of efficacy during clinical trials;

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

Even if we obtain positive results from early stage preclinical studies or clinical trials, we may not achieve the same success in future trials. Clinical trials that we or potential partners conduct may not provide sufficient safety and efficacy data to obtain the requisite regulatory approvals for product candidates. The failure of clinical trials to demonstrate safety and efficacy for our desired indications could harm the development of that product candidate as well as other product candidates, and our business and results of operations would suffer. For example, the efficacy results of our Vascepa Phase 3 clinical trials for the treatment of Huntington's disease were negative. As a result, we stopped development of that product candidate, revised our clinical strategy and shifted our focus to develop Vascepa for use in the treatment of cardiovascular disease. Questions can also arise on the quality of study data or its reliability. For example, during the public advisory committee meeting held by FDA as part of its review of our ANCHOR sNDA, a discussion regarding observed, nominally statistically significant changes from baseline in an adverse direction, while on background statin therapy, in certain lipid parameters, including triglycerides, in the placebo group, raised questions about the possibility that the mineral oil placebo used in the ANCHOR trial (and in the REDUCE-IT trial) might not be biologically inert and might be viewed as artificially exaggerating the clinical effect of Vascepa when measured against placebo in the ANCHOR trial. Ultimately, no strong evidence for biological activity of mineral oil was identified by the FDA before its approval of Vascepa after review of the MARINE and ANCHOR trials and consideration of other data regarding mineral oil. It was ultimately concluded that the between-group differences likely provided the most appropriate descriptions of the treatment effect of Vascepa and that whatever factor(s) led to the within-group changes over time in the placebo group were likely randomly distributed to all treatment groups. Thus, the FDA approved Vascepa for use in the MARINE indication in July 2012, FDA did not dispute the veracity of the ANCHOR trial data and, in connection with the March 2016 agreement we reached with the FDA allowing us to promote the results of the ANCHOR study, the FDA did not seek to require that we include any qualification related to this earlier question regarding the mineral oil placebo. The FDA, early on in the course of the REDUCE-IT trial, directed the DMC for REDUCE-IT to periodically review unblinded lipid data to monitor for signals that the placebo might not be inert. After each such quarterly unblinded safety analysis and review meeting, the DMC recommended to continue the REDUCE-IT study as planned. Each of these DMC recommendations has been shared with FDA. This matter illustrates that concerns such as this may arise in the future that could affect our product development, regulatory review or the public perception of our products and our future prospects, including REDUCE-IT results.

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

As we continue to evolve from a company primarily involved in research and development to a company also focused on establishing an infrastructure for commercializing Vascepa, we may encounter difficulties in managing our growth and expanding our operations successfully.

The process of establishing a commercial infrastructure is difficult, expensive and time-consuming. Prior to REDUCE-IT topline results announcement in September 2018, our sales team consisted of approximately 170 sales professionals, including sales representatives and their managers. We have recently increased the size of our sales force approximately 440 sales professionals, including approximately 400 sales representatives, in the United States and are expanding our promotion of Vascepa. This sales team

promotes Vascepa to a limited group of physicians and other healthcare professionals in select geographies in the United States. Even after planned expansion, this sales team is not large enough to call upon all physicians.

In addition to sales force expansion in the United States, Amarin plans to work with its international partners to support regulatory efforts outside the United States based on REDUCE-IT results. As our operations expand with the anticipated growth of our product sales, we expect that we will need to manage additional relationships with various collaborative partners, suppliers and other third parties. Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. Our future financial performance and our ability to commercialize Vascepa and to compete effectively will depend, in part, on our ability to manage our future growth effectively. To that end, we must be able to manage our development efforts effectively, and hire, train, integrate and retain additional management, administrative and sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

Risks Related to Our Reliance on Third Parties

Our supply of product for the commercial market and clinical trials is dependent upon relationships with third-party manufacturers and 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 our manufacturers 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, government action, 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 have contractual freedom to source the API for Vascepa and to procure other services supporting our supply chain. We have entered into supply agreements with multiple suppliers who also rely on other third-party suppliers to manufacture the API and other elements necessary for the sale of Vascepa. Our strategy in sourcing API and other components in our supply chain from multiple suppliers has been to expand manufacturing capacity, maintain competitive advantages, and mitigate the risk of reliance on any single supplier.

Expanding manufacturing capacity and qualifying such capacity is complex and subject to numerous regulations and other operational challenges. The resources of our suppliers vary and are limited; costs associated with projected expansion and qualification can be significant. 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 continued qualification of our API suppliers and, depending on the ability of existing suppliers to meet our supply demands, potentially the qualifications of new 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.

There can be no guarantee that current suppliers and future suppliers with which we have contracted to encapsulate API will be continually qualified to manufacture the product to our specifications or that current and any future suppliers will have the manufacturing capacity to meet 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 and guidelines who are both capable of manufacturing Vascepa and willing to do so. Failure by us or our third-party manufacturers to comply with applicable regulations, requirements, or guidelines could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our products, delays, suspension or withdrawal of approvals, license revocation, seizures or voluntary recalls of product, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business. If we are not able to manufacture Vascepa to required specifications through our current and potential API suppliers, we may be delayed in successfully supplying the product to meet anticipated demand and our anticipated future revenues and financial results may be materially adversely affected.

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

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

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

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

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

In February 2015, we entered into a Development, Commercialization and Supply Agreement, or the DCS Agreement, with Eddingpharm related to the development and commercialization of Vascepa in the China Territory. Under the DCS Agreement, Eddingpharm is responsible for development and commercialization activities in the China Territory and associated expenses. Additionally, Eddingpharm is required to conduct clinical trials in the China Territory to

secure regulatory approval in certain territories. For example, in December 2017, Eddingpharm commenced a pivotal clinical trial aimed to support the regulatory approval of the first indication of Vascepa in a patient population with severe hypertriglyceridemia in Mainland China. Additional clinical development efforts may be necessary in this market. Significant commercialization of Vascepa in the China Territory is several years away, if at all. If Eddingpharm is not able to effectively develop and commercialize Vascepa in the China Territory, we may not be able to generate revenue from the DCS Agreement resulting from the sale of Vascepa in the China Territory.

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

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

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

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

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

Our relationships with healthcare providers and physicians and third-party payors are subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose use to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Arrangements with third-party payors and customers can expose pharmaceutical manufacturers to broadly applicable fraud and abuse and other healthcare laws and regulations, which may constrain the business or financial arrangements and relationships through which such companies sell, market and distribute pharmaceutical products. In particular, the promotion, sales and marketing of healthcare items and services, as well as a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. The applicable federal and state healthcare laws and regulations laws that may affect our ability to operate include, but are not limited to:

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the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. Liability may be established without a person or entity having actual knowledge of the federal anti-kickback statute or specific intent to violate it. In addition, the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability. Moreover, there are no safe harbors for many common practices, such as educational and research grants or patient or product support programs;

- the federal Civil False Claims Act (FCA), which prohibits, among other things, any person from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds, or knowingly making or using, or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly concealing, or knowingly and improperly avoiding, decreasing, or concealing an obligation to pay money to the federal government. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the statute and to share in any monetary recovery. Recently, several pharmaceutical and other healthcare companies have been investigated or faced enforcement actions under the FCA for a variety of alleged improper marketing activities, including allegations that they caused false claims to be submitted because of the company's marketing of the product for unapproved, and thus allegedly non-reimbursable, uses. Federal enforcement agencies also have showed increased interest in pharmaceutical companies' product and patient assistance programs, including reimbursement and co-pay support services, and a number of investigations into these programs have resulted in significant civil and criminal settlements. Pharmaceutical and other healthcare companies also are subject to other federal false claims laws, including, among others, federal criminal healthcare fraud and false statement statutes that extend to non-government health benefit programs;
- HIPAA, which, among other things, imposes criminal and civil liability for knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payor and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services;
- HIPAA, and its implementing regulations, which impose, among other things, requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;
- the federal Physician Payment Sunshine Act, being implemented as the Open Payments Program, which requires manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to direct or indirect payments and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held in the company by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; and other state or local laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; restrict the ability of manufacturers to offer co-pay support to patients for certain prescription drugs; require drug manufacturers to report information related to clinical trials, or information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and/or require identification or licensing of sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies continue to give regular and close scrutiny to interactions between healthcare companies and healthcare providers, and such scrutiny often leads to investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from the business.

The failure to comply with any of these laws or regulatory requirements subjects entities to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in significant civil, criminal and

administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in federal and state funded healthcare programs (such as Medicare and Medicaid), contractual damages and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Any action for violation of these laws, even if successfully defended, could cause a pharmaceutical manufacturer to incur significant legal expenses and divert management's attention from the operation of the business. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, that person or entity may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way.

Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations.

In addition, the approval and commercialization of any of our AXA Candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

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

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

Risks Related to Our Intellectual Property

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

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

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

We have prosecuted, and are currently prosecuting, multiple patent applications to protect the intellectual property developed during the Vascepa development program. As of the date of this report, we had 79 patent applications in the United States that have been either issued or allowed and more than 30 additional patent applications are pending in the United States. Such 79 allowed and issued applications include the following:

- 2 issued U.S. patents directed to a pharmaceutical composition of Vascepa in a capsule that have terms that expire in 2020 and 2030, respectively;
- 1 issued U.S. patent covering a composition containing highly pure EPA that expires in 2021;
- 3 U.S. patents covering or related to the use of Vascepa in either the MARINE or ANCHOR populations that have terms that expire in 2030 or later;
- 1 U.S. patents covering or related to the use of Vascepa in the REDUCE-IT population with terms expiring in 2033 or later;
- 4 additional patents related to the use of a pharmaceutical composition comprised of free fatty acids to treat the ANCHOR patient population with a term that expires in 2030 or later;

- 2 additional patents related to the use of a pharmaceutical composition comprised of free fatty acids to treat the MARINE patient population with a term that expires in 2030;
- 3 additional patents related to the use of a pharmaceutical composition comprised of free fatty acids to treat the REDUCE-IT population expiring 2033;
- 1 additional patent related to a pharmaceutical composition comprised of free fatty acids and uses thereof to treat both the MARINE and ANCHOR patient populations with a term that expires in 2030;
- 1 additional patent related to the use of a pharmaceutical composition comprised of re-esterified EPA triglyceride to treat the REDUCE-IT population expiring 2033;
- 3 additional patents related to a formulation of EPA/DHA and uses thereof with a term that expires in 2030;
- 2 additional patents related to the use of Vascepa to treat obesity with a term that expires in 2034;
- 2 additional patents covering a pharmaceutical composition comprised of EPA and a hydroxyl compound with a term that expires in 2034; and
- 4 additional patents covering a new combination therapy comprised of EPA and another drug.

A Notice of Allowance is issued after the USPTO makes a determination that a patent can be granted from an application. A Notice of Allowance does not afford patent protection until the underlying patent is issued by the USPTO. No assurance can be given that applications with issued notices of allowance will be issued as patents or that any of our pending patent applications will issue as patents. No assurance can be given that, if and when issued, our patents will prevent competitors from competing with Vascepa. For example, we may choose to not assert all issued patents in patent litigation and patents or claims within patents may be determined to be invalid.

We are the owner of the above-listed patents. We are also the exclusive licensee of certain patents owned by others covering products in development. To secure our debt under our outstanding royalty-like instrument, we have granted the holders of such instrument a security interest in our Vascepa-related patents.

We are also pursuing patent applications related to Vascepa in multiple jurisdictions outside the United States. We may be dependent in some cases upon third-party licensors to pursue filing, prosecution and maintenance of patent rights or applications owned or controlled by those parties, including, for example, under our collaboration with Mochida. It is possible that third parties will obtain patents or other proprietary rights that might be necessary or useful to us. In cases where third parties are first to invent a particular product or technology, or first to file after various provisions of the America Invents Act of 2011 went into effect on March 16, 2013, it is possible that those parties will obtain patents that will be sufficiently broad so as to prevent us from utilizing such technology or commercializing our current and future products.

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

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

We anticipate that competitors may from time to time oppose our efforts to obtain patent protection for new technologies or to submit patented technologies for regulatory approvals. Competitors may seek to oppose our patent

applications to delay the approval process or to challenge our granted patents, for example, by requesting a reexamination of our patent at the USPTO, or by filing an opposition in a foreign patent office, even if the opposition or challenge has little or no merit. For example, one of our patents was revoked in an opposition proceeding in Europe due to a determination of improper claim amendments under a provision of law not applicable in the United States. Such proceedings are generally highly technical, expensive, and time consuming, and there can be no assurance that such a challenge would not result in the narrowing or complete revocation of any patent of ours that was so challenged.

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

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

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

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

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

We have filed and are prosecuting numerous families of patent applications in the United States and internationally with claims designed to protect the proprietary position of Vascepa. For certain of these patent families, we have filed multiple patent applications. Collectively the patent applications include numerous independent claims and dependent claims. Several of our patent applications contain claims that are based upon what we believe are unexpected and favorable findings from the MARINE and ANCHOR trials. If granted, many of the resulting granted patents would expire in 2030 or beyond. However, no assurance can be given that these additional MARINE and ANCHOR patents or any of our pending patent applications intended to cover an indication based on results from the REDUCE-IT clinical trial will be granted or, if they grant, that they will prevent competitors from competing with Vascepa. For example, we expect to engage in new ANDA patent litigation in the United States and elsewhere with respect to method of use patents related to the REDUCE-IT study after any newly granted indications based on that study.

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

certain of the claims we are pursuing. Furthermore, third parties may attempt to submit publications for consideration by the patent office during examination of our patent applications. Providing such additional evidence and publications could prolong the patent office's review of our applications and result in us incurring additional costs. We cannot be certain what commercial value any granted patent in our patent estate will provide to us.

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

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

Risks Related to Our Business

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

In January 2019, we issued financial and business guidance, including expected fiscal year 2019 total net revenue and expectations regarding inventory build, 2019 operating expenses, and timing of an sNDA seeking Vascepa label expansion. All such guidance is based on estimates and the judgment of management. Because of the inherent nature of estimates, there could be significant differences between our estimates and the actual amount of product demand. If, for any reason, we are unable to realize our currently projected 2019 revenue, we may not realize our publicly announced financial guidance. If we fail to realize or if we change or update any element of our publicly disclosed financial guidance as we have done in the past or other expectations about our business change, our stock price could decline in value.

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

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

Our internal computer systems, or those of our third party clinical research organizations or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our research and development programs.

Despite the implementation of security measures, our internal computer systems and those of our third party clinical research organizations and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war, and telecommunication and electrical failures. While we have not experienced any such system failure, accident, or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs. To the extent that any disruption or security breach results in a loss of or damage to our data or applications or other data or applications relating to our technology or products candidates, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and our research and development program could be delayed.

We could be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of information maintained in the information systems and networks of our company and our vendors, including personal information of our employees and patients, and company and vendor confidential data. In addition, outside parties may attempt to penetrate our systems or those of our vendors or fraudulently induce our personnel or the personnel of our vendors to disclose sensitive information in order to gain access to our data and/or systems. We may experience threats to our data and systems, including malicious codes and viruses, phishing and other cyber-attacks. The number and complexity of these threats continue to increase over time. If a material breach of our information technology systems or those of our vendors occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks. In addition, we could be subject to regulatory actions and/or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices. Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have a process to

identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely. As we outsource more of our information systems to vendors, engage in more electronic transactions with payors and patients, and rely more on cloud-based information systems, the related security risks will increase and we will need to expend additional resources to protect our technology and information systems. In addition, there can be no assurance that our internal information technology systems or those of our third-party contractors, or our consultants' efforts to implement adequate security and control measures, will be sufficient to protect us against breakdowns, service disruption, data deterioration or loss in the event of a system malfunction, or prevent data from being stolen or corrupted in the event of a cyberattack, security breach, industrial espionage attacks or insider threat attacks which could result in financial, legal, business or reputational harm.

We are subject to potential product liability.

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

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

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

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

However, we cannot assure you that we are or will continue to be resident only in Ireland for tax purposes. It is possible that in the future, whether as a result of a change in law or the practice of any relevant tax authority or as a result of any change in the conduct of our affairs, we could become, or be regarded as having become resident in a jurisdiction other than Ireland, or not carrying out a trade in Ireland. Our and our subsidiaries' income tax returns are periodically examined by various tax authorities, including the Internal Revenue Service (IRS) and states. We recently completed the audits by the IRS for the years 2013 to 2014, with no material changes to the filed income tax returns. Although the outcome of tax audits is always uncertain and could result in significant cash tax payments, we do not believe the outcome of any future audits will have a material adverse effect on our consolidated financial position or results of operations. The ultimate resolution may result in a payment that is materially different from our current estimate of the tax liabilities. Should we cease to be an Irish tax resident, we may be subject to a charge to Irish capital gains tax on our assets. Similarly, if the tax residency of any of our subsidiaries were to change from their current jurisdiction for any of the reasons listed above, we may be subject to a charge to local capital gains tax charge on the assets.

The effect on us of comprehensive U.S. tax reform legislation whether adverse or favorable, is uncertain.

On December 22, 2017, President Trump signed into law H.R. 1, "An Act to provide for reconciliation pursuant to titles II and V of the concurrent resolution on the budget for fiscal year 2018", or informally, the Tax Cuts and Jobs Act. Among a number of significant changes to the U.S. federal income tax rules, the Tax Cuts and Jobs Act reduces the marginal U.S. corporate income tax rate from 35% to 21%, limits the deduction for net interest expense, shifts the United States toward a more territorial tax system, and imposes new taxes to combat erosion of the U.S. federal income tax base. The effect of the Tax Cuts and Jobs Act on our company and our affiliates, whether adverse or favorable, is uncertain, and may not become evident for some period of time. You are urged to consult your tax adviser regarding the implications of the Tax Cuts and Jobs Act for an investment in our ADSs.

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

We are highly dependent upon the efforts of our senior management. The loss of the services of one or more members of senior management could have a material adverse effect on us. As a small company with a streamlined management structure, the departure of any key person could have a significant impact and would be potentially disruptive to our business until such time as a suitable replacement is hired. Furthermore, because of the specialized

nature of our business, as our business plan progresses we will be highly dependent upon our ability to attract and retain qualified scientific, technical and key management personnel. As we evolve from a development stage company to a commercial stage company we may experience turnover among members of our senior management team. We may have difficulty identifying and integrating new executives to replace any such losses. There is intense competition for qualified personnel in the areas of our activities. In this environment, we may not be able to attract and retain the personnel necessary for the development of our business, particularly if we do not achieve profitability. The failure to recruit key scientific, technical and management personnel would be detrimental to our ability to implement our business plan.

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

A significant portion of our sales are to wholesalers in the pharmaceutical industry. Three customers individually accounted for 10% or more of our gross product sales. Customers A, B, and C accounted for 21%, 39%, and 29%, respectively, of gross product sales for the three months ended March 31, 2019, and represented 32%, 37%, and 21%, respectively, of the gross accounts receivable balance as of March 31, 2019. Customers A, B, and C accounted for 26%,31%, and 31%, respectively, of gross product sales for the three months ended March 31, 2018, and represented 37%, 30%, and 24%, respectively, of the gross accounts receivable balance as of March 31, 2018. There can be no guarantee that we will be able to sustain our accounts receivable or gross sales levels from our key

customers. If, for any reason, we were to lose, or experience a decrease in the amount of business with our largest customers, whether directly or through our distributor relationships, our financial condition and results of operations could be negatively affected.

Risks Related to Our Financial Position and Capital Requirements

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

We have not yet reached profitability. For the fiscal years ended December 31, 2018, 2017, and 2016, we reported losses of approximately $116.4 million, $67.9 million, and $86.4 million, respectively, and we had an accumulated deficit as of December 31, 2018 of $1.4 billion. For the three months ended March 31, 2019 and 2018, we reported losses of approximately $24.4 million and $24.1 million, respectively, and we had an accumulated deficit as of March 31, 2019 of $1.4 billion. Substantially all of our operating losses resulted from costs incurred in connection with our research and development programs, from general and administrative costs associated with our operations, and costs related to the commercialization of Vascepa. Additionally, as a result of our significant expenses relating to research and development and to commercialization, we expect to continue to incur significant operating losses for an indefinite period. Because of the numerous risks and uncertainties associated with developing and commercializing pharmaceutical products, we are unable to predict the magnitude of these future losses. Our historic losses, combined with expected future losses, have had and will continue to have an adverse effect on our cash resources, shareholders' deficit and working capital.

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

Our ability to become profitable depends upon our ability to generate revenue. We have been generating product revenue from sales of Vascepa since January 2013, but we may not be able to generate sufficient revenue to attain profitability. Our ability to generate profits on sales of Vascepa is subject to the market acceptance and commercial success of Vascepa and our ability to manufacture commercial quantities of Vascepa through third parties at acceptable cost levels, and may also depend upon our ability to effectively market and sell Vascepa through our strategic collaborations.

Even though Vascepa has been approved by the FDA for marketing in the United States in the MARINE indication, it may not gain market acceptance or achieve commercial success and it may never be approved for the ANCHOR indication or any other indication. In addition, we anticipate continuing to incur significant costs associated with commercializing Vascepa. We may not achieve profitability in the near term due to high costs associated with our REDUCE-IT study and commercialization efforts, for example. If we are unable to continue to generate robust product revenues, we will not become profitable in the near term, if ever, and may be unable to continue operations without continued funding.

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

As a consequence of the many years developing Vascepa for commercialization and the commercial launch of Vascepa in 2013 in the United States, our historical financial results do not form an accurate basis upon which investors should base their assessment of our business and prospects. In addition, we expect that our costs will increase substantially as we continue to commercialize Vascepa in the MARINE indication and with ANCHOR data and seek to obtain additional regulatory approval of Vascepa from the REDUCE-IT cardiovascular outcomes study. Accordingly, our historical financial results reflect a substantially different business from that currently being conducted and from that expected in the future. In addition, we have a limited history of obtaining regulatory approval for, and no demonstrated ability to successfully commercialize, a product candidate. Consequently, any predictions about our future performance may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.

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

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

- the continuing evolution of the medical community's and the public's perception of the REDUCE-IT study results;
- the level of demand for Vascepa, due to changes in prescriber sentiment, quarterly changes in Distributor purchases, and other factors;
- the extent to which coverage and reimbursement for Vascepa is available from government and health administration authorities, private health insurers, managed care programs and other third-party payers and the timing and extent to which such coverage and reimbursement changes;

- the timing, cost and level of investment in our sales and marketing efforts to support Vascepa sales and the resulting effectiveness of those efforts with our co-promotion partner, Kowa Pharmaceuticals America, Inc.;
- the timing and ability of commercialization partners outside the United States to develop, register and commercialize Vascepa in the China Territory, several Middle Eastern and North African countries, and Canada, for example, including obtaining necessary regulatory approvals and establishing marketing channels;
- additional developments regarding our intellectual property portfolio and regulatory exclusivity protections, if any;
- outcomes of litigation and other legal proceedings; and
- our regulatory dialogue on the REDUCE-IT study.

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

We currently operate with limited resources. We believe that our cash and cash equivalents balance of $211.1 million as of March 31, 2019 will be sufficient to fund our projected operations for at least twelve months and through the likely Prescription Drug User Fee Act (PDUFA) date for approval of a supplemental new drug application (sNDA) by the FDA based on REDUCE-IT study results. Depending on the level of cash generated from operations, and depending in part on the timing and results of the FDA review of the sNDA and rate of prescription growth for Vascepa, additional capital may be required to support planned expansion of Vascepa promotion and potential Vascepa promotion beyond which we are currently executing. If additional capital is required and we are unable to obtain additional capital, we may be forced to delay, limit or eliminate certain promotional activities. We anticipate that quarterly net cash outflows in future periods will be variable.

In order to fully realize the market potential of Vascepa, we may need to enter into a new strategic collaboration or raise additional capital.

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

- the timing, amount and consistency of revenue generated from the commercial sale of Vascepa;
- the costs associated with commercializing Vascepa in the United States, including expenditures such as potential direct-to-consumer advertising and increased sales force sizing, and for additional indications in the United States and in jurisdictions in which we receive regulatory approval, if any, the cost and timing of securing commercial supply of Vascepa and the timing of entering into any new strategic collaboration with others relating to the commercialization of Vascepa, if at all, and the terms of any such collaboration;
- continued costs associated with litigation and other legal proceedings;
- the time and costs involved in obtaining additional regulatory approvals for Vascepa based on REDUCE-IT results;
- the extent to which we continue to develop internally, acquire or in-license new products, technologies or businesses; and
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

If we require additional funds and adequate funds are not available to us in amounts or on terms acceptable to us or on a timely basis, or at all, our commercialization efforts for Vascepa may suffer materially.

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

Tax law and policies in the United States and Ireland are subject to change based on adjustments in political perspectives. In the United States and internationally, how to tax entities with international operations, like Amarin, has been subject to significant re-evaluation. We developed Vascepa in and from Ireland. In recent years, particularly since 2013 when commercial sale of Vascepa commenced in the United States, the majority of our consolidated operations have been in the United States. Ownership to Vascepa continues to reside with our wholly-owned Ireland-based subsidiary, Amarin Pharmaceuticals Ireland Ltd., and oversight and operations of that entity are structured to be maintained in Ireland. In order to effectively utilize our accumulated net operating loss carryforwards

for tax purposes in Ireland, our operations, particularly for this subsidiary, need to be active in Ireland. In addition, utilization of these accumulated net operating loss carryforwards assumes that tax treaties between Ireland and other countries, particularly the United States, do not change in a manner which limit our future ability to offset earnings with these operating loss carryforwards for tax purposes.

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

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

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

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

To the extent we are permitted under our December 2012 Purchase and Sale Agreement with CPPIB Credit Europe S.à r.l., or CPPIB, as successor in interest to BioPharma Secured Debt Fund II Holdings Cayman LP, we may seek additional capital through a combination of private and public equity offerings, debt financings and collaboration, strategic and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a shareholder.

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

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

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

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

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

Risks Related to Ownership of our ADSs and Common Shares

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

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

As of April 26, 2019, we had 330,686,553 common shares outstanding including 330,480,979 shares held as ADSs and 205,574 held as ordinary shares (which are not held in the form of ADSs). There is a risk that there may not be sufficient liquidity in the market to accommodate significant increases in selling activity or the sale of a large block of our securities. Our ADSs have

historically had limited trading volume, which may also result in volatility. If any of our large investors seek to sell substantial amounts of our ADSs, particularly if these sales are in a rapid or disorderly manner, or other investors perceive that these sales could occur, the market price of our ADSs could decrease significantly.

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

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

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

In March and July 2015, we completed a private placement of American Depositary Shares in two tranches representing 352,150,790 and 38,867,180 Series A Preference Shares, respectively, each ten (10) of which may be consolidated and redesignated into one (1) ordinary share in our capital. During the three months ended June 30, 2015, 62,833,330 preferred shares were converted, resulting in the issuance of 6,283,333 ordinary shares and during the three months ended September 30, 2018, 38,867,180 preferred shares were converted, resulting in the issuance of 3,886,718 ordinary shares. The consolidation and redesignation of the Series A Preference Shares currently outstanding would result in an additional 32,818,464 ordinary shares outstanding, resulting in substantial dilution to shareholders who held our ordinary shares or ADSs representing such ordinary shares prior to the private placement. Although the Series A Preference Shares do not have voting rights, in general, upon consolidation and redesignation into ordinary shares some of the investors in the private placement could then have significant influence over the outcome of any shareholder vote, including the election of directors and the approval of mergers or other business combination transactions.

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

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

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

For example, under each of these agreements we have agreed to file and maintain the effectiveness of certain resale registration statements for ADSs representing the ordinary shares underlying the Series A Preference shares we issued

and sold under these agreements. Specifically, we have agreed to pay liquidated damages to the investors in the respective private placements if (a) the applicable resale registration statements we are required to file are not declared effective within 120 days after the closing of the applicable private placement, or (b) after effectiveness and subject to certain specified exceptions, we suspend the use of the applicable registration statement or the registration statement ceases to remain continuously effective as to all the securities for which it is required to be effective. We refer to each of these events as a registration default. Subject to the specified exceptions, for each 30-day period or portion thereof during which a registration default remains uncured, we are obligated to pay liquidated damages to each investor in cash in an amount equal to 1% of the aggregate subscription price paid by each such investor in the private placement, up

to a maximum of 8% of such aggregate subscription price. These amounts could be material, and any liquidated damages we are required to pay could have a material adverse effect on our financial condition.

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

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

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

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

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

We believe it is prudent to assume that we were classified as a PFIC in the past. However, we do not believe that we have been classified as a PFIC beginning in 2013 when we commercially launched Vascepa in the United States and began to derive revenues from sales of Vascepa. Our status as a PFIC is subject to change in future years.

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

Failure to meet our obligations under our December 2012 Purchase and Sale Agreement could adversely affect our financial results and liquidity.

Pursuant to our December 2012 Purchase and Sale Agreement with CPPIB, which was assigned to CPPIB by BioPharma Secured Debt Fund II Holdings Cayman LP in December 2017, we are obligated to make payments based on the amount of our net product sales of Vascepa and any future products based on ethyl-EPA, or covered products, subject to certain quarterly caps.

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

Upon a transaction resulting in a change of control of Amarin, as defined in the agreement, CPPIB will be automatically entitled to receive any amounts not previously paid, up to our maximum repayment obligation. As defined in the agreement, "change of control" includes, among other things, (i) a greater than 50 percent change in the ownership of Amarin, (ii) a sale or disposition of any

collateral securing our debt with CPPIB and (iii), unless CPPIB has been paid a certain amount under the indebtedness, certain licensings of Vascepa to a third party for sale in the United States. The acceleration of the payment obligation in the event of a change of control transaction may make us less attractive to potential acquirers, and the payment of such funds out of our available cash or acquisition proceeds would reduce acquisition proceeds for our shareholders.

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

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

Our indebtedness could adversely affect our financial condition.

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

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

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

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

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

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

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

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

shares voting (in person or by proxy)), including amendments to the Articles of Association. This may make it more difficult for us to complete corporate transactions deemed advisable by our board of directors. Under U.S. law, generally only majority shareholder approval is required to amend the certificate of incorporation or to approve other significant transactions.

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

Shareholder protections found in provisions under the U.K. City Code on Takeovers and Mergers, or the Takeover Code, do not apply to us.

The Takeover Code provides a framework within which takeovers of certain companies organized in the United Kingdom are regulated and conducted. However, because our place of central management and control is currently outside of the United Kingdom, we are not subject to the Takeover Code. As a result, our shareholders are not entitled to the benefit of certain takeover offer protections provided under the Takeover Code. The following is a brief summary of some of the most important rules of the Takeover Code which, as noted, does not apply to us:

- In connection with a potential offer, if following an approach by or on behalf of a potential bidder, the company is "the subject of rumor or speculation" or there is an "untoward movement" in the company's share price, there is a requirement for the potential bidder to make a public announcement about a potential offer for the company, or for the company to make a public announcement about its review of a potential offer.
- When a person or group (a) acquires interests in shares carrying 30% or more of the voting rights of a company (which percentage is treated by the Takeover Code as the level at which effective control is obtained) or (b) increases the aggregate percentage interest they have when they are already interested in not less than 30% and not more than 50%, they must make a cash offer to all other shareholders at the highest price paid by them in the 12 months before the offer was announced.
- When interests in shares carrying 10% or more of the voting rights of a class have been acquired by an offeror (i.e., a bidder) in the offer period (i.e., before the shares subject to the offer have been acquired) and the previous 12 months, the offer must be in cash or be accompanied by a cash alternative for all shareholders of that class at the highest price paid by the offeror in that period. Further, if an offeror acquires any interest in shares during the offer period, the offer for the shares must be in cash or accompanied by a cash alternative at a price at least equal to the price paid for such shares during the offer period.
- If after an announcement is made, the offeror acquires an interest in shares in an offeree company (i.e., a target) at a price higher than the value of the offer, the offer must be increased accordingly.

- The offeree company must appoint a competent independent adviser whose advice on the financial terms of the offer must be made known to all the shareholders, together with the opinion of the board of directors of the offeree company.
- Favorable deals for selected shareholders are not permitted, except in certain circumstances where independent shareholder approval is given and the arrangements are regarded as fair and reasonable in the opinion of the financial adviser to the offeree.

- All shareholders must be given the same information.
- Those issuing takeover circulars must include statements taking responsibility for the contents thereof.
- Profit forecasts, quantified financial benefits statements and asset valuations must be made to specified standards and must be reported on by professional advisers.
- Misleading, inaccurate or unsubstantiated statements made in documents or to the media must be publicly corrected immediately.
- Actions during the course of an offer by the offeree company, which might frustrate the offer are generally prohibited unless shareholders approve these plans. Frustrating actions would include, for example, lengthening the notice period for directors under their service contract or agreeing to sell off material parts of the target group.
- Stringent requirements are laid down for the disclosure of dealings in relevant securities during an offer, including the prompt disclosure of positions and dealing in relevant securities by the parties to an offer and any person who is interested (directly or indirectly) in 1% or more of any class of relevant securities.
- Employees of both the offeror and the offeree company and the trustees of the offeree company's pension scheme must be informed about an offer. In addition, the offeree company's employee representatives and pension scheme trustees have the right to have a separate opinion on the effects of the offer on employment appended to the offeree board of directors' circular or published on a website.

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

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

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

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

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds
Issuer Purchases of Equity Securities

Shares purchased in the first quarter of 2019 are as follows:

Period	Total Number of Shares Purchased [1]	Average Price Paid per Share
January 1 – 31, 2019	485,456	$ 16.94
February 1 – 28, 2019	—	—

March 1 – 31, 2019	41,252	20.76
Total	526,708	$ 17.24

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

Item 6. Exhibits

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

Exhibit Number	Description	Incorporated by Reference Herein Form	Date
10.1	Employment Agreement dated April 20, 2018 with Aaron Berg	Filed herewith	
10.2	Lease Agreement, dated February 5, 2019, by and between 440 Route 22 LLC and Amarin Pharma, Inc.	Annual Report on Form 10-K for the year ended December 31, 2018, File No. 0-21392, as Exhibit 10.69	February 27, 2019
31.1	Certification of President and Chief Executive Officer (Principal Executive Officer) pursuant to Section 302 of Sarbanes-Oxley Act of 2002	Filed herewith	
31.2	Certification of Senior Vice President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer) pursuant to Section 302 of Sarbanes-Oxley Act of 2002	Filed herewith	
32.1	Certification of President and Chief Executive Officer (Principal Executive Officer) and Senior Vice President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer) pursuant to Section 906 of Sarbanes-Oxley Act of 2002	Filed herewith	
101.INS	XBRL Instance Document		
101.SCH	XBRL Taxonomy Extension Schema Document		
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document		
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document		
101.LAB	XBRL Taxonomy Extension Label Linkbase Document		
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document		

SIGNATURE

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

AMARIN CORPORATION PLC

By: /s/ John F. Thero
John F. Thero

President and Chief Executive Officer
(Principal Executive Officer)
(On behalf of the Registrant)

Date: May 1, 2019