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, 2022
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.)**
77 Sir John Rogerson's Quay, Block C, Grand Canal Docklands	**Dublin 2, Ireland**
(Address of Principal Executive Offices)	**(Zip Code)**

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
American Depositary Shares (ADS(s)), each ADS representing the right to receive one (1) Ordinary Share of Amarin Corporation plc	AMRN	NASDAQ Stock Market LLC

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 Exchange Act). YES ☐ NO ☒

397,008,153 common shares were outstanding as of April 29, 2022, including 396,811,326 shares held as American Depositary Shares (ADSs), each representing one Ordinary Share, 50 pence par value per share and 196,827 Ordinary Shares.

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

	March 31, 2022	December 31, 2021
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 219,151	$ 219,454
Restricted cash	3,918	3,918
Short-term investments	143,406	234,674
Accounts receivable, net	110,234	163,653
Inventory	267,818	234,676
Prepaid and other current assets	28,092	22,352
Total current assets	772,619	878,727
Property, plant and equipment, net	1,281	1,425
Long-term investments	26,701	34,996
Long-term inventory	141,052	121,254
Operating lease right-of-use asset	8,689	7,660
Other long-term assets	456	456
Intangible asset, net	22,911	23,547
TOTAL ASSETS	$ 973,709	$ 1,068,065
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 90,753	$ 114,922
Accrued expenses and other current liabilities	207,622	253,111
Current deferred revenue	2,198	2,649
Total current liabilities	300,573	370,682
Long-Term Liabilities:		
Long-term deferred revenue	14,139	14,060
Long-term operating lease liability	10,398	8,576
Other long-term liabilities	7,490	7,648
Total liabilities	332,600	400,966
Commitments and contingencies (Note 5)		
Stockholders' Equity:		
Common stock, £0.50 par, unlimited authorized; 404,588,758 shares issued, 396,940,908 shares outstanding as of March 31, 2022; 404,084,775 shares issued, 396,598,008 shares outstanding as of December 31, 2021	294,364	294,027
Additional paid-in capital	1,861,017	1,855,246
Treasury stock; 7,647,850 shares as of March 31, 2022; 7,486,767 shares as of December 31, 2021	(61,261)	(60,726)
Accumulated deficit	(1,453,011)	(1,421,448)
Total stockholders' equity	641,109	667,099
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 973,709	$ 1,068,065

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,	
	2022	**2021**
Product revenue, net	$ 93,986	$ 141,383
Licensing and royalty revenue	644	787
Total revenue, net	94,630	142,170
Less: Cost of goods sold	22,239	28,326
Gross margin	72,391	113,844
Operating expenses:		
Selling, general and administrative	90,647	105,798
Research and development	10,051	9,377
Total operating expenses	100,698	115,175
Operating loss	(28,307)	(1,331)
Interest income, net	203	471
Other expense, net	(246)	(142)
Loss from operations before taxes	(28,350)	(1,002)
Income tax provision	(3,213)	(624)
Net loss	$ (31,563)	$ (1,626)
Loss per share:		
Basic	$ (0.08)	$ (0.00)
Diluted	$ (0.08)	$ (0.00)
Weighted average shares:		
Basic	397,805	394,638
Diluted	397,805	394,638

See notes to condensed consolidated financial statements.

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

	Common Shares	Treasury Shares	Common Stock	Additional Paid-in Capital	Treasury Stock	Accumulated Deficit	Total
December 31, 2021	**404,084,775**	**(7,486,767)**	**$ 294,027**	**$ 1,855,246**	**$ (60,726)**	**$ (1,421,448)**	**$ 667,099**
Exercise of stock options	10,602	—	6	24	—	—	30
Vesting of restricted stock units	493,381	(161,083)	331	(331)	(535)	—	(535)
Stock-based compensation	—	—	—	6,078	—	—	6,078
Loss for the period	—	—	—	—	—	(31,563)	(31,563)
March 31, 2022	**404,588,758**	**(7,647,850)**	**$ 294,364**	**$ 1,861,017**	**$ (61,261)**	**$ (1,453,011)**	**$ 641,109**

	Common Shares	Treasury Shares	Common Stock	Additional Paid-in Capital	Treasury Stock	Accumulated Deficit	Total
December 31, 2020	**398,425,000**	**(5,886,919)**	**$ 290,115**	**$ 1,817,649**	**$ (51,082)**	**$ (1,429,177)**	**$ 627,505**
Exercise of stock options	783,320	—	536	1,523	—	—	2,059
Vesting of restricted stock units	2,447,405	(1,003,965)	1,709	(1,709)	(7,252)	—	(7,252)
Stock-based compensation	—	—	—	13,925	—	—	13,925
Loss for the period	—	—	—	—	—	(1,626)	(1,626)
March 31, 2021	**401,655,725**	**(6,890,884)**	**$ 292,360**	**$ 1,831,388**	**$ (58,334)**	**$ (1,430,803)**	**$ 634,611**

See notes to condensed consolidated financial statements.

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

	Three months ended March 31,	
	2022	**2021**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (31,563)	$ (1,626)
Adjustments to reconcile loss to net cash used in operating activities:		
Depreciation and amortization	144	150
Amortization of investments	374	649
Stock-based compensation	6,078	13,925
Amortization of intangible asset	636	361
Changes in assets and liabilities:		
Accounts receivable, net	53,419	3,299
Inventory	(52,940)	(42,028)
Prepaid and other current assets	(5,740)	1,251
Other long-term assets	—	(24)
Interest receivable	140	118
Deferred revenue	(372)	(662)
Accounts payable and other current liabilities	(69,658)	6,479
Other long-term liabilities	635	(596)
Net cash used in operating activities	(98,847)	(18,704)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Maturities of securities	113,220	127,925
Purchases of securities	(14,171)	—
Disposal of furniture, fixtures and equipment	—	4
Net cash provided by investing activities	99,049	127,929
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of stock options, net of transaction costs	30	2,059
Taxes paid related to stock-based awards	(535)	(7,252)
Net cash used in financing activities	(505)	(5,193)
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS AND RESTRICTED CASH	(303)	104,032
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH, BEGINNING OF PERIOD	223,372	190,879
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH, END OF PERIOD	$ 223,069	$ 294,911
Supplemental disclosure of cash flow information:		
Cash paid during the year for:		
Income taxes	$ 51	$ 5
Supplemental disclosure of non-cash transactions:		
Initial recognition of operating lease right-of-use asset	$ 1,036	$ —
Laxdale Milestone	$ -	$ 12,000

See 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, or Amarin, or the Company, is a pharmaceutical company focused on the commercialization and development of therapeutics to improve cardiovascular, or CV, health and reduce CV risk. Most of the Company's historical revenue and sales, marketing and administrative activities and costs have been associated with commercial operations in the United States, or U.S. As of September 1, 2021, product was made available in Germany and as of October 1, 2021 was included in the country's electronic prescribing system. The Company continues pre-launch commercial activities throughout the rest of Europe. The Company's operations outside of the U.S. and Europe are in early stages of development with reliance on third-party commercial partners in select geographies, including China where regulatory approval for the Company's lead product is being actively sought.

The Company's lead product, VASCEPA® (icosapent ethyl), was first approved by the U.S. Food and Drug Administration, or U.S. FDA, in July 2012 for use as an adjunct to diet to reduce triglyceride, or TG, levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia. In January 2013, the Company launched 1-gram size VASCEPA in the U.S. and in October 2016, introduced a smaller 0.5-gram capsule size. On December 13, 2019, the U.S. FDA approved another indication and label expansion for VASCEPA based on the results of the Company's long-term cardiovascular outcomes trial, REDUCE-IT®, or Reduction of Cardiovascular Events with EPA – Intervention Trial. VASCEPA is approved by the U.S. FDA as an adjunct to maximally tolerated statin therapy for reducing persistent cardiovascular risk in select high risk patients.

On March 30, 2020, following conclusion of a trial in late January 2020, the U.S. District Court for the District of Nevada, or the Nevada Court, issued a ruling in favor of two generic drug companies, Dr. Reddy's Laboratories, Inc., or Dr. Reddy's, and Hikma Pharmaceuticals USA Inc., or Hikma, and certain of their affiliates, or, collectively, the Defendants, that declared as invalid several of the Company's patents covering the first U.S. FDA-approved use of its drug, for use to reduce severely high triglyceride levels, which is known as the MARINE indication. The Company sought appeals of the Nevada Court judgment up to the United States Supreme Court, but the Company was unsuccessful. Most recently, on June 18, 2021, the Company was notified that its petition for writ of certiorari to the United States Supreme Court was denied.

On May 22, 2020, Hikma received U.S. FDA approval to market its generic version of VASCEPA for the MARINE indication of VASCEPA. In November 2020, Hikma launched their generic version of VASCEPA on a limited scale. On November 30, 2020 the Company filed a patent infringement lawsuit against Hikma for making, selling, offering to sell and importing generic icosapent ethyl capsules in and into the United States in a manner that the Company alleges has induced the infringement of patents covering the use of VASCEPA to reduce specified cardiovascular risk. In January 2021, the Company expanded the scope of the VASCEPA CV risk reduction patent infringement lawsuit against Hikma to include a health care insurance provider in the United States, Health Net, LLC or Health Net. On January 4, 2022, the district court hearing the case granted Hikma's motion to dismiss. The Company intends to appeal the decision of the district court when permitted and also intends to continue to vigorously pursue the ongoing litigation with Health Net, but cannot predict the outcome or impact on its business.

On August 10, 2020, Dr. Reddy's received U.S. FDA approval to market its generic version for the MARINE indication of VASCEPA. In June 2021, Dr. Reddy's launched its generic version of VASCEPA with labeling that is substantially similar to labeling of the Hikma generic product. On September 11, 2020, Teva Pharmaceuticals USA, Inc's., or Teva's, abbreviated new drug application, or ANDA, was approved by the U.S. FDA and on June 30, 2021, Apotex, Inc.'s, or Apotex's, ANDA was approved by the U.S. FDA. In January 2022, Apotex launched its generic version of VASCEPA with labeling that is substantially consistent with the labeling of the Hikma and Dr. Reddy's generic product, not the cardiovascular risk reduction indication, which is known as the REDUCE-IT indication.

On March 26, 2021, the European Commission, or EC, approved the marketing authorization application for VAZKEPA, hereinafter along with the U.S. brand name VASCEPA, collectively referred to as VASCEPA, in the EU to reduce the risk of cardiovascular events in high-risk, statin-treated adult patients who have elevated triglycerides (≥150 mg/dL) and either established cardiovascular disease or diabetes and at least one additional cardiovascular risk event. On September 13, 2021, the Company launched VAZKEPA in Germany, representing the Company's first European launch. On April 22, 2021, the Company announced that the Medicines and Healthcare Products Regulatory Agency, or MHRA, approved VAZKEPA in England, Scotland and Wales to reduce cardiovascular risk through MHRA's new 'reliance' route following the end of the BREXIT transition period. Collectively CHMP, EMA, EC and MHRA are referred to herein as the European Regulatory Authorities.

In November 2020, the Company announced topline results from the Phase 3 clinical trial of VASCEPA conducted by the Company's partner in China. On February 9, 2021, the Company announced that regulatory review processes for approval of VASCEPA in Mainland China and Hong Kong have commenced. The Chinese National Medical Products Administration, or NMPA, has accepted

for review the new drug application for VASCEPA based on the results from the Phase 3 clinical trial and the results from the Company's prior studies of VASCEPA. On February 23, 2022, The Hong Kong Department of Health concluded their evaluation and approved the use of VASCEPA under the REDUCE-IT indication.

The Company currently has strategic collaborations to develop and commercialize VASCEPA in select territories outside the United States. Amarin is responsible for supplying VASCEPA to all markets in which the product is sold, including the United States and Germany, as well as, in Canada, Lebanon and the United Arab Emirates where the drug is promoted and sold via collaboration with third-party companies that compensate Amarin for such supply. Amarin is not responsible for providing any generic company with drug product. The Company operates in one business segment.

Basis of Presentation

The condensed consolidated financial statements included herein have been prepared by the Company in accordance with accounting principles generally accepted in the United States, or GAAP, 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, 2021, or the Form 10-K, filed with the SEC. The balance sheet amounts in this report were derived from the Company's audited consolidated financial statements included in the Form 10-K.

The condensed consolidated financial statements reflect all adjustments of a normal and recurring nature that, in the opinion of management, are necessary to present fairly the Company's financial position, results of operations and cash flows for the periods indicated. The preparation of the Company's condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. The results of operations for the three months ended March 31, 2022 are not necessarily indicative of the results for 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 well as the ongoing global pandemic, COVID-19.

At March 31, 2022, the Company had Total assets of $973.7 million, of which $389.3 million consisted of cash and liquid short-term and long-term investments. More specifically, the Company had Current assets of $772.6 million, including Cash and cash equivalents of $219.2 million, Short-term investments of $143.4 million, Accounts receivable, net, of $110.2 million and Inventory of $267.8 million. In addition, as of March 31, 2022, the Company had Long-term investments of $26.7 million and Long-term inventory of $141.1 million. As of March 31, 2022, the Company had no debt outstanding.

(2) Significant Accounting Policies

Revenue Recognition

In accordance with Accounting Standards Codification, or ASC, Topic 606, *Revenue from Contracts with Customers*, or Topic 606, the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. For a complete discussion of accounting for net product revenue and licensing revenue, see Note 8—Revenue Recognition.

Cash and Cash Equivalents and Restricted Cash

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

Accounts Receivable, net

Accounts receivable, net, comprised of trade receivables, are generally due within 30 days and are stated at amounts due from customers. The Company recognizes an allowance for losses on accounts receivable in an amount equal to the estimated probable losses net of any recoveries. The allowance is based primarily on assessment of specific identifiable customer accounts considered at risk or uncollectible, as well as an analysis of current receivables aging and expected future write-offs. The expense associated with the allowance for doubtful accounts is recognized as Selling, general, and administrative expense. The Company has not historically experienced any significant credit losses. All customer accounts are actively managed and no losses in excess of amounts reserved are currently expected; however, the Company is monitoring the potential negative impact of COVID-19 on the Company's customers' ability to meet their financial obligations.

The following table summarizes the impact of accounts receivable reserves on the gross trade accounts receivable balances as of March 31, 2022 and December 31, 2021:

In thousands	March 31, 2022	December 31, 2021
Gross trade accounts receivable	$ 217,821	$ 262,948
Trade allowances	(93,044)	(86,636)
Chargebacks	(13,598)	(11,714)
Allowance for doubtful accounts	(945)	(945)
Accounts receivable, net	$ 110,234	$ 163,653

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. The Company classify inventory as long-term inventory when consumption of the inventory is expected beyond the normal operating cycle. 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 tax 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 and 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, as applicable.

The Company regularly assesses its ability to realize deferred tax assets. Changes in historical earnings performance, future earnings projections, and changes in tax laws, 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, or IRS, and states. The Company is currently under audit by the IRS for the Company's 2018 U.S. income tax return and by the New Jersey Department of Treasury for the years 2012 to 2015. 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 from the exercise of stock options and vesting of restricted stock units calculated using the treasury stock method and the issuance of contingently issuable shares related to the Company's Laxdale share repurchase agreement. In periods with reported net operating losses, all stock options, restricted stock units and contingently issuable shares outstanding are deemed anti-dilutive such that basic and diluted net loss per share are equal.

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, 2022 and 2021 are as follows:

	For the Three Months Ended March 31,	
In thousands	2022	2021
Net loss—basic and diluted	$ (31,563)	$ (1,626)
Weighted average shares outstanding—basic and diluted	397,805	394,638
Net loss per share—basic and diluted	$ (0.08)	$ (0.00)

For the three months ended March 31, 2022 and 2021, the following potentially dilutive securities were not included in the computation of net loss per share because the effect would be anti-dilutive or because performance criteria were not yet met for awards contingent upon such measures:

	For the Three Months Ended March 31,	
In thousands	2022	2021
Stock options	19,639	19,372
Restricted stock and restricted stock units	15,369	10,252
Laxdale milestone shares	1,984	—

Stock options are anti-dilutive during periods of net earnings when the exercise price of the stock options exceeds the market price of the underlying shares on the last day of the reporting period. Restricted stock and restricted stock units are anti-dilutive during periods of net earnings when underlying performance-based vesting requirements were not achieved as of the last day of the reporting period.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to credit risk consist primarily of cash and cash equivalents, short-term and long-term investments, and accounts receivable. The Company maintains substantially all of its cash and cash equivalents and short-term and long-term investments, 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 31%, respectively, of gross product sales for the three months ended March 31, 2022, and represented 29%, 37%, and 28%, respectively, of the gross accounts receivable balance as of March 31, 2022. Customers A, B, and C accounted for 27%, 35%, and 31%, respectively, of gross product sales for the three months ended March 31, 2021 and represented 35%, 36%, and 24%, respectively, of the gross accounts receivable balance as of March 31, 2021. The Company has not experienced any significant write-offs of its accounts receivable. All customer accounts are actively managed and no losses in excess of amounts reserved are currently expected; however, the Company is monitoring the potential negative impact of COVID-19 on the Company's customers' ability to meet their financial obligations.

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 disruption or termination of the Company's current supply chain, including as a result of COVID-19, or the Company's 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 API manufacturers and several independent API encapsulators and packagers for VASCEPA manufacturing. Each of these API manufacturers, encapsulators and packagers is U.S. FDA-approved and certain of these API manufacturers, encapsulators and packagers are also approved by the European Regulatory Authorities for manufacturing VAZKEPA in Europe. These suppliers are also used by the Company to source supply to meet the clinical trial and commercial demands of its partners in other countries. Each of these suppliers has qualified and validated its manufacturing processes. 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 potential global 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 estimated fair value of the Company's assets and liabilities as of March 31, 2022 and December 31, 2021 and indicate the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value:

	March 31, 2022			
In thousands	**Total**	**Level 1**	**Level 2**	**Level 3**
Asset:				
Money Market Fund	$ 129,031	$ 129,031	$ —	$ —
U.S. Treasury Shares	7,219	7,219	—	—
Corporate Bonds	59,944	—	59,944	—
Commercial Paper	73,652	—	73,652	—
Repo Securities	4,750	—	4,750	—
Asset Backed Securities	6,707	—	6,707	—
Certificate of Deposit	24,603	—	24,603	—
Non-US Government	8,668	—	8,668	—
Total	$ 314,574	$ 136,250	$ 178,324	$ —

	December 31, 2021			
In thousands	**Total**	**Level 1**	**Level 2**	**Level 3**
Asset:				
Money Market Fund	$ 95,063	$ 95,063	$ —	$ —
U.S. Treasury Shares	23,219	23,219	—	—
Corporate Bonds	83,587	—	83,587	—
Commercial Paper	121,773	—	121,773	—
Repo Securities	8,000	—	8,000	—
Asset Backed Securities	8,816	—	8,816	—
Certificate of Deposit	21,553	—	21,553	—
Non-US Government	12,900	—	12,900	—
Total	$ 374,911	$ 118,282	$ 256,629	$ -

The carrying amount of the Company's cash and cash equivalents approximates fair value because of their short-term nature. The cash and cash equivalents consist of cash, deposits with banks and short-term highly liquid money market instruments with remaining maturities at the date of the purchase of 90 days or less.

The Company's held-to-maturity investments are stated at amortized cost, which approximates fair value. The Company does not intend to sell these investment securities and the contractual maturities are not greater than 24 months. Those with original maturities greater than 90 days and maturities less than 12 months are included in short-term investments on its condensed consolidated balance sheet. Those with remaining maturities in excess of 12 months are included in long-term investments on its condensed consolidated balance sheet.

Unrealized gains or losses on held-to-maturity securities are not recognized until maturity, except other-than-temporary unrealized losses which are recognized in earnings in the period incurred. The Company evaluates securities with unrealized losses to determine whether such losses are other than temporary. The unrealized gain or loss for the three months ended March 31, 2022 and 2021 was a loss of $0.9 million and a gain of $0.2 million, respectively. Interest on investments is reported in interest income.

The carrying amounts of accounts payable and accrued liabilities approximate fair value because of their short-term nature.

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.

Restructuring

On September 22, 2021, the Company announced a Go-to-Market strategy for VASCEPA, or the Plan, which aims to expand healthcare professional engagement through a new omnichannel platform, enhance managed care access and optimize VASCEPA prescriptions for cardiovascular risk reduction. As part of the process, the Company completed a reduction of its field force to approximately 300 sales representatives. The Company recognized approximately $13.7 million in charges related to the reduction in force, substantially all of which are cash expenditures for one-time termination benefits and associated costs. No expenses were recognized within Restructuring expense in the condensed consolidated statement of operations during the three ended March 31, 2022 and 2021.

The following table shows the change in restructuring liability, associated with the Plan, which is included within accrued expenses and other current liabilities:

In thousands	Restructuring Liability
Balance at December 31, 2021	$ 1,186
Payments	(948)
Balance at March 31, 2022	$ 238

Recent Accounting Pronouncements

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

The Company has evaluated all recently issued accounting pronouncements through the date of the financial statements and found that no recently issued accounting pronouncements, when adopted, will have a material impact on the Company's condensed 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 milestone payments to the former shareholders of Laxdale related to the 2004 acquisition of the rights to VASCEPA, which is the result of VASCEPA receiving marketing approval in the U.S. for the first indication in 2012, the expanded label in 2019 and marketing approval in Europe in 2021. Upon approval of the marketing authorization application for VAZKEPA in March 2021, a milestone for £7.5 million was achieved, which resulted in the Intangible asset increasing by $12.0 million. Refer to Note 5 – Commitments and Contingencies for further details. In accordance with ASC 350, the Company evaluates the remaining useful life of the intangible asset at each reporting period to determine if any events or circumstances warrant a revision to the

remaining period of amortization. As of March 31, 2022, the intangible asset has an estimated weighted-average remaining life of 9.0 years. The carrying value as of March 31, 2022 and December 31, 2021 is as follows:

In thousands	March 31, 2022	December 31, 2021
Technology rights	$ 32,081	$ 32,081
Accumulated amortization	(9,170)	(8,534)
Intangible asset, net	$ 22,911	$ 23,547

(4) Inventory

The Company capitalizes its purchases of saleable inventory of VASCEPA from suppliers that have been qualified by the U.S. FDA. Inventories as of March 31, 2022 and December 31, 2021 consist of the following:

In thousands	March 31, 2022	December 31, 2021
Raw materials	$ 123,318	$ 107,695
Work in process	56,217	41,965
Finished goods	229,335	206,270
Total inventory	$ 408,870	$ 355,930

As of March 31, 2022 and December 31, 2021, the Company had $141.1 million and $121.3 million of Long-term inventory, respectively, as consumption is expected beyond the Company's normal operating cycle.

(5) Commitments and Contingencies

Litigation – U.S. ANDAs

On March 30, 2020, the Nevada Court, ruled in favor of two generics companies, Hikma and Dr. Reddy's, in Amarin's patent litigation related to its ANDAs that sought U.S. FDA approval for sale of generic versions of VASCEPA for the original indication of VASCEPA as an adjunct to diet to reduce TG levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia. On September 3, 2020, the U.S. Court of Appeals for the Federal Circuit, or the Federal Circuit, upheld the March ruling by the Nevada Court in favor of the two generics companies. On October 2, 2020, the Company filed a combined petition for panel rehearing or rehearing en banc. On November 4, 2020, the Company's rehearing and en banc petitions were denied. On February 11, 2021, Amarin filed a petition for a writ of certiorari with the United States Supreme Court to ask the Court to hear the Company's appeal in this litigation, which was denied on June 18, 2021.

On May 22, 2020 and August 10, 2020, Hikma and Dr. Reddy's, respectively, received U.S. FDA approval to market its generic versions of VASCEPA. During the ANDA litigation, the Company reached agreements with Teva and Apotex, under which they received royalty-free license agreements to promote a generic version of icosapent ethyl in the U.S. under certain circumstances, one of which circumstances was achieved when the Federal Circuit upheld the ruling by the Nevada Court and Hikma launched its generic version of icosapent ethyl. On September 11, 2020, and June 30, 2021, Teva and Apotex, respectively, received U.S. FDA approval to market their respective generic versions of icosapent ethyl. In November 2020, Hikma priced and launched its generic version of icosapent ethyl. In June 2021, Dr. Reddy's announced the price of its generic version of icosapent ethyl and launched its generic version of icosapent ethyl. In January 2022, Apotex announced the price of its generic version of icosapent ethyl and launched its generic version of icosapent ethyl. The generic versions of icosapent ethyl as approved by the U.S. FDA for Hikma, Dr. Reddy's, and Apotex pertains to the MARINE indication of VASCEPA, lowering of TG levels in patients with very high TG (≥500 mg/dL). As of March 31, 2022, Teva had not announced pricing or launched a generic version of icosapent ethyl. Current generic competition, together with past and on-going litigation related to such generic versions of icosapent ethyl are applicable to the U.S. only. The Company did not seek, nor is VAZKEPA approved in Europe for lowering of TG levels in patients with very high TG (≥500 mg/dL).

The active pharmaceutical ingredient in VASCEPA is difficult and time consuming to manufacture, often requires considerable advanced planning and long-term financial commitment, including to manufacturing infrastructure such as dedicated facilities, to ensure sufficient capacity is available when needed. The Company has invested over a decade of resources and expenses to develop with individual members of its third-party, active pharmaceutical ingredient supply chain the technical knowhow, manufacturing processes and related regulatory approvals that have helped enable the Company's suppliers to supply the Company's need for clinical and commercial supply globally. Based on statements made by generic competitors, the active pharmaceutical ingredient of VASCEPA needed to manufacture their generic versions of VASCEPA is in limited supply to them. The Company believes all icosapent ethyl generic manufacturers are similarly situated. The Company believes the limited supply of generic icosapent ethyl may be due to such companies' lack of adequate planning, investment, knowhow and expertise regarding this fragile active ingredient.

In November 2020, the Company filed a patent infringement lawsuit against Hikma in the United States District Court in Delaware. The complaint alleges that Hikma induced the infringement of VASCEPA-related CV risk reduction U.S. Patent Nos. 9,700,537 (Composition for preventing the occurrence of cardiovascular event in multiple risk patient), 8,642,077 (Stable pharmaceutical composition and methods of using same), and 10,568,861 (Methods of reducing the risk of a cardiovascular event in a subject at risk for cardiovascular disease) by making, selling, offering to sell and importing generic icosapent ethyl capsules in or into the United States.

In January 2021, the Company expanded the scope of the VASCEPA CV risk reduction patent infringement lawsuit against Hikma to include a health care insurance provider in the United States, Health Net. Through insurance coverage and economic incentives the Company alleges that Health Net has actively induced pharmacies to dispense, and patients to use, Hikma generic icosapent ethyl capsules in infringement of the related patents. In the complaint, the Company is seeking remedies including a permanent injunction against the unlawful inducement by Hikma and Health Net of infringing uses of the Hikma generic product, i.e., uses to reduce cardiovascular risk as detailed in the patents, and monetary damages in an amount sufficient to compensate the Company for such infringement. On January 4, 2022, the district court hearing the case granted Hikma's motion to dismiss. The Company intends to appeal the decision of the district court when permitted and also intends to continue to vigorously pursue its ongoing litigation with Health Net, but cannot predict the outcome or the impact on its business. The Company will continue to consider its legal options against parties similarly situated to Health Net and Hikma and acting in concert with either by making or selling any drug product or component thereof covered by the subject patents, or inducing others to do the same. The Company intends to vigorously enforce its intellectual property rights relating to VASCEPA, but cannot predict the outcome of these lawsuits or any subsequently filed lawsuits.

As has been a practice in the generic pharmaceutical industry, on April 27, 2021, Dr. Reddy’s filed a complaint against the Company in the United States District Court for the District of New Jersey, Civil action No.21-cv-10309, alleging various antitrust violations stemming from alleged anticompetitive practices related to the supply of active pharmaceutical ingredient of VASCEPA. The complaint also includes a related state law tortious interference claim. Damages sought include recovery for alleged economic harm to Dr. Reddy’s, payors and consumers, treble damages and other costs and fees. Injunctive relief against the alleged violative activities is also being sought by Dr. Reddy’s. Amarin believes it has valid defenses and will vigorously defend against the claims.

In March 2021, Amarin received a civil investigative demand, or CID, from the U.S. Federal Trade Commission and a subpoena from the New York Attorney General with respect to information on the same antitrust topic covered in the Dr. Reddy's litigation. Similarly, in June 2020, the Company received a CID from the U.S. Department of Justice, or the DOJ, informing Amarin that the DOJ is investigating whether aspects of its promotional speaker programs and copayment waiver program during the period from January 1, 2015 to the present violated the U.S. Anti-Kickback Statute and the U.S. Civil False Claims Act, in relation to the sale and marketing of VASCEPA by the Company and its previous co-marketing partner, Kowa Pharmaceuticals America, Inc. The Company believes such contact from the governments may have been prompted by a generic competitor. The inquiries require the Company to produce documents and answer written questions, or interrogatories, relevant to specified time periods. Amarin is cooperating with the government agencies and cannot predict when these investigations will be resolved, the outcome of the investigations or their potential impact on the Company’s business.

As has been a practice of class action legal counsel following governmental investigations and litigation by generics companies, Amarin is also named as a defendant in five antitrust class action lawsuits in the District Court for the District of New Jersey. Amarin is a defendant in a class action lawsuit filed by Uniformed Fire Officers Association Family Protection Plan Local 854 and the Uniformed Fire Officers Association for Retired Fire Officers Family Protection Plan, on behalf of indirect purchasers, in the District Court for the District of New Jersey, Civil Action No. 21-12061, alleging Amarin and its co-defendant suppliers violated state and federal antitrust laws by monopolizing and engaging in a conspiracy to restrain trade in the icosapent ethyl drug and API markets. Amarin is a defendant in a class action lawsuit filed by The International Union of Operating Engineers Locals 137, 137A, 137B, 137C, 137R, on behalf of indirect purchasers, in the District Court for the District of New Jersey, Civil Action No. 21-12416, alleging Amarin violated state and federal antitrust laws by monopolizing and engaging in a conspiracy to restrain trade in the icosapent ethyl drug and API markets. Amarin is a defendant in a class action lawsuit filed by KPH Healthcare Services, Inc., on behalf of direct purchasers, in the District Court for the District of New Jersey, Civil Action No. 21-12747, alleging Amarin and its co-defendant suppliers violated state and federal antitrust laws by monopolizing and engaging in a conspiracy to restrain trade in the icosapent ethyl drug and API markets. Amarin is a defendant in a class action lawsuit filed by Local 464A United Food and Commercial Workers Union Welfare Service Benefit Fund, on behalf of direct purchasers, in the District Court for the District of New Jersey, Civil Action No. 21-13009. Amarin is a defendant in a class action lawsuit filed by Teamsters Health & Welfare Fund of Philadelphia and Vicinity, on behalf of indirect purchasers, in the District Court for the District of New Jersey, Civil Action No. 21-13406, alleging Amarin violated state and federal antitrust laws by monopolizing and engaging in a conspiracy to restrain trade in the icosapent ethyl drug and API markets.

Such antitrust litigation and investigations can be lengthy, costly and could materially affect and disrupt the Company’s business. The Company cannot predict when these matters will be resolved, their outcome or their potential impact on the Company’s business. If a government determines that Amarin has violated antitrust law, the Company could be subject to significant civil fines and penalties.

The Company intends to vigorously enforce its intellectual property rights relating to VASCEPA, but cannot predict the outcome of these lawsuits or any subsequently filed lawsuits.

Litigation – Other

On February 22, 2019, a purported investor in the Company's publicly traded securities filed a putative class action lawsuit against Amarin Corporation plc, the 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). On May 14, 2019 the court consolidated the cases under the caption In re Amarin Corporation PLC Securities Litigation, No. 3:19-cv-06601 and appointed two other purported shareholders, Dan Kotecki and the Gaetano Cecchini Living Trust, as Co-Lead Plaintiffs. Co-Lead Plaintiffs filed a consolidated amended complaint, or Amended Complaint, on July 22, 2019 that added as defendants the Company's former chief medical officer and the Company's former chief executive officer. The Amended Complaint alleged that from September 24, 2018 to November 9, 2018 the Company misled investors by releasing topline results for the REDUCE-IT study without disclosing data on biomarker increases in the placebo group as compared with baseline measurement. The Amended Complaint alleged that these data suggest that the mineral oil placebo used in the REDUCE-IT study may have interfered with statin absorption in the placebo group, which they alleged may have increased adverse outcomes in the placebo group. The Amended Complaint further alleged that these purported misrepresentations and omissions inflated the share price. Based on these allegations, the suit asserted claims under the Securities Exchange Act of 1934 and sought unspecified monetary damages and attorneys' fees and costs.

On March 29, 2021, the court granted the Company's motion to dismiss this litigation for failure to state a valid claim. The litigation was dismissed without prejudice, giving the plaintiffs the right to file an amended complaint. Plaintiffs in this action did not file an amended complaint within the permitted filing deadline. Plaintiffs filed a notice of appeal of the motion to dismiss ruling, which has been denominated *In re: Amarin Corp. PLC*, case number 21-2071 (3d Cir.). The Company intends to vigorously defend against any future complaint in this matter. The Company is unable to reasonably estimate the loss exposure, if any, associated with these claims. The Company has insurance coverage that is anticipated to cover any significant loss exposure that may arise from this action after payment by the Company of the associated deductible obligation.

On October 21, 2021, a purported investor in the Company's publicly traded securities filed a putative class action lawsuit against Amarin Corporation plc, the former chief executive officer and the chief financial officer in the U.S. District Court for the District of New Jersey, Vincent Dang v. Amarin Corporation plc, John F. Thero and Michael W. Kalb, No. 1:21-cv-19212 (D.N.J. Oct. 21, 2021) and a subsequent case, Dorfman v. Amarin Corporation plc, et al., No. 3:21-cv-19911 (D.N.J. filed Nov. 10, 2021), was filed in November 2021. In December 2021, several Amarin shareholders moved to consolidate the cases, or the Securities Litigation, and appoint a lead plaintiff and lead counsel pursuant to the Private Securities Litigation Reform Act. The complaints in these actions are nearly identical and allege that the Company misled investors by allegedly downplaying the risk associated with the ANDA litigation described above and the risk that certain of the Company's patents would be invalidated. Based on these allegations, plaintiff alleges that he purchased securities at an inflated share price and brings claims under the Securities and Exchange Act of 1934 seeking unspecified monetary damages and attorneys' fees and costs. The Company believes it has valid defenses and will vigorously defend against the claims but cannot predict the outcome. The Company is unable to reasonably estimate the loss exposure, if any, associated with these claims.

On April 7, 2022, a purported investor in the Company's publicly traded securities filed a derivative lawsuit naming the same officer defendants from the Securities Litigation, the Officer Defendants, and also the members of the Company's board of directors, and the Company as nominal defendant in the U.S. District Court for the District of New Jersey, Gary Schader v. Amarin Corporation plc, John F. Thero, Michael W. Kalb, Lars G. Ekman, Jan Van Heek, Karim Mikhail, Patrick J. O'Sullivan, Per Wold-Olsen, Kristine Peterson, David Stack, and Joseph S. Zakrzewski, No. 3:22-cv-02017 (D.N.J. Apr. 7, 2022). The complaint alleges, like the Securities Litigation, that the defendants allegedly downplayed the risk associated with the ANDA litigation and the risk that certain of the Company's patents would be invalidated. Based on the allegations, plaintiffs allege that the directors breached their fiduciary duties and that the Officer Defendants were unjustly enriched, and plaintiffs seek contribution from the Officer Defendants for any liability they incur in the Securities Litigation and for which they are indemnified by the Company. The Company cannot predict the outcome and is unable to reasonably estimate the loss exposure, if any, associated with these claims.

In addition to the above, 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.

Milestone and Supply Purchase Obligations

The Company entered into long-term supply agreements with multiple API suppliers and encapsulators. The Company is relying on these suppliers to meet current and potential future global demand for its lead product. 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 U.S. FDA. The Company has incurred certain costs associated with the qualification of product produced by these suppliers.

Pursuant to the supply agreements, there is a total of approximately $49.3 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.

On March 26, 2021, the EC approved the marketing authorization application for VAZKEPA. Under the 2004 share repurchase agreement with Laxdale, upon receipt of pricing approval in Europe for the first indication for VASCEPA (or first indication of any product containing 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. The Company recorded a liability of $12.0 million in Accrued expenses and other current liabilities on the condensed consolidated balance sheet as of March 31, 2022.

Also under the Laxdale agreement, upon receipt of a marketing approval in Europe for a further indication of VASCEPA (or further indication of any other product acquired from Laxdale in 2004), the Company must make an aggregate stock or cash payment (at the sole option of each of the sellers) of £5 million (approximately $6.6 million as of March 31, 2022) for the potential market approval.

The Company has no provision for any of these obligations, except as noted above, since the amounts are either not paid or payable as of March 31, 2022.

(6) Equity

Common Stock

There was no common stock activity during the three months ended March 31, 2022 and 2021 except as described in *Incentive Equity Awards* below.

Incentive Equity Awards

The following table summarizes the aggregate number of stock options and restricted stock units, or RSUs, outstanding under the Amarin Corporation plc 2020 Stock Incentive Plan, or the 2020 Plan, as of March 31, 2022:

	March 31, 2022
Outstanding stock options	19,639,003
% of outstanding shares on a fully diluted basis	5%
Outstanding RSUs	15,369,386
% of outstanding shares on a fully diluted basis	4%

The following table represents equity awards activity during the three months ended March 31, 2022 and 2021:

	For the Three Months Ended March 31,	
	2022	2021
Common shares issued for stock option exercises	10,602	783,320
Gross and net proceeds from stock option exercises	$ 30,000	$ 2,059,000
Common shares issued in settlement of vested RSUs	493,381	940,977
Shares retained for settlement of employee tax obligations ─ RSUs	161,083	365,463
Common shares issued in settlement of vested Performance-Based RSUs [1]	—	1,506,428
Shares retained for settlement of employee tax obligations ─ Performance-Based RSUs	—	638,502

(1) Performance-based RSUs vested in connection with the achievement of certain regulatory and sales performance conditions associated with the REDUCE-IT clinical trial and subsequent revenue growth. These performance-based RSUs have fully vested as of August 2021.

On February 4, 2022, the Company granted a total of 5,987,500 RSUs and 1,976,600 stock options to employees under the 2020 Plan. The RSUs vest annually over a three-year period and the stock options vest quarterly over a four-year period with a one-year cliff vesting. Also on February 4, 2022, the Company granted a total of 1,089,500 RSUs to certain employees under the 2020 Plan that vest upon the achievement of specified sales and operational performance conditions.

On January 10, 2022, the Company granted a total of 81,082 RSUs and 103,569 stock options to a newly appointed member of the Company's Board of Directors under the 2020 Plan and in accordance with the Company's non-employee Director compensation policy. The RSUs vest in equal installments over a three-year period upon the anniversary of the grant date, and are subject to deferred settlement upon the Director's separation of service with the Company. The stock options vest in full upon the one-year anniversary of the grant date. Upon termination of service to the Company or upon a change of control as defined in the 2020 Plan, the 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 June 14, 2021, the Company granted a total of 218,000 RSUs and 278,271 stock options to members of the Company's Board of Directors under the 2020 Plan and in accordance with the Company's non-employee Director compensation policy. 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, and are subject to deferred settlement upon the Director's separation of service with the Company. 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 as defined in the 2020 Plan, 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 January 4, 2021, the Company granted a total of 3,265,700 RSUs and 3,100,200 stock options to employees under the 2020 Plan. The RSUs vest annually over a three-year period and the stock options vest quarterly over a four-year period with a one-year cliff vesting. Also on January 4, 2021, the Company granted a total of 1,345,800 RSUs to certain employees under the 2020 Plan that vest upon the achievement of specified sales and operational performance conditions.

(7) Co-Promotion Agreement

On March 31, 2014, the Company entered into a Co-Promotion Agreement, or the Agreement, with Kowa Pharmaceuticals America, Inc. related to the commercialization of VASCEPA capsules in the United States. The Company and Kowa Pharmaceuticals America, Inc. intentionally designed the Agreement 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 co-promotion of VASCEPA by Kowa Pharmaceuticals America, Inc., the Company incurred expense for co-promotion tail payments which are calculated as a percentage of the 2018 co-promotion fee, which was eighteen and a half percent (18.5%) of VASCEPA gross margin in 2018. The accrued tail payments are paid over three years with declining amounts each year. Kowa Pharmaceuticals America, Inc. was eligible to receive $17.8 million in co-promotion tail payments, the present value of which $16.6 million, was fully accrued as of December 31, 2018.

During the first quarter of 2022, the final co-promotion tail payment was made to Kowa Pharmaceuticals America, Inc. As of December 31, 2021, a net payable to Kowa Pharmaceuticals America, Inc. of $0.6 million was classified as current on the condensed consolidated balance sheet, representing the remaining accrued co-promotion tail payments.

(8) 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 and Europe, or collectively, its distributors or its customers, most of whom 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 the 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 or list price 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 in the U.S. and Germany generally include a 2-3% 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 12 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, 2022 and 2021:

In thousands	Trade Allowances	Rebates, Chargebacks and Discounts	Product Returns	Other Incentives	Total
Balance as of December 31, 2021	**$ 86,636**	**$ 184,726**	**$ 8,090**	**$ 1,241**	**$ 280,693**
Provision related to current period sales	22,697	148,203	549	8,325	179,774
Provision related to prior period sales	—	(301)	—	—	(301)
Credits/payments made for current period sales	(2,753)	(67,700)	—	(6,379)	(76,832)
Credits/payments made for prior period sales	(13,536)	(123,099)	(350)	(2,630)	(139,615)
Balance as of March 31, 2022	**$ 93,044**	**$ 141,829**	**$ 8,289**	**$ 557**	**$ 243,719**

In thousands	Trade Allowances	Rebates, Chargebacks and Discounts	Product Returns	Other Incentives	Total
Balance as of December 31, 2020	**$ 36,242**	**$ 141,201**	**$ 7,797**	**$ 5,587**	**$ 190,827**
Provision related to current period sales	29,134	148,241	828	13,122	191,325
Provision related to prior period sales	—	(854)	—	—	(854)
Credits/payments made for current period sales	(3,582)	(16,136)	—	(9,807)	(29,525)
Credits/payments made for prior period sales	(7,086)	(108,020)	(402)	(5,618)	(121,126)
Balance as of March 31, 2021	**$ 54,708**	**$ 164,432**	**$ 8,223**	**$ 3,284**	**$ 230,647**

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

Licensing Revenue

The Company enters into licensing agreements which are within the scope of Topic 606, 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 and royalty 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 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.

(9) 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., or 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, or 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. 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.

In January 2022 and 2021, the Company exercised certain rights under the agreement, resulting in payments of $1.0 million, respectively, to Mochida, which was recorded as Research and development expense in the condensed consolidated statement of operations.

Out-licenses

Eddingpharm (Asia) Macao Commercial Offshore Limited

In February 2015, the Company entered into a Development, Commercialization and Supply Agreement, or the DCS Agreement, with Eddingpharm (Asia) Macao Commercial Offshore Limited, or Edding, 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 Edding 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, Edding 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. Edding 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 Edding 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 formed a separate joint commercialization committee in advance of expected approval in the China Territory to oversee VASCEPA planning and pre-launch commercialization activities in the China Territory. Development costs are paid by Edding to the extent such costs are incurred in connection with the negotiated development plan or otherwise incurred by Edding. Edding is responsible for preparing and filing regulatory applications in all countries of the China Territory at Edding'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 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, Edding has the right to terminate the DCS Agreement for convenience with 12 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, Edding submitted its clinical trial application, or 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, Edding 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 November 2020, the Company announced statistically significant topline results from the Phase 3 clinical trial of VASCEPA conducted by Edding, which is being used to seek regulatory approval in Mainland China. The Company received approval of VASCEPA under the REDUCE-IT indication in Hong Kong in February 2022.

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, Edding, 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, and (3) ongoing development and regulatory assistance. 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 are 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 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, 2022 and 2021, the Company recognized $0.2 million and $0.3 million, respectively, as licensing revenue related to the up-front and milestone payments received in connection with the Edding agreement. From contract inception through March 31, 2022 and December 31, 2021, the Company recognized $7.3 million and $7.1 million, respectively, as licensing revenue under the DCS Agreement concurrent with the input measure of support hours provided by Amarin to Edding in achieving the combined development and regulatory performance obligation, which in the Company's judgment is the best measure of progress towards satisfying this performance obligation. The remaining transaction price of $9.6 million and $9.8 million is recorded in deferred revenue as of March 31, 2022 and December 31, 2021, respectively, on the condensed consolidated balance sheets and will be recognized as revenue over the remaining period of 12 years.

Biologix FZCo

In March 2016, the Company entered into an agreement with Biologix FZCo, or 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.

The Company received approval of VASCEPA under the MARINE and REDUCE-IT indications in the following countries:

Country	MARINE	REDUCE-IT	Launch Date
Lebanon	March 2018	August 2021	June 2018
United Arab Emirates	July 2018	October 2021	February 2019
Qatar	December 2019	April 2021	—
Bahrain	April 2021	—	—
Kuwait	December 2021	—	—
Saudi Arabia	March 2022	—	—

The Company recognized net product revenue of approximately nil for the three months ended March 31, 2022 and $0.5 million for the three months ended March 31, 2021 related to sales to Biologix.

HLS Therapeutics, Inc.

In September 2017, the Company entered into an agreement with HLS Therapeutics Inc., or 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. Following approval from Health Canada in December 2019, the Company received a non-refundable milestone payment of $2.5 million in February 2020. In addition, in January 2020 HLS obtained regulatory exclusivity from the Office of Patented Medicines and Liaison, or OPML, as a result the Company received a non-refundable $3.8 million milestone payment. In addition to the non-refundable, up-front and regulatory milestone payments just described, the Company is entitled to receive certain sales-based milestone payments of up to an additional $50.0 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, and (3) participate in various steering committees. 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, the $2.5 million milestone related to the achievement of the REDUCE-IT trial primary endpoint, the $2.5 million milestone related to obtaining approval from Health Canada and $3.8 million milestone related to obtaining regulatory exclusivity from the OPML. Any consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur 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, 2022 and 2021, the Company recognized $0.1 million and $0.3 million, respectively, as licensing revenue related to up-front and milestone payments received in connection with the HLS agreement. From the contract's inception through March 31, 2022 and December 31, 2021, the Company has recognized $7.6 million and $7.5 million, respectively, as licensing revenue is recognized under the agreement concurrent with the input measure of support hours provided by Amarin to HLS in achieving this performance obligation, which in the Company's judgment is the best measure of progress towards satisfying the combined development and regulatory performance obligation. The remaining transaction price of $6.1 million and $6.2 million is recorded in deferred revenue as of March 31, 2022 and December 31, 2021, respectively, on the condensed consolidated balance sheets and will be recognized as revenue over the remaining period of 8 years.

The following table presents changes in the balances of the Company's contract assets and liabilities during the three months ended March 31, 2022 and 2021:

In thousands	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
Three months ended March 31, 2022:				
Contract assets	$ —	$ —	$ —	$ —
Contract liabilities:				
Deferred revenue	$ 16,709	$ —	$ (372)	$ 16,337
Three months ended March 31, 2021:				
Contract assets	$ —	$ —	$ —	$ —
Contract liabilities:				
Deferred revenue	$ 18,632	$ —	$ (662)	$ 17,970

During the three months ended March 31, 2022 and 2021, 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,	
Revenue recognized in the period from:	2022	2021
Amounts included in contract liability at the beginning of the period	$ 372	$ 662

(10) 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 February 5, 2019, the Company entered into a lease agreement for new office space in Bridgewater, New Jersey, or the New Jersey Lease. The New Jersey Lease commenced on August 15, 2019, or the New Jersey Commencement Date, for an 11-year period, with two five-year renewal options. Subject to the terms of the New Jersey Lease, Amarin will have a one-time option to terminate the agreement effective on the first day of the 97th month after the New Jersey Commencement Date upon advance written notice and a termination payment specified in the New Jersey Lease. Under the New Jersey Lease, the Company paid monthly rent of approximately $0.1 million for the first year following the New Jersey Commencement Date, and such rent increases by a nominal percentage every year following the first anniversary of the New Jersey Commencement Date. In addition, Amarin receives certain abatements subject to the limitations in the New Jersey Lease.

On November 17, 2021, the Company entered into a lease agreement for new office space in Zug Switzerland, or the Zug Lease. The Zug Lease commenced on February 1, 2022, or the Zug Commencement Date, for a 5-year period, with one five-year renewal option. Under the Zug Lease, the Company will pay annual rent of approximately $0.2 million for the first year following the Zug Commencement Date, and such rent increases by a nominal percentage every year following the first anniversary of the Zug Commencement Date. In addition to the real estate leases, the Company leases various vehicles with terms ranging from month to month up to 36 months.

As of March 31, 2022 and December 31, 2021, the total operating lease liability is $11.3 million and $10.3 million, respectively, and the total operating lease right-of-use asset is $8.7 million and $7.7 million, respectively.

The lease expense for the three months ended March 31, 2022 and 2021 is approximately $0.6 million and $0.4 million, respectively.

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, 2022:

		Undiscounted lease payments ($000s)
Remainder of 2022	$	1,626
2023		2,182
2024		2,138
2025		2,095
2026		2,129
2027 and thereafter		7,213
Total undiscounted payments	$	17,383
Discount Adjustments	$	(6,048)
Current operating lease liability	$	937
Long-term operating lease liability	$	10,398

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

This Quarterly Report on Form 10-Q, or this Quarterly Report, contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. These forward-looking statements reflect our plans, estimates and beliefs. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "anticipates," "believes," "continue," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "would" and similar expressions intended to identify forward-looking statements. Forward-looking statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Because of these risks and uncertainties, the forward-looking events and circumstances discussed in this report may not transpire. We discuss many of these risks in Part I, Item 1A under the heading "Risk Factors" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, or our Annual Report, and under Part II, Item IA, "Risk Factors" of this Quarterly Report.

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.

The following discussion and analysis of our financial condition and results of operations should be read together with our unaudited condensed consolidated financial statements and notes thereto included elsewhere in this Quarterly Report, and the audited consolidated financial statements and accompanying notes, as well as Management's Discussion and Analysis of Financial Condition and Results of Operations contained in our Annual Report.

Overview

We are a pharmaceutical company focused on the commercialization and development of therapeutics to improve cardiovascular, or CV, health and reduce CV risk. Our lead product, VASCEPA® (icosapent ethyl) was first approved by the United States Food and Drug Administration, or U.S. FDA, for use as an adjunct to diet to reduce triglyceride, or TG, levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia, or the MARINE indication. We launched VASCEPA in the United States, or U.S., in January 2013. On December 13, 2019 the U.S. FDA approved an indication and label expansion for VASCEPA based on the landmark results of our cardiovascular outcomes trial, REDUCE-IT®, or Reduction of Cardiovascular Events with EPA – Intervention Trial. VASCEPA is the first and only drug approved by the U.S. FDA as an adjunct to maximally tolerated statin therapy for reducing persistent cardiovascular risk in select high risk-patients, or the REDUCE-IT indication. On March 26, 2021, the European Commission, or EC, granted approval of the marketing authorization application in the EU for VAZKEPA, hereinafter along with the U.S. brand name VASCEPA, collectively referred to as VASCEPA, which is the first and only EC approved therapy to reduce cardiovascular risk in high-risk statin-treated patients with elevated TG levels. On September 13, 2021, we launched VAZKEPA in Germany, representing our first European launch. On April 22, 2021, we announced that we received marketing authorization from the Medicines and Healthcare Products Regulatory Agency, or MHRA, for VAZKEPA in England, Wales and Scotland to reduce cardiovascular risk through MHRA's new 'reliance' route following the end of the Brexit transition period. On March 25, 2022, we received our first national reimbursement in a European country with official confirmation that the Swedish Dental and Pharmaceutical Benefits Agency, or TLV, approved VAZKEPA for national reimbursement in Sweden.

VASCEPA is currently available by prescription in the U.S., Germany, Canada, Lebanon and the United Arab Emirates. We are responsible for supplying VASCEPA to all markets in which the branded product is sold, either to and through our collaborations with third-party companies or by us. Subject to commercial launches in additional countries within Europe and Hong Kong and approval in China, we will be responsible for supplying products to those markets as well. We are not responsible for providing any generic company with drug product. Geographies outside the United States in which VASCEPA is sold and under regulatory review are not subject to the U.S. patent litigation and judgment described below. No similar litigation involving potential generic versions of VASCEPA is pending outside the United States.

United States

We commenced the commercial launch of VASCEPA in the United States in January 2013 based on the MARINE indication for VASCEPA. In October 2016, in addition to the original 1-gram capsule size, we introduced a smaller 0.5-gram capsule size. The U.S. FDA-approved dosing for VASCEPA continues to be 4 grams per day, and as expected, the majority of new and existing patients continue to be prescribed the 1-gram size VASCEPA capsule. VASCEPA is sold principally to a limited number of major wholesalers, as well as selected regional wholesalers and mail order pharmacy providers, or collectively, our distributors or our customers, most of whom in turn resell VASCEPA to retail pharmacies for subsequent resale to patients and healthcare providers. We employ various medical affairs and marketing personnel to support our commercialization of VASCEPA.

On March 30, 2020, following conclusion of a trial in late January 2020, the U.S. District Court for the District of Nevada, or the Nevada Court, issued a ruling in favor of two generic drug companies, Dr. Reddy's Laboratories, Inc., or Dr. Reddy's, and Hikma Pharmaceuticals USA Inc., or Hikma, and certain of their affiliates, or, collectively, the Defendants, that declared as invalid several of

our patents covering the MARINE indication for use to reduce severely high triglyceride levels. We sought appeals of the Nevada Court judgment up to the United States Supreme Court, but we were unsuccessful. Most recently, on June 18, 2021, we were notified that our petition for writ of certiorari to the United States Supreme Court was denied.

On May 22, 2020, Hikma received U.S. FDA approval to market its generic versions of VASCEPA for the MARINE indication of VASCEPA as an adjunct to diet to reduce TG levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia. In November 2020, Hikma launched their generic version of VASCEPA on a limited scale. On November 30, 2020, we filed a patent infringement lawsuit against Hikma for making, selling, offering to sell and importing generic icosapent ethyl capsules in and into the United States in a manner that we allege has induced the infringement of patents covering the use of VASCEPA to reduce specified cardiovascular risk. The earlier ANDA litigation did not pertain to our patents covering cardiovascular risk reduction. On January 25, 2021, we expanded the scope of the patent infringement lawsuit to include a health care insurance provider, Health Net, LLC. On January 4, 2022, the district court hearing the case granted Hikma's motion to dismiss. We intend to appeal the decision of the district court when permitted and also intend to continue to vigorously pursue our ongoing litigation with Health Net, LLC, but cannot predict the outcome or the impact on our business.

On August 10, 2020, Dr. Reddy's received U.S. FDA approval to market its generic version for the MARINE indication of VASCEPA. In June 2021, Dr. Reddy's launched its generic version of VASCEPA with labeling that is substantially similar to labeling of the Hikma generic product. On September 11, 2020, Teva Pharmaceuticals USA, Inc.'s, or Teva's, ANDA was approved by the U.S. FDA and on June 30, 2021, Apotex, Inc.'s, or Apotex's, ANDA was approved by the U.S. FDA. In January 2022, Apotex launched its generic version of VASCEPA with labeling that is substantially consistent with the labeling of the Hikma and Dr. Reddy's generic product, not the cardiovascular risk reduction indication.

We are responsible for supplying VASCEPA to all markets in which the branded product is sold, including Canada, Lebanon and the United Arab Emirates where the drug is promoted and sold via collaborations with third-party companies that compensate us for such supply, and in the United States and Germany where the drug is promoted and sold by us. Subject to commercial launches in additional countries within Europe and Hong Kong and approval in China, we will be responsible for supplying products to those markets as well. We are not responsible for providing any generic company with drug product. Geographies outside the United States in which VASCEPA is sold and under regulatory review are not subject to this U.S. patent litigation and judgment. No similar litigation involving potential generic versions of VASCEPA is pending outside the United States.

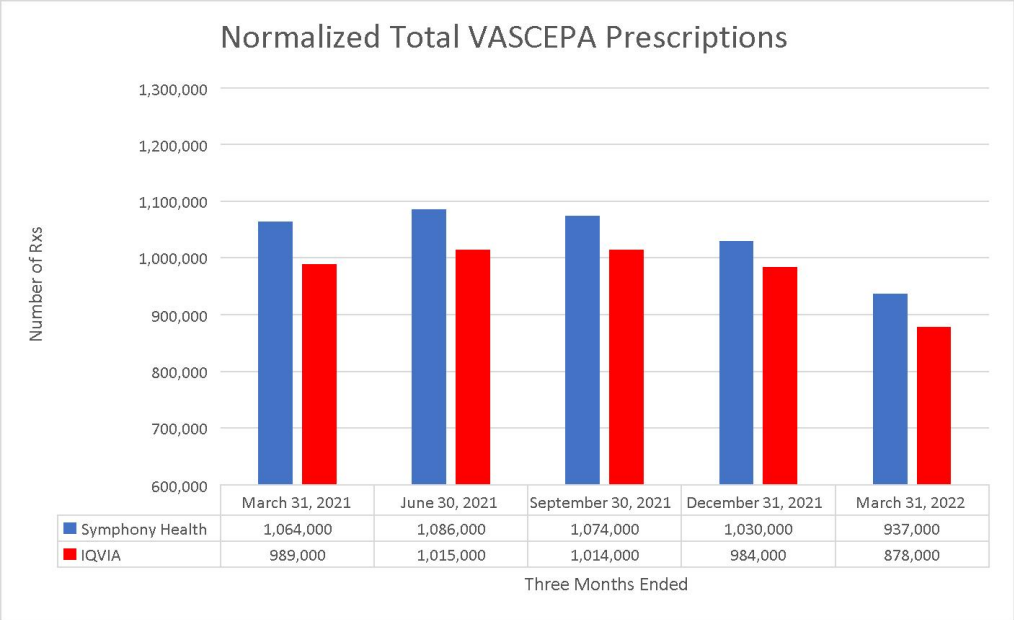
We have continued to monitor the effect of COVID-19 and its impact on patient visits to doctors. Our level and type of promotion has varied during the pandemic based on the determination of whether the cost was justified in light of COVID-19's impact at a given time. We anticipate that at-risk patients will increasingly resume visiting their doctors for non-urgent medical care after they are vaccinated for COVID-19, however, we cannot accurately predict when this resumption in visits to doctors will occur and, because many patients have multiple medical issues, we cannot predict the degree to which healthcare professionals will be proactive in seeking to reduce cardiovascular risk in at-risk patients when these patients resume visiting their doctors. The timing is likely to vary by geography. In September 2021, to accelerate growth of VASCEPA in the United States, we announced our Go-to-Market strategy which contains three key strategic priorities:

- *Expanding healthcare provider engagement:* Our omnichannel approach which is designed to enhance our reach to healthcare professionals, and aims to target a far greater number of the almost 700,000 statin prescribers through high frequency, and tailored messaging regarding the significant benefits of VASCEPA for CV risk reduction. We plan to optimize our U.S. field force and focus on the most productive territories. As a result, we reduced our U.S. field force to approximately 300 sales representatives who will remain a critical part of the commercial strategy going forward.
- *Enhancing managed care access:* We continue working with payers in an effort to enhance our managed care position and further remove barriers to VASCEPA prescriptions to ensure that patients in need of CV risk reduction receive proper therapy. Importantly, several large commercial and Medicare Part D payers currently cover VASCEPA as the exclusive icosapent ethyl product due to its lower net cost compared to generic icosapent ethyl.
- *Optimizing VASCEPA prescriptions for CV risk reduction:* Branded VASCEPA remains the only available U.S. FDA approved icosapent ethyl medication for CV risk reduction. To prevent improper generic substitution for this indication, we continue to aggressively educate critical stakeholders in the prescribing continuum to ensure proper fulfillment at each step. Additionally, we are evaluating various innovative solutions designed to better manage prescriptions for CV risk reduction.

As a result of our Go-to-Market strategy and our omnichannel approach, which we launched in the fourth quarter of 2021, we digitally approached a significant number of physicians across numerous digital channels. In addition, on November 1, 2021, we partnered with BlinkRx to provide patients an enhanced digital prescription fulfillment channel.

As COVID-19 protocols ease and ordinary course activities continue to resume, we will continue to adjust our promotional initiatives accordingly, including pursuit of increased face-to-face interactions with healthcare professionals and expanding various forms of physician and direct-to-patient promotion.

We obtain data from two third parties, Symphony Health and IQVIA, who collect and report estimates of weekly, monthly, quarterly and annual prescription information. There is a limited amount of information available to determine the actual number of total prescriptions for prescription products like VASCEPA during such periods. Each vendor's estimates utilize a proprietary projection methodology and are based on a combination of data received from pharmacies and other distributors, and historical data when actual data is unavailable. Based on data from Symphony Health and IQVIA, the below chart represents the estimated number of normalized total VASCEPA prescriptions.



	March 31, 2021	June 30, 2021	September 30, 2021	December 31, 2021	March 31, 2022
Symphony Health	1,064,000	1,086,000	1,074,000	1,030,000	937,000
IQVIA	989,000	1,015,000	1,014,000	984,000	878,000

Normalized total prescriptions represent the estimated total number of VASCEPA prescriptions dispensed to patients, calculated on a normalized basis (i.e., one month's supply, or total capsules dispensed multiplied by the number of grams per capsule divided by 120 grams). Inventory levels at wholesalers tend to fluctuate based on seasonal factors, prescription trends and other factors.

The resulting conclusions from Symphony Health and IQVIA are rarely identical and should be viewed with caution. The previous calculations of prescription levels by these vendors can change between periods and 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. Further, data for a single and limited period may not be representative of a trend or otherwise predictive of future results. We are not responsible for the accuracy of these companies' information and we do not receive prescription data directly from retail pharmacies.

Europe

In December 2019, we announced that the European Medicines Agency, or EMA, validated the marketing authorization application seeking approval for VAZKEPA. The validation confirmed the submission was sufficiently complete for the EMA to begin its review. In August 2020, we announced our plans to launch VAZKEPA in major markets in Europe through our own European sales and marketing team. Such an approach allows us to retain substantially all of the economic potential of VAZKEPA in Europe and helps ensure that VAZKEPA would get the highest level of priority and focus. On January 28, 2021, the Committee for Medicinal Products for Human Use, or CHMP, of the EMA adopted a positive opinion, recommending that a marketing authorization be granted to icosapent ethyl in the EU for the reduction of risk of cardiovascular events in patients at high cardiovascular risk, under the brand name VAZKEPA. On March 26, 2021, the EC granted approval of the marketing authorization application in the EU.

In Europe, launch of VAZKEPA in individual countries is gated by timing of achieving product reimbursement on a country-by-country basis as is typical for new drugs. In seeking market access, we have filed ten dossiers in European countries, including in all of the largest countries in Europe, and expect to file additional dossiers in Europe and select other parts of the world in the first half of 2022. In most European countries, securing product reimbursement is a requisite to launching. In certain countries, such as Denmark, individual patient reimbursement is allowed prior to national, general organization reimbursement. In all countries, securing adequate reimbursement is a requisite for commercial success of any therapeutic. The time required to secure reimbursement tends to vary from country to country and cannot be reliably predicted at this time. While we believe that we have strong arguments regarding the cost effectiveness of VAZKEPA, the success of such reimbursement negotiations could have a significant impact on the assessment of the

commercial opportunity of VAZKEPA in Europe. On March 25, 2022, we received our first national reimbursement in a European country with official confirmation that the TLV approved VAZKEPA for national reimbursement in Sweden.

On September 1, 2021, VAZKEPA was made available in Germany and was included in the country's electronic prescribing system as of October 1, 2021. The commercial launch in Germany was accompanied by a scientific conference in Berlin titled, “New therapeutic strategies for residual CV risk management,” which highlighted the scientific underpinnings and clinical benefits of VASCEPA/VAZKEPA in reducing cardiovascular risk. We are building a digitally native commercial model balancing optimally digital and face-to-face approach for more impact and cost efficiency, which will also be utilized as other countries throughout Europe are launched.

In order to launch impactfully in other countries throughout Europe, we are building a core team of experienced professionals and a highly capable commercial team involved with pre-launch planning and other commercial preparation activities and are leveraging third-party relationships for various support activities. In Europe, patients at high risk for cardiovascular disease tend, in contrast to the United States, to be treated more often by specialists, such as cardiologists rather than by physicians who are general practitioners. Privacy laws and other factors impact the availability of data to inform European commercial operations at an individual physician level. Generally, less data is available and at reduced frequencies as compared to the United States. However, this greater concentration of at-risk patients being treated by specialists in Europe should allow for more efficient promotion in Europe than in the United States. In Europe, VAZKEPA has the benefit of ten years of market protection, and we have been issued a patent that expires in 2033 with additional pending applications that could extend exclusivity into 2039.

Rest of World

China

In February 2015, we announced an exclusive agreement with Eddingpharm (Asia) Macao Commercial Offshore Limited, or Edding, 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. Edding, with our support, conducted a clinical trial of VASCEPA in China, which evaluated the effect of VASCEPA on patients with very high triglyceride levels (≥500 mg/dL). In November 2020, we announced statistically significant topline positive results from this Phase 3 clinical trial of VASCEPA conducted by Edding. The study, which investigated VASCEPA as a treatment for patients with very high triglycerides (≥500 mg/dL), met its primary efficacy endpoint as defined in the clinical trial protocol and demonstrated a safety profile similar to placebo. Importantly, the VASCEPA 4 grams per day dose in this study appeared to be well-tolerated with a safety profile similar to placebo. There were no treatment-related serious adverse events in this study. On February 9, 2021, we announced that the regulatory review processes in Mainland China and Hong Kong have commenced. The National Medical Products Administration, or NMPA, has accepted for review the new drug application for VASCEPA, submitted by Edding, based on the results from the Phase 3 clinical trial and the results from our prior studies of VASCEPA. We expect to receive a decision from the NMPA in Mainland China in the second half of 2022. On February 23, 2022 the Hong Kong Department of Health completed their evaluation and approved the use of VASCEPA under the REDUCE-IT indication.

Middle East and North Africa (MENA)

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. Biologix obtained approval of VASCEPA under the MARINE and REDUCE-IT indications, and subsequently launched commercially, in the following countries:

Country	MARINE	REDUCE-IT	Launch Date
Lebanon	March 2018	August 2021	June 2018
United Arab Emirates	July 2018	October 2021	February 2019
Qatar	December 2019	April 2021	—
Bahrain	April 2021	—	—
Kuwait	December 2021	—	—
Saudi Arabia	March 2022	—	—

Canada

In September 2017, we entered into an agreement with HLS Therapeutics Inc., or 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. In December 2019, HLS received formal confirmation from Health Canada that the Canadian regulatory authority granted approval for VASCEPA to reduce the risk of cardiovascular events (cardiovascular death, non-fatal myocardial infarction, non-fatal stroke, coronary revascularization or hospitalization for unstable angina) in statin-treated patients with elevated triglycerides, who are at high risk of cardiovascular events due to: established cardiovascular disease, or diabetes, and at least one other cardiovascular risk factor. In January 2020, HLS obtained a regulatory exclusivity designation and launched commercially in February 2020. In July 2020, the Canadian Agency for Drugs and Technologies in Health recommended that VASCEPA be reimbursed by participating public drug plans for statin-treated patients with established cardiovascular diseases and elevated triglycerides. In April 2022, HLS completed

negotiations with Canada's pan-Canadian Pharmaceutical Alliance for the terms and conditions under which VASCEPA would qualify for public market reimbursement in Canada. Following these negotiations, HLS has signed a Letter of Intent which allows HLS to work with all participating provincial jurisdictions to secure coverage from publicly funded drug plans across Canada, and for VASCEPA to potentially be added to their respective plans. HLS also received notification by the Patented Medical Prices Review Board that, further to its review, VASCEPA's price did not trigger the investigation criteria for excessive pricing. Coverage of patients with established cardiovascular disease represents a substantial portion of VASCEPA's approved label in Canada. VASCEPA has the benefit of data protection afforded through Health Canada until the end of 2027, in addition to separate patent protection with expiration dates that could extend into 2039.

Other

We plan to continue to assess other potential partnership opportunities for VASCEPA with partners outside of the United States and Europe with the intention of partnering in all other international markets. Our plan is to file three waves of regulatory submissions for approval of VASCEPA in 20 additional countries in order to ensure that patients in the top 50 cardiometabolic markets worldwide can benefit from VASCEPA. We have initiated the first wave of regulatory filings in 2022 and have obtained acceptances of VASCEPA for regulatory reviews in Australia, Israel and New Zealand.

Research and Development

Based on REDUCE-IT results, as of the date of the filing of this Quarterly Report, 27 clinical treatment guidelines, consensus statements or scientific statements from medical societies or journals have been updated recommending the use of icosapent ethyl in appropriate at-risk patients, including those statements which we were informed of by our global partners in Canada, China and the Middle East as well as guidelines which were newly received during the first quarter of 2022 through the filing date of this Quarterly Report as listed below:

- A panel of regional experts in plasma lipid disorders met to update the 2016 *Consensus Clinical Recommendations for the Management of Plasma Lipid Disorders in the Middle East*, using the latest evidence and recommendations from international guidelines. The published update:
  - Refers to the REDUCE-IT results and the cardiovascular disease, or CVD risk–lowering effects of IPE and noted that CVD reduction may be related to action of eicosapentaenoic acid, or EPA, independent of TG lowering
  - States that elevated TG levels are associated with increased atherosclerotic cardiovascular disease, or ASCVD, risk and patients with elevated TG levels (≥150 mg/dL) should be considered for more aggressive low-density lipoprotein cholesterol, or LDL-C, lowering as well as lowering of TGs
  - Recommends that if TG, non-high-density lipoprotein, or non-HDL-C, or ApoB goals are not met with statins and lifestyle modifications, further options include ezetimibe, PCSK9 inhibitors, or IPE

During 2022, we added to our growing body of knowledge on VASCEPA as a result of our continued analysis of the REDUCE-IT trial results. A new post hoc sub-analysis of REDUCE-IT, published in the Journal of the American Heart Association, or JAHA, found VASCEPA reduced the risk of cardiovascular death, strokes, heart attacks, coronary revascularization and unstable angina by 34% in patients with a history of percutaneous coronary intervention, or PCI, noting 8.5% and 5.4% absolute risk reductions, respectively, for the primary and secondary composite endpoints. In addition, in vitro research results showed that EPA in combination with widely prescribed statins, contributed to a reduction in lipid oxidation in membranes in a manner that may be enhanced with the use of these statins. The combinations of EPA and atorvastatin active metabolite and of EPA and rosuvastatin reduced lipid oxidation by 86% and 75%, respectively.

On January 10, 2022, we announced that we have initiated development of a fixed dose combination product that has both icosapent ethyl and a statin.

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 the U.S. 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 U.S. FDA-approved international API suppliers, encapsulators and packagers to support the VASCEPA commercial franchise. We also have multiple international API suppliers, encapsulators and packagers to support the commercialization of VASCEPA in geographies where the drug is approved outside the United States. Not all of our suppliers approved by the U.S. FDA are approved in every other geography. The regulatory process generally requires extensive details as part of the submission provided to a country or region in connection with a company's request for regulatory approval. Suppliers must be specifically identified as part of the submission for qualification and approval for commercialization in a country or region. As a result, only supply, as approved, may be used in finished goods available for sale in a

specific country or region. 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.

Impact of COVID-19

As of March 31, 2022, according to CDC data, approximately 65% of the U.S. population has been fully vaccinated, of which 45% have received one booster shot, and approximately 77% of the U.S. population has received at least one dose of a vaccine. In addition, cases have declined throughout the first quarter of 2022, coming off of a surge in cases at the end of 2021 driven by the Omicron variant.

Our ability to directly promote VASCEPA to healthcare professionals has been limited due to appropriate social distancing practices associated with COVID-19 and by patients electing to forego visiting their doctors for non-urgent medical examinations and/or choosing to not get blood tests, the results of which blood tests provide useful information to the treatment of cardiovascular risk. These limitations have had a significant impact on slowing VASCEPA prescription and revenue growth. While COVID-19 continues to impact promotion of VASCEPA and access remains variable, we have seen signs of improvement in access to face-to-face interactions with healthcare providers.

In the United States, at-risk patients increasingly resumed visiting their doctors for non-urgent medical care after they are vaccinated for COVID-19 and we anticipate that to continue. We continued to adjust our promotional initiatives, including pursuing increased face-to-face interactions with health care professionals and expanding various forms of direct-to-patient promotion based on COVID-19 protocols that are in place.

In Europe, the rapid spread of the Omicron variant throughout Europe has led to a significant increase in COVID-19 related patients for healthcare professionals and hospitals. This has limited our access to and ability to directly promote VAZKEPA to healthcare professionals. We continue to explore other avenues, including digital, to reach and engage healthcare professionals despite the current restrictions and challenges.

Thus far, while COVID-19 has created some added logistical challenges regarding supply deliveries, these challenges have been manageable and COVID-19 has not materially impacted our ability to secure and deliver supply of VASCEPA. And, thus far, COVID-19 is not known to have significantly impacted ongoing clinical trials of VASCEPA.

The extent to which COVID-19 impacts our business, results of operations and financial condition will depend on future developments, which, despite progress in vaccination efforts, are highly uncertain and cannot be predicted with confidence, including the duration of the pandemic, new information that may emerge concerning the severity of COVID-19, such as new strains of the virus that may emerge, which may impact rates of infection and vaccination efforts, developments or perceptions regarding the safety of vaccines and the extent and effectiveness of actions to contain COVID-19 or treat its impact, including vaccination campaigns and lockdown measures, among others. We are actively monitoring the situation and evaluating the pandemic's effect on patients, distributors, customers and our employees, as well as on our operations and the operations of our business partners and communities. We may take precautionary and preemptive or reactive actions that we determine are in the best interests of our business. We cannot predict the effects that such actions may have on our business or on our financial results, in particular with respect to demand for or access to VASCEPA.

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. In the United States, we sell product to a limited number of major wholesalers, as well as selected regional wholesalers and mail order pharmacy providers, or collectively, our distributors or our customers, most of whom resell the product to retail pharmacies for purposes of their reselling the product to fill patient prescriptions. Revenues from product sales are recognized when the customer obtains control of our product, which occurs at a point in time, typically upon delivery to the customer. Timing of shipments to wholesalers, as used for revenue recognition, and timing of prescriptions as estimated by third-party sources such as Symphony Health and IQVIA may differ from period to period. During the quarters ended March 31, 2022 and 2021, our Product revenue, net, included adjustment for co-pay mitigation rebates provided by us to commercially insured patients. Such support is intended to offset a portion of the out-of-pocket expense that patients are required to pay for VASCEPA based upon the benefit design of their prescription drug coverage. Our cost for these co-payment support payments in both of the quarters ended March 31, 2022 and 2021 was up to $150 per 30-day prescription filled and up to $450 per 90-day prescription filled. Currently the majority of our product revenue is derived from direct sales of VASCEPA in the United States.

Outside of the United States, currently the majority of our product revenue is derived from the sales of VASCEPA to our commercial partners based on the net price for VASCEPA established in our contracts with such partners. These commercial partners then resell the product in their agreed commercial territory. Revenues from product sales to our international commercial partners are recognized when the commercial partners obtain control of our product, which occurs at a point in time, typically upon delivery to the commercial partner. The net price of VASCEPA sold by us to our customers where we directly sell VASCEPA is generally significantly higher than the net price of VASCEPA that we sell to commercial partners who then incur the cost of promoting and reselling the product in their territories. As a result, even when the net price of VASCEPA to patients is similar in various parts of the world, our gross margin on sales is higher where we sell VASCEPA directly. We also derive product revenue from sales of our product to a limited number of wholesalers in Europe, most of whom in turn resell the product to pharmacies for purposes of their reselling the product to fill patient prescriptions.

Licensing and royalty revenue. Licensing and royalty revenue currently consists of revenue attributable to receipt of up-front, non-refundable payments, milestone payments and sales-based 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. Our cost of goods sold is not materially impacted by whether we sell VASCEPA directly in a country or we sell VASCEPA to a commercial partner for resale in a country.

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. 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., or Mochida. We expense research and development costs as incurred.

Interest income, net and other (expense), net. Interest income, net consists primarily of interest earned on our cash and cash equivalents, as well as our short-term and long-term investments. Other (expense), net, consists primarily of foreign exchange losses and gains.

Income tax provision. Income tax provision, 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 guidance prescribed under ASC 740 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 for the first quarters of 2022 and 2021 are not more likely than not to be realized.

Critical Accounting Policies and Significant Judgments and Estimates

This management's discussion and analysis of our financial condition and results of operations is based on our unaudited condensed consolidated financial statements and notes, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of these condensed consolidated financial statements in conformity with GAAP requires us to make estimates, judgments and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses. On an ongoing basis, we evaluate our estimates and judgments. 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. There have been no material changes to our critical accounting policies, significant judgments and estimates described in our Annual Report.

Recent Accounting Pronouncements

For a discussion of recent accounting pronouncements, see Note 2—Significant Accounting Policies to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report.

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, 2022 and March 31, 2021

Total revenue, net. We recorded total revenue, net, of $94.6 million and $142.2 million during the three months ended March 31, 2022 and 2021, respectively, a decrease of $47.5 million, or 33%. Total revenue, net, consists primarily of revenue from the sale of VASCEPA in the United States. In addition to the United States, we also sell VASCEPA by prescription in Germany and VASCEPA is available by prescription in Canada, Lebanon and the United Arab Emirates through collaborations with third-party companies. As further discussed below, this decrease consists of a $47.4 million decrease in U.S. net product revenue and a $0.1 million decrease in licensing and royalty revenue.

Product revenue, net. We recorded product revenue, net, of $94.0 million and $141.4 million during the three months ended March 31, 2022 and 2021, respectively, a decrease of $47.4 million, or 34%.

This decrease was driven primarily by a 34% decrease in VASCEPA sales in the United States. Approximately half of this decrease was driven by a decline in volume due to the impact of generics. The balance of the decrease was a result of selling initiatives focused on certain customers to maximize prescription fulfillment. During the three months ended March 31, 2022 there were three generics in the market, including the launch of a third generic in January 2022. During the three months ended March 31, 2021 there was only one generic in the market. The increase in generic competition, including the impact of the initial launch of the third generic, adversely impacted the volume and net pricing of branded sales in the three months ended March 31, 2022. In addition, compared with other quarters of the year, beginning of the year deductibles under patient insurance plans, which are not unique to VASCEPA, tend to cause some patients to not fill prescriptions particularly for asymptomatic medical conditions.

The overall icosapent ethyl market in the United States, based on prescription levels reported by Symphony Health increased for the three months ended March 31, 2022 by 11% as compared to the three months ended March 31, 2021 despite a COVID-19 resurgence. Our share of the icosapent ethyl market has decreased to approximately 72% in the three months ended March 31, 2022 compared to approximately 91% in the three months ended March 31, 2021. Additionally, based on prescription levels reported by Symphony Health, VASCEPA branded prescriptions decreased by 12% in the three months ended March 31, 2022 compared to the three months ended March 31, 2021. Further, while still remaining within normal industry ranges, the wholesalers decreased their branded VASCEPA inventory levels as of March 31, 2022 by 40% in terms of bottles from the beginning of the quarter. By comparison, wholesaler inventory balances decreased by 10% during the first quarter of 2021. The inventory balances for the first quarter of 2022, as calculated based on days of sales on hand, were near the high-end of the range at the beginning of the quarter and reduced to the low-end of the range at the end of the first quarter of 2022 compared to a slight increase at the end of the first quarter of 2021 compared to the beginning of the first quarter of 2021.

Companies such as Symphony Health collect and report estimates of weekly, monthly, quarterly and annual 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. Each vendor's estimates utilize a proprietary projection methodology and 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. Further, data for a single and limited period may not be representative of a trend or otherwise predictive of future results. Data reported by Symphony Health and IQVIA are rarely identical. As such, the resulting conclusions from such sources should be viewed with caution. We are not responsible for the accuracy of these companies' information and we do not receive prescription data directly from retail pharmacies.

We will continue to monitor the generic prescription market in the U.S. and will vigorously protect our cardiovascular risk reduction patents, as deemed appropriate. In addition, based on available information, we believe that a significant number of icosapent ethyl prescriptions in the U.S. have gone unfilled in the three months ended March 31, 2022, due to general market disruption of order fulfillment processes. These processes at the pharmacy level have favored generic products in that in anticipation of receiving generic supply, in certain circumstances pharmacists have opted to wait to fill prescriptions with generic product by ordering product for later fulfillment. In the case of icosapent ethyl, in many U.S. markets generic product has been delayed or unavailable. In addition, we have heard multiple reports of patients finding that the generic product is more expensive than they have historically paid for the branded product resulting in their refusal to fill their prescriptions.

In Europe, our commercial launch and growth of the market has been slower than expected due to the resurgence of COVID throughout Europe and political unrest in eastern Europe resulting in product revenue, net, of $0.5 million during the three months ended March 31, 2022. We began commercialization in Europe in September 2021, and as such recorded product revenue, net of nil during the three months ended March 31, 2021.

VASCEPA is currently available by prescription in Canada, Lebanon and the United Arab Emirates through collaborations with third-party companies. For the three months ended March 31, 2022 we did not record any product revenue, net, to our collaboration partners compared to $0.5 million during the three months ended March 31, 2021.

Despite the generic competition in the U.S., including a third generic entrant in January 2022, we remain confident that the patient need for VASCEPA is high. We continue to believe that our promotion and medical education efforts drive growth in the market and provide greater financial results for the us compared to the financial results if we halted these activities, however, we continue to monitor and assess these efforts in a dynamic environment, including the impact of factors outside of our control. As a result of the continued uncertainty of the global impact of COVID-19, the impact of generic competition in the U.S. and challenges for most drugs seeking market access in Europe, we are not providing revenue guidance at this time. We will consider resuming revenue guidance when there is greater clarity on the impact of these items.

Licensing and royalty revenue. Licensing and royalty revenue during the three months ended March 31, 2022 and 2021 was $0.6 million and $0.8 million, respectively, a decrease of $0.1 million, or 18%. Licensing and royalty revenue relates to the recognition of amounts received in connection with the following VASCEPA licensing agreements:

- Edding – a $15.0 million up-front payment received in February 2015 and a $1.0 million milestone payment achieved in March 2016.
- HLS – a $5.0 million up-front payment which was received upon closing of the agreement in September 2017, a $2.5 million milestone payment that was received following achievement of the REDUCE-IT trial primary endpoint in September 2018, a $2.5 million milestone payment that was received following U.S. FDA approval of another indication and label expansion in December 2019, and a $3.8 million milestone payment that was received as a result of obtaining a regulatory exclusivity designation in January 2020.

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 and royalty 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.

As part of our licensing agreements covering certain territories outside of the United States, we are entitled to a percentage of revenue earned based on sales by our partners. The royalty payments are being recognized as earned based on revenue recognized by our current partners.

Cost of goods sold. Cost of goods sold during the three months ended March 31, 2022 and 2021 was $22.2 million and $28.3 million, respectively, a decrease of $6.1 million, or 21%. 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, 2022 and 2021 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 2022 to be similar to or modestly lower than 2021. The average cost may be variable from period to period depending upon the timing and quantity of API purchased from each supplier.

Our overall gross margin on product sales for the three months ended March 31, 2022 and 2021 was 76% and 80%, respectively. The decrease in gross margin is as a result of a decrease in net selling price.

Selling, general and administrative expense. Selling, general and administrative expense for the three months ended March 31, 2022 and 2021 was $90.6 million and $105.8 million, respectively, a decrease of $15.2 million, or 14%. Selling, general and administrative expenses for the three months ended March 31, 2022 and 2021 are summarized in the table below:

	Three months ended March 31,	
In thousands	**2022**	**2021**
Selling expense [(1)]	$ 62,252	$ 66,567
General and administrative expense [(2)]	23,766	27,160
Non-cash stock-based compensation expense [(3)]	4,629	12,071
Total selling, general and administrative expense	$ 90,647	$ 105,798

(1) Selling expense for the three months ended March 31, 2022 and 2021 was $62.3 million and $66.6 million, respectively, a decrease of $4.3 million, or 6%. This decrease is primarily due to a decrease in marketing and direct-to-consumer promotions, as a result of the impact of COVID-19 and our focus on improving the profitability of our operations in the United States. The decrease also includes a reduction in costs associated with our Go-to-Market strategy resulting in decreased promotional initiatives, reduced travel and a decrease in our U.S. sales force. The decrease in selling expense was offset by increased costs associated with commercialization related activities in European countries.

(2) General and administrative expense for the three months ended March 31, 2022 and 2021 was $23.8 million and $27.2 million, respectively, a decrease of $3.4 million, or 12%. This decrease is primarily due to a decrease in legal fees related to the ANDA patent litigation in the United States during the three months ended March 31, 2022.

(3) Non-cash stock-based compensation expense for the three months ended March 31, 2022 and 2021 was $4.6 million and $12.1 million, respectively, a decrease of $7.4 million, or 62%. Non-cash stock-based compensation expense represents the estimated costs associated with equity awards issued to internal personnel supporting our selling, general and administrative functions. The decrease is primarily due to the decrease in U.S. field force as well as a reversal of expense related to certain awards.

We are investing in building an appropriate foundation for the successful launch of VAZKEPA throughout Europe, advancing regulatory filings internationally and continuing our orchestrated omnichannel engagement for VASCEPA in the U.S. As a result, we will continue to evaluate all of our spending commitments and priorities as well as adjust our level of education and promotional activities based on various factors, including the impact of COVID-19 and U.S. generic competition.

Research and development expense. Research and development expense for the three months ended March 31, 2022 and 2021 was $10.1 million and $9.4 million, respectively, an increase of $0.7 million, or 7%. Research and development expenses for the three months ended March 31, 2022 and 2021 are summarized in the table below:

	Three months ended March 31,	
In thousands	**2022**	**2021**
REDUCE-IT study [(1)]	$ 730	$ 1,015
Regulatory filing fees and expenses [(2)]	739	341
Internal staffing, overhead and other [(3)]	7,133	6,167
Research and development expense, excluding non-cash expense	8,602	7,523
Non-cash stock-based compensation expense [(4)]	1,449	1,854
Total research and development expense	$ 10,051	$ 9,377

(1) In September 2018, we announced landmark positive topline results of the REDUCE-IT cardiovascular outcomes trial. The decrease in expenses is primarily driven by the completion of certain analyses performed beyond the REDUCE-IT cardiovascular outcomes trial.

(2) The regulatory filing fees in each of the quarters ended March 31, 2022 and 2021 included annual U.S. FDA fees for maintaining manufacturing sites. Such fees primarily represent fees for qualification of new suppliers, including increasing capacity capabilities, and fees to support international regulatory review of VASCEPA, particularly in Europe, 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, including costs associated with securing regulatory approvals for VAZKEPA in Europe as achieved in 2021. Also included are costs related to qualifying suppliers, costs related to development of a fixed dose combination product and costs associated with various other investigations, including other costs in collaboration with Mochida and pilot studies regarding VASCEPA.

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

We continuously evaluate all of our spending commitments and priorities and we plan to adjust our level of research and development activities based on the impact of COVID-19 and generic competition.

Interest income, net. Interest income, net, for the three months ended March 31, 2022 and 2021 was $0.2 million and $0.5 million, respectively, a decrease of $0.3 million, or 57%. Interest income represents income earned on cash and investment balances. The decrease is primarily due to a decrease in the Company's cash balance and short-term and long-term investments.

Other expense, net. Other expense, net, for the three months ended March 31, 2022 and 2021 was expense of $246 thousand and $142 thousand, respectively. Other expense, net, primarily consists of gains and losses on foreign exchange transactions.

Income tax provision. Income tax provision for the three months ended March 31, 2022 and 2021 was $3.2 million and $0.6 million, respectively. The provision for the three months ended March 31, 2022 is the result of income generated by our U.S. operations for which tax expense has been recognized based on a full year estimated U.S. income tax liability.

Liquidity and Capital Resources

Our aggregate sources of liquidity as of March 31, 2022 include cash and cash equivalents and restricted cash of $223.1 million, short-term investments of $143.4 million and long-term investments of $26.7 million, with no debt. Our cash and cash equivalents primarily include checking accounts and money market funds with original maturities less than 90 days. Our short-term investments consist of held-to-maturity securities that will be due in one year or less. Our long-term investments consist of held-to-maturity securities that will be due in more than one year. We invest cash in excess of our immediate requirements, in accordance with our investment policy, which limits the amounts we may invest in any one type of investment and requires all investments held by us to maintain minimum ratings from Nationally Recognized Statistical Rating Organizations so as to primarily achieve our goals of liquidity and capital preservation.

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	**2022**	**2021**
Cash (used in) provided by:		
Operating activities	$ (98.8)	$ (18.7)
Investing activities	99.0	127.9
Financing activities	(0.5)	(5.2)
Increase (decrease) in cash and cash equivalents and restricted cash	$ (0.3)	$ 104.0

Net cash used in operating activities during the three months ended March 31, 2022 as compared to the same period in 2021 is primarily as a result of an increase in inventory purchases during 2022 as well as costs associated with commercial operations in Germany and planning for commercial launch in additional countries in Europe.

Net cash provided by investing activities during the three months ended March 31, 2022 is primarily due to the proceeds from the maturity of $113.2 million in investment-grade interest bearing instruments, partially offset by $14.2 million in purchases of investment-grade interest bearing instruments as compared to the same period in 2021 where proceeds from the maturity and sale of securities was $127.9 million, with no purchases of additional securities.

Net cash used in financing activities decreased during the three months ended March 31, 2022 as compared to the same period in 2021 primarily as a result of costs associated with our stock compensation plan.

As of March 31, 2022, we had net accounts receivable of $110.2 million, current inventory of $267.8 million and long-term inventory of $141.1 million. We have incurred annual operating losses since our inception and, as a result, we had an accumulated deficit of $1.5 billion as of March 31, 2022. 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, the impact from COVID-19 on our operations, the generic competition in the United States as a result of our ANDA litigation and commercialization of VAZKEPA in Europe. For Europe, we launched VAZKEPA in Germany in September 2021 and we commenced pre-launch planning and other commercial preparation activities, and continue to grow our European staff by hiring Market access and Medical affairs teams, among others, across Europe as deemed appropriate on a country by country basis.

We believe that our cash and cash equivalents of $219.2 million as of March 31, 2022 together with our short-term investments of $143.4 million as of March 31, 2022, will be sufficient to fund our projected operations for at least 12 months from the issuance date of our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report and is adequate to support continued operations based on our current plans. We have based this estimate on assumptions that may prove to be wrong, including as a result of the risks discussed under "Risk Factors" in this Quarterly Report, and we could use our capital resources sooner than we expect or fail to achieve positive cash flow.

Contractual Obligations

Our contractual obligations consist mainly of payments related to purchase obligations with certain supply chain contracting parties and operating leases related to real estate used as office space. There have been no material changes during the three months ended March 31, 2022 to our contractual obligations as presented in Part II, Item 7 of our Annual Report.

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.

Item 4. ***Controls and Procedures***

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act, or the Exchange Act) that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under 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.

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 management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2022. Based on such evaluation, our principal executive officer and principal financial officer have concluded that as of March 31, 2022, 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, 2022, there were no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15(d)-15(f) 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 includes a discussion of our current legal proceedings. Refer to Note 5 – Commitments and Contingencies to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report for further details on our legal proceedings during the three months ended March 31, 2022.

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 and VAZKEPA, collectively referred to as 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.

These risk factors have not been materially updated from our Annual Report on 10-K for the year ended December 31, 2021 filed with the SEC on March 1, 2022, or our Annual Report.

Summary Risk Factors

Our business is subject to numerous risks and uncertainties that you should be aware of in evaluating our business. These risks include, but are not limited to, the following:

- We are substantially dependent upon VASCEPA® (icosapent ethyl), its commercialization in the United States and its development and commercialization in Europe and other major markets. In the United States, VASCEPA is facing increasing competition from generic versions of the drug. In Europe, VAZKEPA launched in Germany following approval from the central regulatory authority and we are in the process of obtaining relevant pricing approvals in various countries; however, we may not be successful in obtaining such approvals in a timely manner, or at all and, even if successfully obtained, we may not be successful in commercializing VAZKEPA in Europe or elsewhere.
- In the United States, we face increasing competition from generic drug companies in the near term and our revenues and results of operations could be materially and adversely affected.
- Factors outside of our control may make it more difficult for VASCEPA to achieve a level of market acceptance by physicians, patients, healthcare payors and others in the medical community at levels sufficient to meet our expectations for commercial success.
- The continued scale, scope and duration of business interruptions caused by the ongoing COVID-19 pandemic and related recovery efforts are uncertain as the impact of the pandemic continues to cause negative effects on our business.
- Our current and planned commercialization efforts, including our implemented Go-to-Market strategy, may not be successful in increasing sales of VASCEPA in the United States and developing sales internationally.
- Our promotion and supply of VASCEPA is subject to regulatory scrutiny and associated risk.
- We may not be able to compete effectively against our competitors' pharmaceutical products.
- 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.
- The commercial value of VASCEPA outside the United States may be smaller than we anticipate, including adequacy of product reimbursement which can vary from country to country. If we are unable to realize product reimbursement rates at reasonable levels, or at all, patient access to VASCEPA may be limited.
- Our supply of product for the commercial market and clinical trials is dependent upon relationships with third-party manufacturers and suppliers.
- Our dependence on third parties in the distribution channel from our manufacturers to patients subject us to risks that limit our profitability and could limit our ability to supply VASCEPA to large market segments.

- Our commercialization of VASCEPA outside the United States is substantially dependent on third parties and other circumstances outside our control.
- We are dependent on patents, proprietary rights and confidentiality to protect the commercial value and potential of VASCEPA.
- Our issued patents may not prevent competitors from competing with VASCEPA, even if we are successful in enforcing our patent rights.
- There can be no assurance that any of our pending patent applications relating to VASCEPA or its use will issue as patents.

The summary risk factors described above should be read together with the text of the full risk factors below and in the other information set forth in our Annual Report and this Quarterly Report on Form 10-Q, including our consolidated financial statements and the related notes, as well as in other documents that we file with the SEC. If any such risks and uncertainties actually occur, our business, prospects, financial condition and results of operations could be materially and adversely affected. The risks summarized above or described in full below are not the only risks that we face. Additional risks and uncertainties not currently known to us, or that we currently deem to be immaterial may also materially adversely affect our business, prospects, financial condition and results of operations.

Risks Related to the Commercialization and Development of VASCEPA

We are substantially dependent upon VASCEPA (icosapent ethyl), its commercialization in the United States and its development, launch and commercialization in Europe and other major markets. In the United States, VASCEPA is facing increasing competition from generic versions of the drug. In Europe, VAZKEPA launched in Germany following approval from the central regulatory authority and we are in the process of obtaining relevant pricing approvals in various countries; however, we may not be successful in obtaining such approvals in a timely manner or at all and even if successfully obtained, we may not be successful in commercializing VAZKEPA in Europe or elsewhere.

The success of our company depends on our ability to successfully commercialize our only product, VASCEPA (icosapent ethyl) capsules, in major markets globally. In recent years and currently, much of our financial results and revenue has been dependent on our ability to execute our development and commercial strategy for VASCEPA in the United States. Generic version of VASCEPA launched in the United States in November 2020, June 2021 and January 2022. We expect that VASCEPA could face more competition from generic companies in the United States in the near term in light of the patent litigation rulings against us, applicable only in this territory. Increasing sales of generic versions of VASCEPA could continue to have a material and adverse impact on our revenues and results of operations in the United States. We implemented a Go-to-Market strategy in an effort to optimize provider engagement and drive demand of VASCEPA in the United States by shifting reliance on sales force interactions with healthcare professionals to providing managed care and prescription access through an omnichannel platform, and, in connection with this initiative, we reduced our U.S. field force to approximately 300 sales representatives. Although we believe this initiative will provide greater access to VASCEPA and ultimately result in an improved expense structure, such efforts are costly to implement, could impact employee morale and make hiring and retaining talented personnel more challenging, and may not result in all or any of the benefits we anticipate.

We continue our development efforts to support commercialization of VASCEPA in major markets outside the United States. In March 2021 we announced that the European Commission, or the EC, approved the marketing authorization application for icosapent ethyl, under the brand name VAZKEPA, hereafter along with VASCEPA, collectively referred to as VASCEPA, to reduce the risk of cardiovascular events in high-risk, statin-treated adult patients who have elevated triglycerides (≥150 mg/dL) and either established cardiovascular disease or diabetes and at least one additional cardiovascular risk factor. In September 2021, we launched VAZKEPA in Germany, representing our first European launch, In March 2022, we received national reimbursement for VAZKEPA in Sweden, representing our first national reimbursement in a European country. We are in the process of obtaining further pricing and reimbursement approvals for VAZKEPA in relevant jurisdictions in Europe. This process is conducted on a country-by-country basis and is time-consuming and complex. On March 25, 2022, Amarin received its first national reimbursement in a European country with official confirmation that the Swedish Dental and Pharmaceutical Benefits Agency (TLV) approved VAZKEPA for national reimbursement in Sweden. We may not be successful in obtaining such approvals in a timely manner with acceptable terms, or in additional countries.

Our expansion and development of VASCEPA outside the United States is generally not subject to the adverse patent ruling in the United States. Development outside the United States is primarily based on the second indication approval for VASCEPA in the United States. That second indication, which we believe has significantly more value potential, is for use of the drug in the reduction of cardiovascular risk in select high-risk patients.

We have been developing VAZKEPA on our own in Europe for the approved cardiovascular risk reduction indication and are exploring possible strategic collaborations in smaller markets within Europe and in other major markets. We currently have multiple partners for the development and commercialization of VASCEPA in select geographies and intend to assess potential partners to

commercialize VASCEPA in other parts of the world. For example, we have strategic collaborations for the development and commercialization of VASCEPA in Canada, the Middle East and Greater China. However, we cannot make any guarantees as to the success of these efforts or that our beliefs about the value potential are accurate, and if commercialization plans for VASCEPA do not meet expectations in major markets such as the United States and Europe, our business and prospects could be materially and adversely affected.

The development and commercial time cycle for VASCEPA or other products that we may develop from our research and development efforts could result in delays in our ability to achieve commercial success. For example, it took over a decade of preceding product development before we received marketing approval for VAZKEPA in March 2021 from the EC.

Likewise, if we seek to diversify our development programs or product offerings through licensing or acquisitions, such transactions are also time-consuming, may be dilutive to existing shareholdings, and can be disruptive to operations. These transactions may not be available on favorable terms, or at all. These dynamics can restrict our ability to respond rapidly to adverse business conditions for VASCEPA. If development of, or demand for, VASCEPA does not meet expectations, 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.

In the United States, we face increasing competition from generic drug companies in the near term and our revenues and results of operations could be materially and adversely affected.

On March 30, 2020, following conclusion of a trial in late January 2020, the U.S. District Court for the District of Nevada, or the Nevada Court, issued a ruling in favor of two generic drug companies, Dr. Reddy's Laboratories, Inc., or Dr. Reddy's, and Hikma Pharmaceuticals USA Inc., or Hikma, and certain of their affiliates, or, collectively, the Defendants, that declared as invalid several patents of ours protecting the first U.S. FDA-approved use of our drug, for use to reduce severely high triglyceride levels, which is known as the MARINE indication. We sought appeals of the Nevada Court judgment up to the United States Supreme Court, but, we were unsuccessful.

In November 2020, Hikma launched its generic version of VASCEPA on a limited scale and with a label that reflects the MARINE indication, and revised labeling based on the results of the REDUCE-IT trial. On November 30, 2020, we filed a patent infringement lawsuit against a Hikma affiliate for making, selling, offering to sell and importing generic icosapent ethyl capsules in and into the United States in a manner that we allege has induced the infringement of patents covering the use of VASCEPA to reduce specified cardiovascular risk. On January 25, 2021 we expanded the scope of this patent infringement lawsuit to include a health care insurance provider, Health Net, LLC. On January 4, 2022, the district court hearing the case granted Hikma's motion to dismiss. We intend to appeal the decision of the district court when permitted and also intend to continue to vigorously pursue our ongoing litigation with Health Net, LLC, but cannot predict the outcome or the impact on our business.

In June 2021, Dr. Reddy's launched its generic version of VASCEPA with labeling that is substantially similar to labeling of the Hikma generic product. In addition to ANDAs approved for Hikma and Dr. Reddy's, on September 11, 2020, Teva Pharmaceuticals USA, Inc's., or Teva's, ANDA was approved by the U.S. Food and Drug Administration, or U.S. FDA. On June 30, 2021, Apotex Inc.'s, or Apotex's, ANDA was approved by the U.S. FDA. In January 2022, Apotex launched its generic version of VASCEPA with labeling that is substantially consistent with the labeling of the Hikma and Dr. Reddy's generic product, not the cardiovascular risk reduction indication.

The rulings of the Nevada Court and related appeal losses detailed above could permit each of Teva and Apotex to launch a generic version of VASCEPA under certain circumstances pursuant to their respective settlement agreement with us. For example, Teva and Apotex settlement agreements permit such companies to launch their generic version of VASCEPA under royalty-free licenses from us given that our petition for en banc Federal Circuit review was not granted, after issuance of the Federal Circuit mandate on November 12, 2020. Each generic launch is subject to procurement of adequate product supply.

Generally, once a generic version of a drug is available in the market, the generic version is typically used in many U.S. states to fill a prescription for any use of the drug, subject, to state reimbursement laws. Although, in our case, use of generic versions of VASCEPA, whether with primarily a MARINE indication label or REDUCE-IT indication label, could be further subject to the potential for patent infringement under certain case law and subject to certain Teva and Apotex settlement agreement terms, we currently face generic competition from Hikma's and Dr. Reddy's generic versions of VASCEPA in the United States, and could face increased competition from these or additional generic entrants in the near term, which could have a material and adverse impact on our revenues and our results of operations. There can be no assurance that we will be successful in preventing use of generic versions of VASCEPA in indications for which they have not been approved by U.S. FDA, even if such use is determined to infringe certain of our patent claims.

Although we continue to believe that VASCEPA is difficult to manufacture and that building capacity to manufacture VASCEPA would be time-consuming and expensive for generic companies, such as Hikma, Dr. Reddy and Apotex, we do not have direct visibility into the supply levels of any of the generic companies and we rely on our own experience together with information from third parties, which information may not be reliable. As such, generic companies could potentially find or develop sources of qualified

VASCEPA supply that are not known to us and that are more efficient or less expensive than our sources. Furthermore, generic companies could potentially convince our suppliers to prioritize supply to the generic companies ahead of any applicable contractual commitments to supply us. While we anticipate that our suppliers will honor their commitments to us, if generic competitors are successful in gaining an advantage in the supply chain, manufacturing and supply with respect to VASCEPA will suffer and consequentially VASCEPA prescriptions will likely decrease. In addition, we may need to litigate with such suppliers to protect our rights, which can be costly and distracting to management. Such circumstances could have a material and adverse impact on our revenues and results of operations directly in the United States and potentially outside of the United States as well if supply costs and availability are affected or promotion and education programs reduced.

We have limited experience as a company in commercializing VASCEPA outside of the United States and may be unsuccessful in developing sales internationally.

While we have been working internally and with partners to support efforts toward approvals and commercialization outside the United States in light of the REDUCE-IT results and the recent EC approval of VAZKEPA, we may be unsuccessful in expanding our global footprint. For example, we plan to launch VAZKEPA on our own in the most commercially significant markets in Europe and launched VAZKEPA in Germany, representing our first European launch. The commercial launch of a new pharmaceutical product is a complex and resource heavy undertaking for a company to manage, and we have no prior experience as a company operating a commercial-stage pharmaceutical business in Europe. Given the amount of time and resources, including capital, needed to support regulatory and commercial efforts aimed at international expansion, if we are unsuccessful or delayed in generating revenues overseas, our results of operations could be materially and adversely impacted.

Factors that could inhibit our efforts to successfully commercialize VASCEPA include:

- the impact of the expiration of regulatory exclusivities and entry into the market of additional generic versions of VASCEPA;
- our inability to attract and retain adequate numbers of effective sales and marketing personnel, particularly in light of our recent reduction in force;
- our inability to adequately train our sales and marketing personnel and our inability to adequately monitor compliance with applicable regulatory and other legal requirements;
- the inability of our new sales personnel, to obtain access to or persuade adequate numbers of physicians to prescribe VASCEPA;
- if our Go-to-Market strategy and omnichannel approach does not provide improved managed care and prescription access, or if healthcare providers are reluctant or delayed in shifting to the omnichannel platform;
- regulators may impose restrictions on VASCEPA's conditions for use, distribution or marketing, and may impose ongoing requirements for post-market surveillance, post-approval studies or clinical trials, which may be costly or result in label or other use restrictions;
- complexities and challenges in connection with pricing and reimbursement, including our ability to secure adequate reimbursement coverage, which in Europe is almost exclusively covered through public national funding, and not individual private insurance companies;
- if we have overestimated the addressable market or are unable to convince healthcare providers to prescribe, or if patients are unwilling to use, 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;
- unforeseen costs and expenses associated with operating a new independent sales and marketing organization; and
- the continued impact from COVID-19 on healthcare providers, patients and personnel which may vary considerably from jurisdiction to jurisdiction, as well as on local restrictions and practices, including the complexities of having to understand and navigate multiple sets of protocols and the accessibility and rates of vaccinations in various geographies.

If we experience one or more of the setbacks described above, we may not be able to pursue international regulatory and commercial efforts in a cost effective manner, or at all, which could cause our stock price to decline.

Our ability to generate meaningful revenues outside of the United States may be limited, including due to the strict price controls and reimbursement limitations imposed by payors outside of the United States.

Our ability to generate meaningful revenues of VASCEPA outside of the United States is dependent on the availability and extent of coverage and reimbursement from third-party payors. In many markets around the world, these payors, including government health systems, private health insurers and other organizations, remain focused on reducing the cost of healthcare, and their efforts have intensified as a result of rising healthcare costs and economic challenges. Drugs remain heavily scrutinized for cost containment. As a result, payors are becoming more restrictive regarding the use of biopharmaceutical products and scrutinizing the prices of these products while requiring a higher level of clinical evidence to support the benefits such products bring to patients and the broader healthcare system. These pressures are intensified where our products are subject to competition, including from biosimilars.

In many countries outside the United States, government-sponsored healthcare systems are the primary payors for drugs. With increasing budgetary constraints and differing views on or challenges in valuing medicines, governments and payors in many countries are applying a variety of measures to exert downward price pressure. These measures can include mandatory price controls, price referencing, therapeutic-reference pricing, increases in mandates, incentives for generic substitution and biosimilar usage and government-mandated price cuts. In this regard, many countries have health technology assessment organizations that use formal economic metrics such as cost-effectiveness to determine prices, coverage and reimbursement of new therapies; and these organizations are expanding in established and emerging markets. Many countries also limit coverage to populations narrower than the regulatory agency approved product label or impose volume caps to limit utilization. We expect that countries will continue to take aggressive actions to seek to reduce expenditures on drugs. Similarly, fiscal constraints may also affect the extent to which countries are willing to approve new and innovative therapies and/or allow access to new technologies.

The dynamics and developments discussed above serve to create pressure on the pricing and potential usage of our products and the industry. Given the diverse interests in play among payors, biopharmaceutical manufacturers, policy makers, healthcare providers and independent organizations, if and whether the parties involved can achieve alignment on the matters discussed above remains unclear and the outcome of any such alignment is difficult to predict. We are committed to working with the entire healthcare community to ensure continued innovation and to facilitate patient access to needed medicines; however, if reimbursement of VASCEPA is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our ability to successfully commercialize VASCEPA outside of the United States may be harmed, which could have a material and negative impact on our overall business.

Government and commercial payor actions outside the United States have affected and will continue to affect access to and sales of our products

Outside the United States, we expect countries will continue to take actions to reduce their drug expenditures. International reference pricing, or IRP, has been widely used by many countries outside the United States to control costs based on an external benchmark of a product's price in other countries. IRP policies can change quickly and frequently and may not reflect differences in the burden of disease, indications, market structures, or affordability differences across countries or regions. In addition, countries may refuse to reimburse or may restrict the reimbursed population for a product when their national health technology assessments do not consider a medicine to demonstrate sufficient clinical benefit beyond existing therapies or to meet certain cost effectiveness thresholds. Some countries also allow additional rebates or discounts to be negotiated. The outcome of such negotiations can be uncertain and could become publicly disclosed in the future. Some countries decide on reimbursement between potentially competing products through national or regional tenders that often result in one product receiving most or all of the sales in that country or region. Thus, there can be no certainty that we will negotiate satisfactory reimbursement or pricing rates in markets outside the United States in a timely manner, or at all, or even if we are successful in obtaining satisfactory coverage and reimbursement, we may be unsuccessful in sustaining such coverage and reimbursement, or could face challenges as to the timeliness or certainty of payment by payors to physicians and other providers, which would have a material and adverse impact on our commercialization efforts outside of the United States. Furthermore, despite having skilled and experienced individuals deployed in such efforts, we as an organization have limited experience in navigating the pricing and reimbursement regimes, outside of the United States, which foreign regimes are varied and complex, which might hinder our effectiveness in establishing satisfactory pricing, coverage and reimbursement levels in a timely manner or at all.

Factors outside of our control may make it more difficult for VASCEPA to achieve market acceptance by physicians, patients, healthcare payors and others in the medical community at levels sufficient to meet our expectations for commercial success.

In January 2013, we launched VASCEPA based on the U.S. 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 the risk for pancreatitis in patients with severe hypertriglyceridemia has not been determined and our U.S. FDA-approved labeling and promotional efforts state this fact.

In September 2018, we announced topline results from the REDUCE-IT®, or Reduction of Cardiovascular Events with EPA—Intervention Trial cardiovascular 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 MACE in the intent-to-treat patient population with use of VASCEPA 4 grams per 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 U.S. FDA-approved labeling.

In December 2019, the U.S. FDA approved another indication and label expansion for VASCEPA as an adjunct to statin therapy to reduce the risk of MACE events in adult patients with elevated TG levels (≥150 mg/dL) and established cardiovascular disease or diabetes mellitus and two or more additional risk factors for cardiovascular disease.

Despite U.S. FDA approval for this indication and expanded label for VASCEPA, we may not meet expectations for market acceptance by physicians, patients, healthcare payors and others in the medical community for this approved use, especially in light of our unsuccessful appeals efforts. If VASCEPA does not achieve an adequate level of acceptance, we may not generate product revenues sufficient to become profitable on an ongoing basis. The degree of market acceptance of VASCEPA for its approved indications and uses or otherwise will depend on a number of factors, including:

- the impact of and outcome of pending patent litigation;
- the commercialization and pricing of any current or potential generic versions of VASCEPA;
- the perceived efficacy and safety of VASCEPA by prescribing healthcare professionals and patients, as compared to no treatment and as compared to alternative treatments in various at-risk patient populations;
- peer review of different elements of REDUCE-IT results over time;
- continued review and analysis of the results of REDUCE-IT by regulatory authorities internationally;
- 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 and the success of our omnichannel platform;
- publicity concerning VASCEPA or competing products;
- our ability to continually promote VASCEPA in the United States consistent with and outside of U.S. FDA-approved labeling and the related perception thereof;
- sufficient third-party coverage or reimbursement for VASCEPA and its prescribed uses, on-label and off-label;
- natural disasters, including pandemics such as COVID-19 and political unrest that could inhibit our ability to promote VASCEPA regionally and that could 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 and perceived efficacy of the product and the prevalence and severity of any side effects and warnings in VASCEPA's approved labeling internationally.

For example, two major factors that affect market use of prescription drugs are their perceived cost-effectiveness and the breadth of their use among different patient populations, both on label and off-label. In October 2019, the Institute for Clinical and Economic Review, or ICER, released its final evidence report regarding clinical effectiveness and economic impacts on VASCEPA. The conclusion from the report is that VASCEPA easily met even the most stringent "commonly cited thresholds for cost-effectiveness and therefore represent(s) a high long-term value for money," based on the organization's value assessment framework. As part of the public meeting held by ICER analyzing REDUCE-IT data, the ICER review committee discussed whether, based on REDUCE-IT, VASCEPA should be considered for use in patients as an add-on to statin therapy generally, and not just in patients with persistent elevated triglyceride levels after statin therapy, which ICER defined as triglyceride levels of at least 135 mg/dL. Use as an add-on to statin therapy generally represents a larger patient population than studied in REDUCE-IT and larger than covered by U.S. FDA-approved labeling. By contrast, U.S. FDA-approved labeling for VASCEPA reflects limitations such as use in patients with persistent elevated triglyceride levels defined as triglyceride levels of at least 150 mg/dL after statin therapy and specific criteria designed to ensure the patient populations approved for use had sufficiently high degrees of CV risk. While the clinical judgment of prescribing physicians is the most important factor that determines the breadth of a drug's use in the United States and often results in prescriptions in patient populations that go beyond U.S. FDA labeling, U.S. FDA-approved labeling that is more closely tied to the patient population studied in a clinical trial could limit use generally and could make reimbursement more difficult.

The continued scale, scope and duration of business interruptions caused by the ongoing COVID-19 pandemic are uncertain as the impact of the pandemic continues to cause negative effects on our business.

The global spread of COVID-19, has created significant volatility, uncertainty and disruption in healthcare, social, supply and economic infrastructures. The extent to which the coronavirus pandemic will continue to impact our business, operations and financial results will depend on numerous evolving factors that we may not be able to accurately predict or plan around, including:

- the duration, volatility and scope of the pandemic and the efficacy of recovery efforts;
- governmental, business and individuals' actions that have been and continue to be taken in response to the pandemic;
- the impact of the pandemic on economic and political activity and actions taken in response;
- the effect on patients, healthcare providers and business partners, including patients' ability to access supplies of VASCEPA and the willingness of patients to visit doctors for non-urgent medical examination or to visit labs for blood tests to assess biomarkers such as lipid levels;
- our ability to commercialize VASCEPA, including as a result of ongoing travel restrictions, social distancing and other containment measures or the restoration of such measures;
- the enrolment or monitoring of patients in clinical trials, particularly at clinical trial sites located in highly impacted jurisdictions and jurisdictions where vaccination rates are low;
- the ability to access, secure and otherwise obtain and deliver sufficient and timely commercial or clinical supplies of VASCEPA at reasonable prices and sufficient to meet demand if the production capabilities of suppliers is disrupted;
- disruptions in regulatory oversight and actions if regulators and industry professionals continue to expend significant and unexpected resources addressing COVID-19;
- the availability of coverage and reimbursement from government and health administration authorities, private health insurers and other third-party payors if the system continues to be overly strained;
- the ability of regulators to complete inspections and reviews of operations and applications, respectively, in a timely manner; and
- any further, prolonged or reinstated closures of our and our partners' offices, operations and facilities impeding our ability to work together as a company and with our business and healthcare partners.

To comply with travel restrictions, social distancing, quarantines and other containment measures implemented in various geographies, in March 2020, we suspended field based face-to-face interactions. Although by the end of summer of 2020, substantially all of our field force personnel had the ability to resume face-to-face customer interactions, in a manner consistent with state and local guidance, limitations on such interactions have been imposed. As variants emerge and as vaccine protocols develop, face-to-face interactions are challenging for us to predict and the number of patient visits to doctors' offices and patients undergoing blood testing remains down considerably from pre-COVID-19 levels. In September 2021, to optimize provider engagement and drive demand for VASCEPA in the United States and to counteract the changing engagement dynamics, including those introduced as a result of COVID-19, we announced our Go-to-Market strategy which incorporates omnichannel communications with healthcare providers. The circumstances surrounding COVID-19 vary geographically and vary over time, with continued risk of resurgences in COVID-19 cases, and reinstitution of protocols, in various geographies and as the efficacy of the vaccine on various strains remains uncertain. While we have supplemented our face-to-face interactions with virtual outreach and our omnichannel platform, these efforts may not

be as impactful as traditional, in-person interactions. Specifically, access to healthcare professionals through the internet or other channels, may not be as productive as in-person interactions.

Although we have a geographically diversified supply chain for VASCEPA and believe we have sufficient inventory on hand at pharmacies throughout the United States and other markets where it is approved for sale, and at various stages of manufacturing with our suppliers, the global spread of the pandemic and containment measures has been unprecedented and could have a negative impact on the availability of VASCEPA at various points in our supply chain, including limiting the ability of new suppliers to be inspected, which would have a material and adverse effect on our business. Since the beginning of the COVID-19 pandemic, three vaccines for COVID-19 have received Emergency Use Authorization by the U.S. FDA and two of those later received marketing approval. Additional vaccines may be authorized or approved in the future. The ongoing demand for vaccines, including boosters, and potential for manufacturing facilities and materials to be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, may make it more difficult to obtain materials or manufacturing slots for the products needed for our commercial product, which could lead to issues with our commercial supply.

The disruptions associated with the coronavirus pandemic could also delay the timing of a determination on our ability to seek legal remedies as travel, operational resources and personnel are disrupted or slow to resume pre-pandemic levels, with respect to our efforts and capabilities, as well as those of our advisors and the courts. The disruptions associated with the coronavirus pandemic could delay the potential timing of subsequent steps for the launch of commercialization of VAZKEPA in Europe, including plans to hire additional employees in Europe. Additionally, COVID-19 has already and could continue to limit our ability to have access with healthcare professionals to help educate them regarding VAZKEPA so that they are more likely to prescribe it to their at-risk patients. And, similar to our experience in the United States, the effects of COVID-19 and social distancing considerations may reduce the frequency at which at-risk patients seek non-urgent preventative medical care.

As with any cardiovascular outcomes trial, over time further data assessment related to REDUCE-IT by international regulatory authorities or otherwise could yield additional useful information to inform greater understanding of study outcome. If the additional data or related interpretations do not meet expectations, the perception of REDUCE-IT results and VASCEPA revenue potential may suffer and our stock price may decline.

In December 2019, the U.S. FDA approved another indication and label expansion for VASCEPA as an adjunct to statin therapy to reduce the risk of MACE events in adult patients with elevated TG levels (≥150 mg/dL) and established cardiovascular disease or diabetes mellitus and two or more additional risk factors for cardiovascular disease. Even though U.S. FDA has approved VASCEPA for this expanded label and indication based on the REDUCE-IT results, additional data assessment by international regulatory authorities or otherwise could yield additional useful information to inform greater understanding of study outcome. Generally, trial data assessment sufficient to convey a complete picture of trial outcome can take years to complete and publish. When new data are assessed and released or presented it could exceed, match or may not meet investor expectations.

In addition, the same set of data can sometimes be interpreted to reach different conclusions, as when Health Canada approved an indication based on REDUCE-IT data that was different in certain respects than that approved by U.S. FDA and by the EC in Europe. It is possible the scope of subsequent regulatory approvals, if any, could likewise differ based on the same data. 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.

Regulatory authorities and medical guideline committees outside of the United States and Europe may consider the following additional factors, which could lead to evaluations of the totality of the efficacy and safety data from REDUCE-IT that differ from those of the U.S. FDA or the EC:

- the magnitude of the treatment benefit and related risks 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 (such as those related to adverse events, including bleeding and atrial fibrillation generally and in different sub-populations);
- 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, including aspects such as analyses regarding the placebo used in REDUCE-IT and other studies of VASCEPA and its impact, if any, on the reliability of clinical data.

If regulatory authorities and medical guideline committees outside of the United States and Europe draw conclusions that differ from those of the U.S. FDA or the EC, the U.S. FDA or the EC could reevaluate its conclusions as to the safety and efficacy of VASCEPA. Likewise, if additional data or analyses released from time to time do not meet expectations, the perception of REDUCE-IT results and the perceived and actual value of VASCEPA may suffer. In these instances our revenue and business could suffer and our stock price could significantly decline.

Ongoing clinical trials or new clinical data involving VASCEPA and similar moderate-to-high doses of eicosapentaenoic acid or icosapent ethyl 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, or a similar eicosapentaenoic acid product could provide further information on the effects of VASCEPA and its commercial and regulatory prospects.

For example, 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 per day of eicosapentaenoic acid), 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 arachidonic acid and incidence of events will also be examined. Results from this study are expected in the second half of 2022, though the study and results are not under the Company's control and may be delayed as a result of COVID-19 impacts.

In November 2020, we announced statistically significant topline results from a Phase 3 clinical trial of VASCEPA, conducted by our partner in China, Eddingpharm (Asia) Macao Commercial Offshore Limited, or Edding, which investigated VASCEPA as a treatment for patients with very high triglycerides (≥500 mg/dL). Even though such results are similar to the results of the MARINE study, additional clinical development efforts may be necessary in this market to demonstrate the effectiveness of VASCEPA in reducing major adverse cardiovascular events in Chinese patients with persistent cardiovascular risk.

We have also funded investigational studies on the use of VASCEPA in the setting of COVID-19 infection. On December 12, 2020, we announced at the National Lipid Association Scientific Sessions 2020 positive clinical results from the CardioLink-9 Trial, the first results of a study of VASCEPA in COVID-19 infected outpatients. Results from the investigator sponsored study in Argentina called PREPARE-IT-1 were presented by the lead trial investigator at the European Society of Cardiology on August 29, 2021 and the results did not meet the primary and/or other endpoints studied. Results from the investigator sponsored study in Argentina called PREPARE-IT-2 were presented by the lead trial investigator at the American Heart Association Scientific Sessions in November 2021 and the results did not meet the primary and/or other endpoints studied. Results from the other investigational study, called MITIGATE, is expected during 2022.

If the outcomes of one or more of these studies do not meet expectations, the perception of existing clinical results of VASCEPA, such as MARINE or REDUCE-IT, or the perceived clinical profile and commercial value of VASCEPA and its regulatory status may suffer. If this occurs our revenue and business could suffer and our stock price could significantly decline.

Our current and planned commercialization efforts, including our implemented Go-to-Market strategy, may not be successful in increasing sales of VASCEPA in the United States and developing sales internationally.

If we are not successful in maintaining a sales force that is rightsized for our efforts to market and sell VASCEPA in the United States, including in light of our Go-to-Market strategy, including our omnichannel approach and reduced sales force, our anticipated revenues or our expenses could be materially and negatively affected, and we may not obtain profitability, may need to cut back on research and development activities or implement other cost-containment measures, or we may need to raise additional funding that could result in substantial dilution or impose considerable restrictions on our business.

Given the dynamics related to COVID-19, we cannot predict when we will be able to substantially resume and sustain our business efforts, or how those efforts will be impacted in the long term. While we have supplemented traditional face-to-face interactions with virtual outreach, including our omnichannel platform, these efforts may not be as successful as in-person interactions. Specifically, access to healthcare professionals through digital or other channels, may not be as productive as in-person interactions in promoting use of VASCEPA. We continued to adjust our promotional initiatives, including pursuing increased face-to-face interactions with health care professionals and expanding various forms of direct-to-patient promotion based on COVID-19 protocols that are in place. Such efforts are costly and there can be no assurance that they will result in an increase in VASCEPA prescriptions and sales in the near future, or at all.

Our promotion and supply of VASCEPA is subject to regulatory scrutiny and associated risk.

The federal Food, Drug, and Cosmetic Act, or FDCA, has been interpreted by the U.S. FDA and the U.S. government to make it illegal for pharmaceutical companies to promote their U.S. FDA-approved products for uses that have not been approved by the U.S. 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 FCA. However, case law over the last several years has called into question the extent to which government in the United States, including the U.S. FDA, can, and is willing to seek to, prevent truthful and non-misleading speech related to off-label uses of U.S. FDA-approved products such as VASCEPA.

In May 2015, we and a group of independent physicians filed a lawsuit against the U.S. 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 at the time but was not approved by the U.S. FDA and was thus not covered by then U.S. FDA-approved labeling for the drug. Promotion of an off-label use has generally been considered by the U.S. 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 U.S. 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 U.S. 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 U.S. 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 U.S. FDA did not appeal the court's ruling. In March 2016, we settled this litigation under terms by which the U.S. 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 U.S. 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. In addition to claims classically considered to be on-label based on our expanded label for VASCEPA based on the REDUCE-IT results, we proactively communicate information related to VASCEPA in a manner that 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.

Promotional activities in the biotechnology and pharmaceutical industries generally are subject to considerable regulatory scrutiny and, even though we have the benefit of a final settlement in this litigation, our efforts may be subject to enhanced 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, which is subject to a considerable amount of judgment. We, the U.S. 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. 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.

In June 2020, we received a civil investigative demand, or CID, from the U.S. Department of Justice, or the DOJ, informing us that the DOJ is investigating whether aspects of our promotional speaker programs and copayment waiver program during the period from January 1, 2015 to the present violated the U.S. Anti-Kickback Statute and the U.S. Civil False Claims Act, or the FCA, in relation to the sale and marketing of VASCEPA by us and our previous co-marketing partner, Kowa Pharmaceuticals America, Inc., or Kowa America. Similarly, in March 2021, the United States Federal Trade Commission, or the FTC, issued a CID to us in connection with the FTC's investigation of whether we have engaged in, or are engaging in, anticompetitive practices or unfair methods of competition relating to VASCEPA. The New York State attorney general similarly issued a subpoena to us regarding the same subject matter on which the FTC CID is focused. The inquiries require us to produce documents and answer written questions, or interrogatories, relevant to specified time periods. We are cooperating with the government. We cannot predict when these investigations will be resolved, the outcome of the investigations or their potential impact on our business. Such investigations can be

lengthy, costly and could materially affect and disrupt our business. If the government determines that we have violated the U.S. Anti-Kickback Statute, the FCA or antitrust regulations, we could be subject to significant civil and criminal fines and penalties.

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 be subject to liability based on fair competition-based statutes, such as the Lanham Act. Any allegations that our promotional activities are not truthful or misleading, even allegations without merit, could cause reputational harm and 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. Further, results of trials for similar or competing products could have a negative impact on the perceived safety and efficacy of VASCEPA, which could have a materially adverse impact on sales of VASCEPA.

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 product. It is probable that the number of companies seeking to develop products and therapies similar to VASCEPA will increase. Many of these and other existing or potential competitors may 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, more efficient than 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 include large, well-established pharmaceutical and generic companies, specialty and generic pharmaceutical sales and marketing companies, and specialized cardiovascular treatment companies. With generic versions of VASCEPA launched in the U.S. by Hikma in November 2020, Dr. Reddy's in June 2021 and Apotex in January 2022, and with the potential for further generic versions being launched, it may not be viable for us to continue to invest in market education to grow the market and our ability to maintain current promotional efforts and attract favorable commercial terms in several aspects of our business will likely be adversely affected as we face increased generic competition, or if we launch our own generic version of VASCEPA.

Woodward Pharma Services LLC currently sells Lovaza®, which it acquired from GlaxoSmithKline plc in the third quarter of 2021. Lovaza® a prescription-only omega-3 fatty acid indicated for patients with severe hypertriglyceridemia, was approved by the U.S. 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 U.S. FDA-approved indicated uses, even though such products do not have U.S. FDA approval to reduce CV risk on top of statin therapy.

In addition, in April 2014, Omtryg (omega-3-acid ethyl esters A) capsules, a free fatty acid form of omega-3 (comprised of 50% EPA and 40% DHA), developed by Trygg Pharma AS, received U.S. FDA approval for severe hypertriglyceridemia. Omtryg has not been commercially launched, but could launch at any time.

AstraZeneca conducted a long-term outcomes study to assess Statin Residual Risk Reduction With EpaNova in HiGh Cardiovascular Risk PatienTs With Hypertriglyceridemia, or STRENGTH. The study was 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. On January 13, 2020 following the recommendation of an independent Data Monitoring Committee, AstraZeneca decided to close the STRENGTH trial due to its low likelihood of demonstrating benefit to patients with mixed dyslipidemia who are at increased risk of cardiovascular disease. Full data from the STRENGTH trial was presented at the AHA's Scientific Sessions in November 2020, confirming that Epanova failed to meet the primary endpoint of CV risk reduction, and published in Journal of the American Medical Association (JAMA) in December 2020. In addition, in March 2017, Kowa Research Institute (a subsidiary of the Japanese company Kowa Co., Ltd) initiated a Phase 3 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. In April 2022, Kowa Research Institute announced the decision to not continue the PROMINENT study as the primary endpoint was unlikely to be met.

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 of are not effective in lowering cardiovascular risk. Results of these failed outcomes studies, as described below and analysis, while not done with VASCEPA, may negatively affect sales of VASCEPA if omega-3 mixtures are broadly viewed as ineffective.

For example, results of one of these two studies, the VITamin D and OmegA-3 TriaL, or VITAL, as announced immediately before the presentation of REDUCE-IT results at the 2018 Scientific Sessions of the 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 mixture 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 the other outcome study, A Study of Cardiovascular Events iN Diabetes (ASCEND) trial were released and showed negligible results for omega-3 fatty acid mixtures 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 acid mixtures 1 gram daily versus placebo, reduce the risk of cardiovascular events in a nationwide United Kingdom, or UK, cohort of over 15,000 individuals with diabetes who do not have ASCVD.

In a meta-analysis, presented in 2018 by the Cochrane 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 showed a positive outcome benefit but had significant limitations in its application to a wider population. 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.

More recently, in 2020, an additional Nordic trial known as OMEMI failed to demonstrate a reduction in cardiovascular events with an omega-3 fatty acid mixture. OMEMI, an investigator-initiated, multi-center, randomized clinical trial, was designed to evaluate the effects of daily treatment with omega-3 fatty acids compared with placebo among elderly patients (age 70-82) with recent myocardial infarction. Patients received 1.8 g omega-3 fatty acids (930 mg EPA and 660 mg DH) or placebo (corn oil) daily added to standard of care. Results presented in November 2020 at the AHA's Scientific Sessions showed no significant differences in cardiovascular events between the treatment groups for the composite primary endpoint (non-fatal MI, unscheduled revascularization, stroke, hospitalization for heart failure or all-cause mortality), nor for the individual component of this endpoint after 2 years.

Matinas BioPharma, Inc., or Matinas, is developing an omega-3-based therapeutic (MAT9001 also known as LYPDISO) for the treatment of severe hypertriglyceridemia and mixed dyslipidemia. In the fourth quarter of 2014 Matinas filed an IND with the U.S. 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 short duration pharmacokinetic and pharmacodynamic study of LYPDISO versus VASCEPA in patients under conditions inconsistent with the U.S. 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 LYPDISO In March 2019, Matinas announced that net proceeds from a public offering of common stock would be used for development activities for LYPDISO In March 2020, Matinas announced that it completed the clinical dosing for a comparative clinical bridging bioavailability study and the in-life portion of a 90-day comparative toxicology study in the first quarter of 2020. Both studies were conducted to support a planned 505(b)(2) registration pathway. In March, Matinas also initiated an additional Phase 2 head-to-head pharmacokinetic and pharmacodynamic study, ENHANCE-IT, against VASCEPA in patients with elevated triglycerides (150-499 mg/dL), while the study was paused in the first quarter of 2020 due to the COVID-19 pandemic, enrollment resumed in June and was completed in August 2020. In the first quarter of 2021, Matinas announced topline results from the ENHANCE-IT study, stating that LYPDISO, or MAT9001, did not meet statistical significance over VASCEPA on the primary endpoint of percent change from baseline to end of treatment in triglycerides in the PD population. A key secondary endpoint in ENHANCE-IT was the measurement of eicosapentaenoic acid levels in the blood, which is regarded as a key surrogate marker in determining cardiovascular risk reduction. In ENHANCE-IT, plasma EPA concentrations were significantly higher with LYPDISO versus VASCEPA, with a 46% relative percentage increase in the change from baseline EPA level versus VASCEPA. Matinas has announced that the results from ENHANCE-IT suggest potential for LYPDISO as a drug for cardiovascular risk reduction and announced that it is pursuing external partnerships to further develop LYPDISO for cardiovascular outcomes indication. As a result, Matinas no longer plans to pursue an indication for the treatment of severe HTG, instead focusing on the broader cardiovascular risk reduction indication.

In June 2018, NeuroBo Pharmaceuticals, Inc. (previously named Gemphire Therapeutics) announced positive topline results from a Phase 2b trial, or 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 U.S. FDA requested that Gemphire conduct an additional long-term toxicity study before commencing any further clinical testing, thereby effectively placing Gemcabene on clinical hold. In March 2020 NeuroBo announced the completion of the requested studies, and in May 2020 the company announced that it received written communication from the U.S. FDA that the clinical development program for Gemcabene remains on partial clinical hold for severe HTG. In June 2019, Gemphire announced top-line clinical results from a Phase 2 trial in Familial Partial Lipodystrophy (FPL)/NASH in which Gemcabene safely met the primary endpoint in a sub-set of patients. Phase 3 studies for homozygous familial (hypercholesterolemia, or HoFH), heterozygous familial hypercholesterolemia, or HeFH, and non-familial hypercholesterolemia in ASCVD patients are planned. NeuroBO is currently assessing Gemcabene as an acute treatment for COVID-19.

Afimmune Ltd. has an oral, small molecule drug candidate, epeleuton (DS-102), in development for a number of conditions of the liver, lung, and metabolic system, including hypertriglyceridemia and cardiovascular risk reduction, Phase 2 clinical trials are currently ongoing for non-alcoholic fatty liver disease, or NAFLD, chronic obstructive pulmonary disease, or COPD, and planned for hypertriglyceridemia and Type 2 diabetes (TRIAGE), in the United States. In November 2019, Afimmune Ltd. announced positive results from an exploratory Phase 2 study of epeleuton in patients with NAFLD in which the molecule decreased triglycerides, improved glycemic control, and decreased markers of inflammation. In August 2020, Afimmune reported Ph2a study results of epeleuton in patients with NAFLD. Although epeleuton failed to meet the primary endpoint to demonstrate effects on liver enzyme elevation, it demonstrated significant reduction of triglycerides, HbA1c and potential for CV risk reduction. In September 2020, Afimmune announced the start of TRIglyceride And Glucose control with Epeleuton in Metabolic Syndrome Patients, or TRIAGE, a Phase IIb study of epeleuton in patients with high triglycerides and type 2 diabetes to assess the safety and efficacy of orally administered epeleuton capsules vs placebo in the treatment of hypertriglyceridemia and type 2 diabetes. Results are expected in the third quarter of 2022.

Based on prior communications from the U.S. FDA, including communications in connection with its review of the ANCHOR indication for VASCEPA, it is our understanding that the U.S. FDA is not prepared to approve any therapy for treatment of cardiovascular risk based on biomarker modification without cardiovascular outcomes study data, with the potential exception of therapies which lower LDL-cholesterol, depending on the circumstances. In particular, it is our understanding that the U.S. FDA is not prepared to approve any therapy based primarily on data demonstrating lowering of triglyceride levels. In our view, this position from the U.S. FDA did not change based on the REDUCE-IT study particularly in light of significant 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 U.S. FDA were to change this position, it could potentially have a negative impact on us 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.

VASCEPA also faces competition from dietary supplement manufacturers marketing omega-3 products as nutritional supplements. Such products are classified as food, not as prescription drugs or over-the-counter drugs, by the U.S. FDA in the United States. Most regulatory regimes outside the United States are similar in this regard. Some of the promoters of such products have greater resources than us and are not restricted to the same standards as are prescription drugs with respect to promotional claims or manufacturing quality, consistency and subsequent product stability. Although we have taken successful legal action against supplement manufacturers attempting to use the REDUCE-IT results to promote their products, we cannot be sure physicians and pharmacists will view the U.S. FDA-approved, prescription-only status, and EPA-only purity and stability of VASCEPA or U.S. FDA's stringent regulatory oversight, as significant advantages versus omega-3 dietary supplements regardless of clinical study results and other scientific data.

Although VASCEPA is currently the only drug that is approved for cardiovascular risk reduction in Europe in the at-risk patient population studied in REDUCE-IT, and there is currently no other direct competition for Canada and the Middle East, consistent with the U.S., our competitors include large, well-established and experienced pharmaceutical companies, specialty and generic pharmaceutical companies, marketing companies, and specialized cardiovascular treatment companies and we have no experience as a company self-commercializing a product outside of the United States.

Recent CV outcomes trials and meta-analyses with low and high dose omega-3 fatty acid mixtures containing DHA have not shown substantial benefit in patients receiving contemporary medical therapy, including statins. Due to failed low dose omega-3 CV outcomes trials, the European regulatory authorities have concluded that omega-3 fatty acid medicines (specifically Lovaza®/Omacor®) at a dose of 1-gram per day are not effective in preventing further events for patients who have had a heart attack. The STRENGTH trial of an omega-3 mixture studied at 4-grams per day also failed to demonstrate cardiovascular benefit.

As generic company competitors seek to compete with copies of VASCEPA in the United States and elsewhere we could face additional challenges to our patents and additional patent litigation.

The FDCA, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, as amended, or the Hatch-Waxman Amendments, permits the U.S. 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 U.S. FDA approval for modifications of products previously approved by the U.S. 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 U.S. FDA findings of safety and effectiveness of a drug that has obtained U.S. FDA approval based on preclinical or clinical studies conducted by others. In addition to

relying on U.S. FDA prior findings of safety and effectiveness for a referenced drug product, the U.S. 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 U.S. FDA finding of safety and effectiveness of a previously-approved product including an alternative strength thereof, the applicant is required to certify to the U.S. FDA concerning any patents listed for the referenced product in the U.S. 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:

- there is no patent information listed for the reference drug;
- the listed patent has expired for the reference drug;
- 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
- 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 U.S. 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 U.S. 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 U.S. 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 U.S. 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 U.S. 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 U.S. 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 addition to the ANDA patent litigation described above, we could face patent litigation related to the patents filed in the Orange Book related to the REDUCE-IT study. 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 received three-year exclusivity in connection with the approval of our sNDA for REDUCE-IT study results. Such three-year exclusivity protection precludes, unless otherwise agreed, the U.S. FDA from approving a marketing application for an ANDA, a product candidate that the U.S. 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 U.S. FDA with VASCEPA as the reference product until December 13, 2022, three years from the date of U.S. FDA approval of the REDUCE-IT sNDA. While this three-year exclusivity would generally prevent such an approval based on our REDUCE-IT indication during such time, it does not preclude tentative or final approval of an ANDA based on our MARINE indication. The U.S. FDA may accept and commence review of such REDUCE-IT-related applications during the three-year exclusivity period. Such three-year exclusivity grant does not prevent a company from challenging the validity of REDUCE-IT patents during such period. This three-year form of exclusivity may also not prevent the U.S. FDA from approving an NDA that relies only on its own data to support the change or innovation. Regulatory exclusivity is in addition to exclusivity afforded by issued patents related to VASCEPA.

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, of the USPTO. Such a proceeding could be introduced against us within the statutory one-year window triggered by service of a complaint for infringement related to an ANDA filing 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, any appeals, or any subsequently filed lawsuits or inter partes review.

Generally, if an ANDA filer meets the approval requirements for a generic version of VASCEPA to the satisfaction of the U.S. FDA under its ANDA, U.S. FDA may grant tentative approval to the ANDA during a Hatch-Waxman 30-month stay period and during the Hatch-Waxman 36-month regulatory exclusivity 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 applicable exclusivity protections have expired.

Generic versions of VASCEPA made available in the market, even if based on a MARINE indication, only are often used to fill a prescription for any intended use of the drug. If any approved ANDA filers are able to supply the product in significant commercial quantities, generic companies could introduce generic versions of VASCEPA in the market, as did Hikma in November 2020, Dr. Reddy's in June 2021 and Apotex in January 2022, although each on a limited scale to date. Although any such introduction of a generic version of VASCEPA would also be subject to any litigation settlement terms and patent infringement claims (including any new claims and those that may then be subject to an appeal), pursuing such litigation may be prohibitively costly or could put a substantial constraint on our resources.

On July 9, 2021, President Biden issued an executive order directing the U.S. FDA to, among other things, continue to clarify and improve the approval framework for generic drugs and identify and address any efforts to impede generic drug competition.

Any significant degree of 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 or news related to litigation outcomes could materially affect the reputation of VASCEPA or the perceived value of our company and our stock price. In addition, generic market entry, whether limited to its approved indication or not, can create market disruption which leads to an overall slowing of market growth regardless of whether the net price of the generic entry is higher or lower than the net price of the branded drug. Such disruption includes potential stock shortages of the generic market entry at retail pharmacies and wholesalers which can cause filling of prescriptions for patients to be delayed or abandoned. Sponsors of generic entries typically do not fund market education initiatives to help healthcare professionals and at-risk patients learn about a new drug, which, particularly for a recently launched drug, can potentially limit overall growth. And certain States impose restrictions on the promotion of branded drugs, particularly if the generic market entry is less expensive than the branded drug. While some companies with generic competition elect to launch an authorized generic form of the drug to counter the perception, real or imagined, that generics are less expensive, if launched, an authorized generic is typically aligned with reduction or elimination of promotion of the associated branded drug, thus limiting the extent of market growth and potentially contracting the overall size of the realized market penetration. While an authorized generic could be profitable the market opportunity for growth from an authorized generic is likely less than from promotion of a branded drug, and as such we have not launched an authorized generic version of VASCEPA to date, but may elect to do so in the future.

The active pharmaceutical ingredient in VASCEPA is difficult and time consuming to manufacture, often requires considerable advanced planning and long-term financial commitments to ensure sufficient capacity is available when needed and, perhaps not surprisingly, is reportedly in limited supply to our generic competitors, one of which has filed a lawsuit against us claiming we have engaged in anticompetitive practices related to our building of adequate supply for our needs and, in activities we believe were prompted by the generic competitor, government agencies are investigating our business as it relates to the supply of the active pharmaceutical ingredient in VASCEPA. Consumer lawsuits with similar allegations have also been filed. This dynamic could interfere with our business plans.

The active pharmaceutical ingredient in VASCEPA is difficult and time consuming to manufacture, often requires considerable advanced planning and long-term financial commitments to ensure sufficient capacity is available when needed. We have invested over a decade of resources and expenses to develop with our third-party, active pharmaceutical ingredient supply chain the technical knowhow, manufacturing processes and related regulatory approvals that have helped enable our suppliers to supply our clinical and commercial needs globally. Based on statements made by Hikma and Dr. Reddy’s, the active pharmaceutical ingredient of VASCEPA needed to manufacture their generic versions of VASCEPA is in limited supply to them. We believe this may be due to their lack of adequate planning, knowhow and expertise regarding this fragile active ingredient.

As has been a practice in the generic pharmaceutical industry, on April 27, 2021, Dr. Reddy’s filed a complaint against us in the United States District Court District of New Jersey (case no. 2:21-cv-10309) alleging various antitrust violations stemming from alleged anticompetitive practices related to the supply of active pharmaceutical ingredient of VASCEPA. Damages sought include recovery for alleged economic harm to Dr. Reddy’s, payors, and consumers, treble damages and other costs and fees. Injunctive relief against the alleged violative activities is also being sought by Dr. Reddy’s. Consumer group lawsuits followed claiming similar violations and alleging, for example, that such alleged violations resulted in higher prices to consumers. Such litigation can be lengthy, costly and could materially affect and disrupt our business. We believe we have valid defenses and will vigorously defend against the claims but cannot predict the outcome.

We have also received a civil investigative demand from the U.S. FTC and a subpoena from the New York Attorney General with respect to practices relating to our supply of the active pharmaceutical ingredient in VASCEPA. We believe such contact from the governments may have been prompted by a generic competitor. The government inquiries require us to produce documents and answer related questions relevant to specified time periods. We are cooperating with the agencies. Such investigations can be lengthy, costly and could materially affect and disrupt our business. We cannot predict when these investigations will be resolved, the outcome of the investigations or their potential impact on our business. If a government determines that we have violated antitrust law, we could be subject to significant civil fines and penalties.

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, in the U.S. VASCEPA is subject to non-prescription competition and consumer substitution. This dynamic also exists in markets outside the United States.

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 and other providers will view the U.S. FDA approval, 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 U.S. 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 over a decade, subject to certain limitations, the U.S. 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.* Such companies are not, however, permitted, based on U.S. FDA enforcement activity, to make claims that suggest or imply treatment of cardiovascular disease.

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 October 29, 2018, we filed two lawsuits in U.S. federal court, each against a different dietary supplement company for unlawfully using the results from the REDUCE-IT cardiovascular outcomes study to falsely and deceptively claim that their omega-3 dietary supplement products are effective in reducing cardiovascular risk. The defendants in the cases were Omax Health, Inc., or Omax, and The Coromega Company, Inc., or Coromega. In April 2019, based on the strength of our case and available legal remedies, Omax and Coromega settled these litigations under terms by which Omax and Coromega agreed to substantially all the demands in our complaints. Under the settlements, Coromega and Omax agreed to publicly correct their prior statements that wrongly suggested the REDUCE-IT cardiovascular outcomes trial supports the safety and efficacy of omega-3 dietary supplements. Each dietary supplement company also acknowledged that as a general matter under federal law dietary supplements may be lawfully marketed to supplement the diet, but they cannot be lawfully marketed to treat, mitigate, or prevent disease, such as cardiovascular disease.

Similarly, on August 30, 2017, we 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. In October 2017, the ITC determined to not institute our requested investigation. We appealed this determination to the U.S. Federal Circuit, but that court upheld ITC's determination. On July 30, 2019, we filed a petition with the U.S. Supreme Court seeking to appeal the Federal Circuit decision, which petition was denied on December 9, 2019, ending this litigation. We have also engaged with U.S. FDA on the topic of synthetically produced omega-3 products through the citizen's petition process and otherwise.

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 the lack of coverage by insurers or otherwise), physicians and pharmacists may recommend these retail 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 directly or indirectly favor supplement use over VASCEPA. While VASCEPA is priced comparatively with, or in some cases lower than, many competing treatments, particularly when taking into account insurance coverage, such pricing might not be sufficient for healthcare providers or patients to elect VASCEPA over alternative treatments that may be perceived as less expense or more convenient to access. If healthcare providers or patients favor dietary supplements over prescribing VASCEPA, we may be constrained in how we price our product or VASCEPA's market acceptance may be less than expected, which would have a negative impact on our revenues and results of operations.

The commercial value to us of sales of VASCEPA outside the United States may be smaller than we anticipate, including adequacy of product reimbursement such as in Europe, which can vary from country to country resulting in potential patient access restrictions.

There can be no assurance as to the market for VASCEPA outside the United States. For example, despite having received EC approval to commercialize VAZKEPA in Europe and as we expect to obtain further, through our partner Edding, marketing approval for VASCEPA 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.

Further, securing adequate reimbursement is critical for commercial success of any therapeutic and pricing and reimbursement levels of medications in markets outside the United States can be unpredictable and vary considerably on a country-by-country basis. In some foreign countries, including major markets in Europe, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with individual governmental authorities can take six to 12 months or longer after the receipt of regulatory marketing approval for a product. The time required to secure reimbursement tends to vary from country to country and cannot be reliably predicted at this time. In certain European countries, securing product reimbursement is a requisite to commercial launch. 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, delayed or limited in scope or amount or if pricing is set at unsatisfactory levels. 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.

We or our partners may even choose to not proceed with marketing VASCEPA in a market, even after a regulatory approval, due to negative commercial dynamics. Further, 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. In addition, we could face competition from products similar or deemed equivalent to VASCEPA in various jurisdictions through regulatory pathways that are more lenient than in the United States or in jurisdictions in which we do not have exclusivity from regulations or intellectual property. If any of these market dynamics exist, the commercial potential in these territories for our product would suffer.

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

Once a product candidate receives U.S. 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 U.S. 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, advertising and promotional materials must comply with U.S. 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 U.S. 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 U.S. FDA inspection and must continue to adhere to the U.S. FDA's pharmaceutical current good manufacturing practice requirements, or cGMPs. Application holders must obtain U.S. FDA approval for product and manufacturing changes, depending on the nature of the change. In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are subject to periodic unannounced inspections by the U.S. FDA and state agencies for compliance with cGMP requirements.

We participate in the U.S. Medicaid Drug Rebate Program, the Federal Supply Schedule, or FSS, of the U.S. Department of Veterans Affairs, or the VA, and other government drug programs, and, accordingly, are 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. 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 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 America. As discussed above, in June 2020, we received a CID from the DOJ informing us that the DOJ is investigating whether aspects of our promotional speaker programs and copayment waiver programs during the period from January 1, 2015 to the present violated the U.S. Anti-Kickback

Statute and the U.S. FCA in relation to the sale and marketing of VASCEPA by us and our previous co-marketing partner, Kowa America. The New York State attorney general similarly issued a subpoena to us regarding the same subject matter on which the FTC CID is focused. The inquiries require us to produce documents and answer written questions, or interrogatories, relevant to specified time periods. We are cooperating with the government. We cannot predict when these investigations will be resolved, the outcome of the investigations or their potential impact on our business. Such investigations can be lengthy, costly and could materially affect and disrupt our business. If the government determines that we have violated the U.S. Anti-Kickback Statute, the FCA or antitrust regulations, we could be subject to significant civil and criminal fines and penalties. In addition, even if we comply with U.S. FDA and other requirements, new information regarding the safety or effectiveness of a product could lead the U.S. 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 and marketing, 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. In Europe, for example, restrictions regarding off-label promotion are in some ways more stringent than in the United States, including restrictions covering certain communications with shareholders. Given our inexperience with marketing and commercializing products outside the United States, in certain territories we may need to rely on third parties, such as our partners in Canada, China and the Middle East, to assist us in dealing with any such issues and we will have limited or no control over such partners.

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 VASCEPA or any 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 changes and proposed changes to the healthcare system in ways that could affect our ability to sell our products profitably. For example, on August 2, 2011, the Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals for spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction, which triggered the legislation's automatic reductions. In concert with subsequent legislation, this has resulted in aggregate reductions to Medicare payments to providers of, on average, 2% per fiscal year through 2030 with the exception of a temporary suspension from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic. Following the suspension, a 1% payment reduction took place beginning April 1, 2022 and will continue through June 30, 2022, and the 2% payment reduction will resume on July 1, 2022. These cuts reduce reimbursement payments related to our products, which could potentially negatively impact our revenue. Also for example, the ACA has substantially changed the way healthcare is financed by both governmental and private insurers and has significantly impacted the U.S. pharmaceutical industry. Among other cost-containment measures, the 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; and
- a new formula that increases the rebates a manufacturer must pay under the Medicaid Drug Rebate Program and extends the Medicaid Drug Rebate Program to individuals enrolled in Medicaid managed care organizations.

There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, and review the relationship between pricing and manufacturer patient programs. At a federal level, President Biden signed an Executive Order on July 9, 2021 affirming the administration's policy to (i) support legislative reforms that would lower the prices of prescription drug and biologics, including by allowing Medicare to negotiate drug prices, by imposing inflation caps, and, by supporting the development and market entry of lower-cost generic drugs and biosimliars; and (ii) support the enactment of a public health insurance option. Among other things, the Executive Order also directs HHS to provide a report on actions to combat excessive pricing of prescription drugs, enhance the domestic drug supply chain, reduce the price that the federal government pays for drugs,

and address price gouging in the industry; and directs the FDA to work with states and Indian Tribes that propose to develop section 804 Importation Programs in accordance with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and the FDA's implementing regulations. FDA released such implementing regulations on September 24, 2020, which went into effect on November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. On September 25, 2020, CMS stated drugs imported by states under this rule will not be eligible for federal rebates under Section 1927 of the Social Security Act and manufacturers would not report these drugs for "best price" or Average Manufacturer Price purposes. Since these drugs are not considered covered outpatient drugs, CMS further stated it will not publish a National Average Drug Acquisition Cost for these drugs. If implemented, importation of drugs from Canada may materially and adversely affect the price we receive for any of our product candidates. Further, on November 20, 2020 CMS issued an Interim Final Rule implementing the Most Favored Nation, or MFN, Model under which Medicare Part B reimbursement rates would have been calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. However, on December 29, 2021 CMS rescinded the Most Favored Nations rule. Additionally, on November 30, 2020, HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Pursuant to court order, the removal and addition of the aforementioned safe harbors were delayed and recent legislation imposed a moratorium on implementation of the rule until January 1, 2026. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs.

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.

These and similar regulatory dynamics, including the recent entry of generic versions of VASCEPA into the market, and the potential for additional generic versions in the near term, can affect our ability to commercialize VASCEPA on commercially reasonable terms and limit the commercial value of VASCEPA.

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 VA's 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 commercial 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. We also 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, as noted above, we participate in the VA's 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 (the VA, U.S. Department of Defense, or DOD, Public Health Service, and the 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 FCA 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., Europe and other regions globally, 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 decide which products and services they will cover and the conditions for such coverage. Third party payors also establish reimbursement rates for those products and services. Increasingly, third-party payors are 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 U.S. based 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 and executive

proposals, as well as the availability of generic versions of VASCEPA. In addition, we may confront limitations in, or exclusions from, insurance coverage for our products, particularly as generic competition intensifies. 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.

Certain provisions of the ACA have been subject to judicial challenges, as well as efforts to repeal or replace them or to alter their interpretation or implementation. Multiple Executive Orders were signed during the Trump administration which were 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. For example, the previous administration terminated the cost-sharing subsidies 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 HHS from paying out more in risk corridor payments than it collected, HHS was not required to pay more than $12.0 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. This decision was appealed to the U.S. Supreme Court, which on April 27, 2020, reversed the U.S. Court of Appeals for the Federal Circuit's decision and remanded the case to the U.S. Court of Federal Claims, concluding the government has an obligation to pay these risk corridor payments under the relevant formula. It is not clear what effect this result will have on our business, but we will continue to monitor any developments. Moreover, the Tax Act included a provision that 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. The Bipartisan Budget Act of 2018, or the BBA, among other things, amends the ACA to create a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% (an increase from 50% effective as of January 1, 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D. Under the Trump administration, CMS issued regulations that gave states greater flexibility, starting in 2020, in the identification of the essential health benefits benchmarks for non-grandfathered individual and small group market health insurance coverage, including plans sold through the health insurance exchanges established under the ACA. On December 14, 2018, the U.S. District Court for the Northern District of Texas ruled (i) that the "individual mandate" was unconstitutional as a result of the associated tax penalty being repealed by Congress as part of the Tax Act; and (ii) the individual mandate is not severable from the rest of the ACA, as a result the entire ACA is invalid. On December 18, 2019, the U.S. Court of Appeals for the Fifth Circuit affirmed the district court's decision that the individual mandate is unconstitutional, but remanded the case to the district court to reconsider the severability question. On March 2, 2020, the U.S. Supreme Court granted the petitions for writs of certiorari to review this case and held oral arguments on November 10, 2020. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for the purpose of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how other healthcare reform measures of the Biden administration or other efforts, if any, to challenge, repeal or replace the ACA will impact our business.

In addition, there have been several changes to the 340B drug pricing program, which imposes ceilings on prices that drug manufacturers can charge for medications sold to certain health care facilities. On December 27, 2018, the District Court for the District of Columbia invalidated a reimbursement formula change under the 340B drug pricing program, and CMS subsequently altered the FYs 2019 and 2018 reimbursement formula on specified covered outpatient drugs, or SCODs. The court ruled this change was not an "adjustment" which was within the Secretary's discretion to make but was instead a fundamental change in the reimbursement calculation. However, on July 31, 2020, the U.S. Court of Appeals for the District of Columbia Circuit overturned the district court's decision and found that the changes were within the Secretary's authority. On September 14, 2020, the plaintiffs-appellees filed a Petition for Rehearing En Banc (i.e., before the full court), but was denied on October 16, 2020. On February 10, 2021, plaintiffs-appellees filed a writ of certiorari with the U.S. Supreme Court. The U.S. Supreme Court granted the writ of certiorari on July 2, 2021 and oral arguments were held on November 30, 2021. The Court's decision should be released in the coming months. It is unclear how these developments could affect covered hospitals who might purchase our future products and affect the rates we may charge such facilities for our approved products in the future, if any. 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 enactment and 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 the federal Health Insurance Portability and Accountability Act of 1996, or 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.

The REDUCE-IT cardiovascular outcomes trial was conducted in part through clinical sites in the EEA. As a result, we are subject to additional privacy restrictions. The collection and use of personal health data in the EU is governed by the provisions of the GDPR. The GDPR imposes several requirements relating to the legal basis for processing personal data which may include the consent of the individuals to whom the personal data relates, the information provided to the individuals and the security and confidentiality of the personal data. The GDPR also imposes strict rules on the transfer of personal data out of the EEA to the United States. A decision by the Court of Justice of the European Union, or CJEU, in 2020 invalidated the EU-U.S. Privacy Shield Framework, which was one of the primary mechanisms used by U.S. companies to import personal information from Europe in compliance with the GDPR's cross-border data transfer restrictions, and raised questions about whether the EC's Standard Contractual Clauses, or SCCs, one of the primary alternatives to the Privacy Shield, can lawfully be used for personal information transfers from Europe to the United States or most other countries. Furthermore, on June 4, 2021, the EC issued new forms of standard contractual clauses for data transfers from controllers or processors in the EEA, or otherwise subject to the GDPR, to controllers or processors established outside the EEA, and not subject to the GDPR. The new forms of standard contractual clauses have replaced the standard contractual clauses that were adopted previously under the Data Protection Directive. We will be required to transition to the new forms of standard contractual clauses and doing so will require significant effort and cost. The new standard contractual clauses may also impact our business as companies based in Europe may be reluctant to utilize the new clauses to legitimize transfers of personal information to third countries given the burdensome requirements of transfer impact assessments and the substantial obligations that the new standard contractual clauses impose upon exporters. Failure to comply with the requirements of the GDPR, and the related national data protection laws of the EEA Member States may result in restrictions against regulatory approval in the EEA or substantial fines for breaches of the data protection rules. The GDPR 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 U.S. FDA, other regulatory agencies and industry organizations strictly regulate the promotional claims that may be made about prescription products and promotional efforts such as speaker programs. If we or our partners are found to have improperly promoted uses, efficacy or safety of VASCEPA or otherwise are found to have violated the law or applicable regulations, 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 or seek to find violations of other laws or regulations in connection with the promotional efforts we undertake on our own or through third parties.

The U.S. 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 U.S. FDA as reflected in the product's approved labeling. 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 U.S. FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. Even though we received U.S. FDA marketing approval for VASCEPA for the MARINE indication and for cardiovascular risk reduction based on the REDUCE-IT study, and our settlement with the U.S. FDA 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 U.S. 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 FCA, or other theories of liability. Government may also seek to hold us responsible for the non-compliance of our former co-promotion partner, Kowa America, or our commercialization partners outside the United States or other third-parties that we retain to help us implement our business plan.

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.

In June 2020, we received a CID from the DOJ informing us that the DOJ is investigating whether aspects of our promotional speaker programs and copayment waiver program during the period from January 1, 2015 to the present violated the U.S. Anti-Kickback Statute and the FCA in relation to the sale and marketing of VASCEPA by us and our previous co-marketing partner, Kowa America. Similarly, in March 2021, the FTC issued a CID to us in connection with the FTC's investigation of whether we have engaged in, or are engaging in, anticompetitive practices or unfair methods of competition relating to VASCEPA. The New York State attorney general similarly issued a subpoena to us regarding the same subject matter on which the FTC CID is focused. The inquiries require us to produce documents and answer written questions, or interrogatories, relevant to specified time periods. We are cooperating with the government. We cannot predict when these investigations will be resolved, the outcome of the investigations or their potential impact on our business. Such investigations can be lengthy, costly and could materially affect and disrupt our business. If the government determines that we have violated the U.S. Anti-Kickback Statute, the FCA or antitrust regulations we could be subject to significant civil and criminal fines and penalties.

We may not be successful in developing and receiving regulatory approval for VASCEPA in other jurisdictions or marketing future products if we cannot meet the extensive regulatory requirements of regulatory agencies such as for quality, safety, efficacy and data privacy.

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 U.S. 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, among others:

- 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;
- compliance with laws and regulations related to patient data privacy;
- government or regulatory delays or "clinical holds" requiring suspension or termination of a trial; and
- political instability or other social or government protocols affecting our clinical trial sites.

Even if we obtain positive results from our efforts to seek regulatory approvals, from early stage preclinical studies or clinical trials, we may not achieve the same success in future efforts. 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, during the public advisory committee meeting held by U.S. FDA as part of its review of our ANCHOR data and sNDA in October 2013, a discussion regarding observed, nominally statistically significant changes from baseline in an adverse direction, while on background statin therapy, in certain lipid parameters, including LDL cholesterol and triglycerides, in the placebo group, raised questions about the possibility that the light liquid paraffin oil, or mineral oil, placebo used in the ANCHOR trial and then in use 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. Ultimately, in 2012, before the U.S. FDA approval of VASCEPA after review of the MARINE and ANCHOR trials and consideration of other data regarding mineral oil, no strong evidence for biological activity of mineral oil was identified by the agency. 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 U.S. FDA approved VASCEPA for use in the MARINE indication in July 2012, U.S. FDA did not dispute the veracity of the ANCHOR trial data and, in connection with the March 2016 agreement we reached with the U.S. FDA allowing us to promote the results of the ANCHOR study, the U.S. FDA did not seek to require that we include any qualification related to this earlier question regarding the mineral oil placebo. In addition, in connection with U.S. FDA's review of REDUCE-IT data and sNDA in 2019, the agency determined that an interaction between mineral oil and statins leading to decreased absorption of statins cannot be excluded when the two are co-administered as could have been the case in some patients in REDUCE-IT and that, in the agency's view, indirect evidence suggested the presence of a potential inhibitory effect on statin absorption by mineral oil. However, U.S. FDA's exploratory analysis indicated that the effect of LDL cholesterol values on the time to the primary endpoint was numerically small and unlikely to change the overall conclusion of treatment benefit. U.S. FDA then relied on this assessment and all data available to it to approve a new indication statement and labeling based on REDUCE-IT results. This matter illustrates that concerns such as this may arise in the future that could affect our product development, regulatory reviews 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, including boxed warnings, 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 commercialization, 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 build our infrastructure for commercializing VASCEPA, we may encounter difficulties in managing the scale of our operations successfully.

The process of establishing, maintaining, expanding and streamlining a commercial infrastructure is difficult, expensive and time-consuming. We implemented a Go-to-Market strategy in an effort to optimize provider engagement and drive demand for VASCEPA in the United States by shifting reliance on sales force interactions with healthcare professionals to providing managed care and prescription access through an omnichannel platform. Accordingly, as announced on September 22, 2021 we reduced our U.S. field force to approximately 300 sales representatives. As we observe the results of the Go-to-Market strategy and as practices impacted by COVID-19 stabilize, we will continue to evaluate our needs, including the need to fill open positions, or expand or further streamline our sales force, as appropriate to meet our business needs. Our sales team promotes VASCEPA to a limited group of physicians and other healthcare professionals in select geographies in the United States and is not large enough to call upon all physicians.

In addition to sales force reductions and the shift to omnichannel in the United States, we continue to work on our own and with our 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 and streamlining efforts will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate the right number of employees. For example, in Europe we have built out our team subsequent to EC approval of the marketing authorization acceptance in 2021, with plans to continue to expand our European staff as deemed appropriate on a country by country basis. The time required to secure reimbursement tends to vary from country to country and cannot be reliably predicted at this time. While we believe that we have strong arguments regarding the cost effectiveness of VAZKEPA, the success of such reimbursement negotiations could have a significant impact on our ability to hire and retain personnel and realize the commercial opportunity of VAZKEPA in Europe. 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, and such efforts may be disrupted by ongoing or reinstated COVID-19 protocols. To that end, we must be able to manage our development efforts effectively, and hire, train, integrate and retain an appropriate level of management, administrative and sales and marketing personnel and have limited experience managing a commercial organization. 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.

Our life-cycle management, in large part, currently depends on our ability to develop, obtain regulatory approval and commercialize a fixed-dose combination of VASCEPA and yet to be disclosed statins.

Specifically, our drug development efforts are subject to the risks and uncertainties inherent in any drug development program. Due to the risks and uncertainties involved in progressing through development and bioequivalence or even potential additional trials (as may be required by specific regulatory agencies), and the time and cost involved in obtaining regulatory approvals, among other factors, we cannot reasonably estimate the timing, completion dates and costs, or range of costs, of our drug development program, or of the successful development of any particular fixed-dose combination. The potential success of any fixed-dose combination will depend on a number of factors, including the following:

- Our ability to successfully manufacture a combination of VASCEPA and statin;
- Our ability to maintain a supply of necessary statin for use in the fixed-dose combination;
- Our ability to obtain regulatory approvals for any and all markets in which we intend to commercialize a fixed-dose combination of VASCEPA and a statin;
- Our ability to obtain payor acceptance and market access for a fixed-dose combination product of VASCEPA and a statin; and
- Our ability to achieve market acceptance of a fixed-dose combination of VASCEPA and a statin.

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 provide assurance 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. If we are not able to continue to operate our business relationships in a manner that is sufficiently profitable for us and our suppliers, certain members of our supply chain could compete with us through supply to competitors, such as generic drug companies, through breach of our agreements or otherwise.

Any manufacturing problem, natural or manmade 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, API, (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. We require supply capacity to support our direct commercialization of VASCEPA in the United States and VAZKEPA in Europe. We are also committed to providing supply to our commercial partners and distributors in Canada, China, the Middle East and North Africa, and we anticipate potential additional supply requirements as we pursue commercial opportunities in other countries. The resources of our suppliers vary and are limited; costs associated with projected expansion and qualification can be significant, and lead-times for supply purchases and capacity expansion are long requiring certain supply related decisions and commitment to be made in advance, for example, prior to commercial launch in China and in various European countries. 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, with certain of these expansion plans delayed due to COVID-19 and other market uncertainties. If no additional API supplier is approved by the U.S. FDA as part of an sNDA, our API supply will be limited to the API we purchase from previously approved suppliers. Similarly, the EMA has not initially approved use of each of our suppliers used for VASCEPA in the United States for VAZKEPA in the EU. While we believe that we have sufficient supply of VAZKEPA to support our initial launch plans in Europe, our supply in Europe will be limited until additional suppliers are qualified which qualifications may be delayed by COVID-19 and our exposure to manufacturing issues with our approved suppliers for the EU is less mitigated than is our objective by having more suppliers qualified. 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 12-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 12-month forecasts. We may not purchase sufficient quantities of VASCEPA to meet actual demand or we may be required to purchase more supply than needed to meet actual demand. In either case, such event could have a material adverse effect on our financial results and financial condition.

Our dependence on third parties in the distribution channel from our manufacturers to patients subject us to risks 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 mail order 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 may 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.

The manufacture, packaging and distribution of pharmaceutical products such as VASCEPA are subject to U.S. 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 U.S. FDA and similar foreign regulatory bodies and must be conducted in accordance with the U.S. FDA's cGMPs and comparable requirements of foreign regulatory bodies. There are a limited number of manufacturers that operate under these cGMPs as well as the International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, or ICH, regulations and guidelines, that 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 and penalties, 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 U.S. FDA review and pre-approval of the manufacturing process and procedures in accordance with the U.S. FDA's cGMPs. Any new facility may be subject to a pre-approval inspection by the U.S. FDA and would again require us to demonstrate product comparability to the U.S. FDA. If any third-party manufacturer with whom we contract fails to perform its obligations, we may be forced to manufacture the materials ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different third-party manufacturer, which we may not be able to do on reasonable terms, if at all. In either scenario, our clinical trials or commercial distribution could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original third-party manufacturer and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change third-party manufacturer for any reason, we will be required to verify that the new third-party manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product according to the specifications previously submitted to or approved by the U.S. FDA or another regulatory authority. The delays associated with the verification of a new third-party manufacturer could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a third-party manufacturer may possess technology related to the manufacture of our product candidate that such third-party manufacturer owns independently. This would increase our reliance on such third-party manufacturer or require us to obtain a license from such third-party manufacturer in order to have another third-party manufacturer manufacture our products or product candidates. In addition, in the case of the third-party manufacturers that supply our product candidates, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials.

There are comparable foreign requirements under ICH guidelines. In addition, certain COVID-19 restrictions have affected Regulatory Agencies' ability to conduct facility inspections and may affect the timing of further approvals. This review may be costly and time consuming and could delay or prevent the launch of a product.

Furthermore, the U.S. 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. Process validation includes stability testing, measurement of impurities and testing of other product specifications by validated test methods. If the U.S. 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. On March 27, 2020, former President Trump signed into law the CARES Act in response to the COVID-19 pandemic. Throughout the COVID-19 pandemic, there has been public concern over the availability and accessibility of critical medical products, and the CARES Act enhances U.S. FDA's existing authority with respect to drug shortage measures. Under the CARES Act, we must have in place a risk management plan that identifies and evaluates the risks to the supply of approved drugs for certain serious diseases or conditions for each establishment where the drug or API is manufactured. The risk management plan will be subject to U.S. FDA review during an inspection. If we experience shortages in the supply of our marketed products, our results could be materially impacted.

The U.S. 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, or we may be prevented from manufacturing or selling VASCEPA, all of which could significantly and adversely affect our business. Furthermore, reductions in government operations due to pandemic mitigation efforts, or other factors, may delay timely regulatory review by U.S. FDA or similar foreign regulatory bodies. For example, since March 2020 when foreign and domestic inspections of facilities were largely placed on hold, the

U.S. FDA has been working to resume routine surveillance, bioresearch monitoring and pre-approval inspections on a prioritized basis. Since April 2021, the U.S. FDA has conducted limited inspections and employed remote interactive evaluations, using risk management methods, to meet user fee commitments and goal dates. Ongoing travel restrictions and other uncertainties continue to impact oversight operations both domestic and abroad and it is unclear when standard operational levels will resume. The U.S. FDA is continuing to complete mission-critical work, prioritize other higher-tiered inspectional needs (e.g., for-cause inspections), and carry out surveillance inspections using risk-based approaches for evaluating public health. Should the U.S. FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, and the U.S. FDA does not determine a remote interactive evaluation to be adequate, the agency has stated that it generally intends to issue, depending on the circumstances, a complete response letter or defer action on the application until an inspection can be completed. During the COVID-19 public health emergency, a number of companies announced receipt of complete response letters due to the U.S. FDA's inability to complete required inspections for their applications. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the ongoing COVID-19 pandemic and may experience delays in their regulatory activities.

Our commercialization of VASCEPA outside the United States is substantially dependent on third parties and other circumstances outside our control.

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 Edding, related to the development and commercialization of VASCEPA in the China Territory. Under the DCS Agreement, Edding is responsible for development and commercialization activities in the China Territory and associated expenses. Additionally, Edding is required to conduct clinical trials in the China Territory to secure regulatory approval in certain territories. In December 2017, Edding commenced a pivotal Phase 3 clinical trial aimed to demonstrate that VASCEPA lowers triglyceride levels and otherwise has beneficial effects in Chinese patients with severe hypertriglyceridemia (TG >500 mg/dL), as we previously demonstrated with VASCEPA in the more diverse population studied in the MARINE study. In November 2020, we announced statistically significant positive topline results from Edding's Phase 3 clinical trial of VASCEPA. On February 9, 2021, we announced that the regulatory review processes for approval of VASCEPA in Mainland China and Hong Kong have commenced. The Chinese National Medical Products Administration, or NMPA, has accepted for review the new drug application for VASCEPA, submitted by Edding, based on the results from the Phase 3 clinical trial and the results from our prior studies of VASCEPA. We expect to receive a decision from the NMPA in Mainland China in the second half of 2022. On February 23, 2022 the Hong Kong Department of Health completed their evaluation and approved the use of VASCEPA under the REDUCE-IT indication. Even though such results are similar to the MARINE study, additional clinical development efforts may be necessary in this market to demonstrate the effectiveness of VASCEPA in reducing major adverse cardiovascular events in Chinese patients with persistent cardiovascular risk. Any development and regulatory efforts in the China Territory may be negatively impacted if the coronavirus pandemic continues or spreads, and if resources by regulators and industry professionals continue to be diverted to address the prolonged coronavirus pandemic. Any development and regulatory efforts in the China Territory may be negatively impacted by heightened political tension between China and the United States, including in connection with COVID-19 and other issues expressed between the countries regarding trade practices, tariffs and honoring intellectual property rights. If Edding 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. Biologix was approved under the MARINE indication in the following countries: Lebanon in March 2018, United Arab Emirates in July 2018, Qatar in December 2019, Bahrain in April 2021, Kuwait in December 2021 and Saudi Arabia in March 2022. VASCEPA was approved under the REDUCE-IT indication in the following countries: Qatar in April 2021, Lebanon in August 2021 and United Arab Emirates in October 2021. VASCEPA was launched in Lebanon and the United Arab Emirates in June 2018 and February 2019, respectively. VASCEPA is under registration in additional countries in the Middle East and North Africa regions. Commercialization across the Middle East and North Africa is subject to similar risks as in the China Territory, and has been negatively impacted by COVID-19 and the destabilized local economies in the region.

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. We are 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. In December 2019, VASCEPA was approved for use in Canada to reduce the risk of cardiovascular events in statin-treated patients with elevated triglycerides, who are at high risk of cardiovascular events due to established cardiovascular disease, or diabetes, and at least one other cardiovascular risk factor. In January 2020, HLS obtained an extended regulatory exclusivity designation. In February 2020, HLS

launched VASCEPA in Canada, with strong initial uptake before the impact of COVID-19 pandemic. In July 2020, Patented Medicine Prices Review Board confirmed VASCEPA price is compliant with current guidelines, and CADTH recommended reimbursement for VASCEPA in Canada in secondary prevention population. However, if HLS is not able to effectively commercialize VASCEPA in Canada through effective pricing (initially and over time), reimbursement or otherwise we may not be able to generate revenue from the sale of VASCEPA in Canada.

Our efforts to launch and support commercialization of VAZKEPA on our own in Europe is a complex undertaking for a company that, other than our recent launch of VAZKEPA in Germany in September 2021, has not launched or otherwise commercialized a product in Europe and could be subject to significant risks of execution to our successful development and revenue generation of VAZKEPA in Europe. While various of our suppliers have been inspected and we do not anticipate supply availability limiting our launch in Europe, COVID-19 has limited the ability of suppliers to be inspected and not all of our suppliers have completed all of the requirements of the European regulatory authorities.

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 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:

- the U.S. 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 FCA. 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. Violations are subject to significant civil and criminal fines and penalties for each violation, plus up to three times the renumeration involved, imprisonment, and exclusion from government healthcare workers;
- the federal civil and criminal false claims laws and civil monetary penalties laws, including the 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. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to “case” the submission of false or fraudulent claims. 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. A claim that includes items or services resulting from a violations of the U.S. Anti-Kickback Statute constitutes a false or fraudulent claim under the FCA. When an entity is determined to have violated the FCA, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs. 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. The Health Information Technology for Economic and Clinical Health Act of 2009, or 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 (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors) 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 governmental price reporting laws, which require the calculation and reporting of complex pricing metrics in an accurate and timely manner to government programs;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- 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. In addition, manufacturers and other parties involved in the drug supply chain for prescription drug products must also comply with product tracking and tracing requirements and for notifying U.S. FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are otherwise unfit for distribution in the United States.

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. For example, in June 2020, we received a CID from the DOJ informing us that the DOJ is investigating whether aspects of our promotional speaker programs and copayment waiver program during the period from January 1, 2015 to the present violated the U.S. Anti-Kickback Statute and the FCA in relation to the sale and marketing of VASCEPA by us and our previous co-marketing partner, Kowa America. Similarly, in March 2021, the FTC issued a CID to us in connection with the FTC's investigation of whether we have engaged in, or is engaging in, anticompetitive practices or unfair methods of competition relating to VASCEPA. The New York State attorney general similarly issued a subpoena to us regarding the same subject matter on which the FTC CID is focused. The investigations require us to produce documents and answer written questions, or interrogatories, relevant to specified time periods. We are cooperating with the government. We cannot predict when these investigations will be resolved, the outcome of the investigations or their potential impact on our business. Such investigations can be lengthy, costly and could materially affect and disrupt our business. If the government determines that we have

violated the U.S. Anti-Kickback Statute, the FCA or antitrust regulations, we could be subject to significant civil and criminal fines and penalties. 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.

Third party patient assistance programs that receive financial support from companies have become the subject of enhanced government and regulatory scrutiny. Government enforcement agencies have shown increased interest in pharmaceutical companies' product and patient assistance programs, including reimbursement support services, and a number of investigations into these programs have resulted in significant civil and criminal settlements. The U.S. government has established guidelines that suggest that it is lawful for pharmaceutical manufacturers to make donations to charitable organizations who provide co-pay assistance to Medicare patients, provided that such organizations, among other things, are bona fide charities, are entirely independent of and not controlled by the manufacturer, provide aid to applicants on a first-come basis according to consistent financial criteria and do not link aid to use of a donor's product. However, donations to patient assistance programs have received some negative publicity and have been the subject of multiple government enforcement actions, related to allegations regarding their use to promote branded pharmaceutical products over other less costly alternatives. Specifically, in recent years there have been multiple settlements resulting out of government claims challenging the legality of their patient assistance programs under a variety of federal and state laws. It is possible that we may make grants to independent charitable foundations that help financially needy patients with their premium, co-pay, and co-insurance obligations. If we choose to do so, and if we or our vendors or donation recipients are deemed to fail to comply with relevant laws, regulations or evolving government guidance in the operation of these programs, we could be subject to damages, fines, penalties, or other criminal, civil, or administrative sanctions or enforcement actions. We cannot ensure that our compliance controls, policies, and procedures will be sufficient to protect against acts of our employees, business partners, or vendors that may violate the laws or regulations of the jurisdictions in which we operate. Regardless of whether we have complied with the law, a government investigation could impact our business practices, harm our reputation, divert the attention of management, increase our expenses, and reduce the availability of foundation support for our patients who need assistance. Further, it is possible that changes in insurer policies regarding co-pay coupons and/or the introduction and enactment of new legislation or regulatory measures impacting patients using affected products could have a material adverse effect on our sales, business and financial condition. For example, on December 31, 2020, CMS published a new rule, effective January 1, 2023, requiring manufacturers to ensure the full value of co-pay assistance is passed on to the patient or these dollars will count toward the Average Manufacturer Price and Best Price calculation of the drug. On May 21, 2021, PhRMA sued the HHS in the U.S. District Court for the District of Columbia, to stop the implementation of the rule claiming that the rule contradicts federal law surrounding Medicaid rebates. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the current U.S. presidential administration may reverse or otherwise change these measures, both the current U.S. presidential administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs. We cannot predict how the implementation of and any further changes to this rule will affect our business.

In addition, with the approval and commercialization of any of our products outside the United States, we will also likely be subject 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 U.S. 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. While certain key patents related to our product based on the MARINE clinical study were determined to be invalid as obvious by a district court in the United States, and we are pursuing an appeal process, it remains the case that 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 124 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 124 allowed and issued applications include the following:

- one issued U.S. patent directed to a pharmaceutical composition of VASCEPA in a capsule that expires in 2030;
- 62 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;
- 27 U.S. patents covering or related to the use of VASCEPA in the REDUCE-IT population with terms expiring in 2033 or later;
- three additional U.S. patents directed to a pharmaceutical composition comprised of free fatty acids with a term that expires in 2030;
- five 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;
- two 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;
- three additional patents related to the use of a pharmaceutical composition comprised of free fatty acids to treat the REDUCE-IT population expiring 2033;
- four additional patents 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;
- one additional patent related to the use of a pharmaceutical composition comprised of re-esterified EPA triglyceride to treat the REDUCE-IT population expiring 2033;
- four additional patents related to a formulation of EPA/DHA and uses thereof with a term that expires in 2030;
- two additional patents related to the use of VASCEPA to treat obesity with a term that expires in 2034;
- one additional patent related to the use of VASCEPA to treat prostate cancer with a term that expires in 2037;

- four additional patents covering a pharmaceutical composition comprised of EPA and a hydroxyl compound with a term that expires in 2034; and
- five 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 and products in development.

We are also pursuing patent applications related to VASCEPA in multiple jurisdictions outside the United States. Geographies outside the United States in which VASCEPA is sold and under regulatory review are not subject to the U.S. patent litigation and judgment. No litigation involving potential generic versions of VASCEPA is pending outside the United States. VASCEPA is currently available by prescription in Canada, Lebanon and the United Arab Emirates. In Canada, VASCEPA has the benefit of data protection afforded through Health Canada (until the end of 2027), in addition to separate patent protection with expiration dates that could extend into 2039. We are pursuing additional regulatory approvals for VASCEPA in Europe, China and the Middle East. In China and the Middle East, we are pursuing such regulatory approvals and subsequent commercialization of VASCEPA with commercial partners. The EC approval provides ten years of market protection in the EU. Furthermore, patent protection in Europe includes:

One granted patent related to the use of a pharmaceutical composition comprised of 4g of 96% EPA ethyl ester to treat the REDUCE-IT population expiring 2033.

Pending patent applications in Europe, if granted, may have the potential to extend exclusivity into 2039.

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, on November 30, 2020 we filed a patent infringement lawsuit against Hikma for making, selling, offering to sell and importing generic icosapent ethyl capsules in and into the United States in a manner that we allege has induced the infringement of patents covering the use of VASCEPA to reduce specified cardiovascular risk. On January 25, 2021, we expanded the scope of this patent infringement lawsuit to include a health care insurance provider, Health Net, LLC. On January 4, 2022, the district court hearing the case granted Hikma's motion to dismiss. We intend to

appeal the decision of the district court when permitted and also intend to continue to vigorously pursue our ongoing litigation with Health Net, LLC, but cannot predict the outcome or the impact on our business.

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 our clinical trials. If granted, one or more of the resulting granted patents from REDUCE-IT, for example, would expire in 2039, beyond the 2030 and 2033 expiration dates of currently issued REDUCE-IT patents. However, no assurance can be given that any of our pending patent applications will be granted or, if they grant, that they will prevent competitors from competing with VASCEPA.

Securing patent protection for a product is a complex process involving many legal and factual questions. The patent applications we have filed in the United States and internationally are at varying stages of examination, the timing of which is outside our control. The process to getting a patent granted can be lengthy and claims initially submitted are often modified in order to satisfy the requirements of the patent office. This process includes written and public communication with the patent office. The process can also include direct discussions with the patent examiner. There can be no assurance that the patent office will accept our arguments with respect to any patent application or with respect to any claim therein. 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 2022, we disclosed our 2022 financial outlook. Such outlook is based on estimates, assumptions and the judgment of management. Because of the inherent nature of estimates, including during the uncertainty of COVID-19's impact on our business, we have suspended providing net revenue guidance and there could be significant differences between our estimates and the actual amount of product demand. 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.

The loss of key personnel could have an adverse effect on our business, particularly in light of our recent announcement of management succession plan.

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. Given our rapidly expanding enterprise coupled with a streamlined management structure and sales force, 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 continue to expand our commercialization efforts, particularly on a global scale, we may experience increased turnover among members of our senior management team. We may have difficulty identifying, attracting and integrating new executives to replace any such losses. As we prepare for commercialization in Europe, we need to rapidly hire employees and ensure that they are well trained and working cohesively with core values which are consistent with our existing operations and which, we believe, help improve our position for success. In the United States, employees are increasingly being recruited by other companies. While our business priorities emphasize continued promotion of VASCEPA in the United States, the current and potential threat of generic competition can create employee uncertainty which could lead to increased employee turnover. 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.

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 commercial, research and development and other 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. Any such incident could cause interruptions in our operations or 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. For example, in June 2019, a report published by security researchers claimed that a database belonging to one of our vendors containing information about individuals who use or have expressed interest in VASCEPA was accessible to unauthorized users. Although we were informed that such breach did not include social security numbers or credit card information, we cannot guarantee that a more material breach will not occur in the future. 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 and to repair reputational costs. 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. We may incur significant costs or divert significant internal resources as a result of any regulatory actions or private litigation. Any of the foregoing consequences may adversely affect our business and financial condition.

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.

We are 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 and/or tax laws could have a negative effect on our future profitability.

We expect that our tax jurisdiction will remain in Ireland. 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. Up to December 31, 2019, where a company was 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 Agreement, or DTA, between the UK and Ireland provided that such enterprise would be treated as resident only in the jurisdiction in which its place of effective management is situated. We had at all times sought to conduct our affairs in such a way so as to be solely resident in Ireland for tax purposes by virtue of having our place of effective management situated in Ireland.

These rules regarding determination of tax residence changed effective January 1, 2020, when a modified Ireland-UK DTA came into effect pursuant to the OECD's Multilateral Instrument, or MLI. Under the modified Ireland-UK DTA, from January 1, 2020, we would be solely tax resident in Ireland and not tax resident in the UK if we continued to be centrally managed and controlled in Ireland and if it were mutually agreed between the Irish and UK tax authorities under the MLI "tie-breaker rule" that we are solely tax resident in Ireland. Having made the relevant submission under the amended provisions, we received confirmation effective January 1, 2020 of the mutual agreement of Irish and UK tax authorities that we are solely tax resident in Ireland for the purposes of the modified DTA.

However, we cannot assure you that we are or will continue to be solely resident in Ireland for tax purposes. It is possible that in the future, whether as a result of a change in law or the practice of any relevant tax authority or as a result of any change in the conduct of our affairs, we could become, or be regarded as having become resident in a jurisdiction other than Ireland. Should we cease to be an Irish tax resident, we may be subject to a charge to Irish capital gains tax on our assets and the basis on which our income is taxed may also change. Similarly, if the tax residency of our Irish or UK subsidiaries were to change from their current jurisdiction, they may be subject to a charge to local capital gains tax on their assets and the basis on which their income is taxed may also change.

Our and our subsidiaries' income tax returns are periodically examined by various tax authorities, including the Internal Revenue Service, or the IRS, and states. For example, the IRS began an examination of our 2018 U.S. income tax return in the first quarter of 2020. 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 ongoing or future audits will have a material adverse effect on our consolidated financial position or results of operations.

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 U.S. gross product sales. Customers A, B, and C accounted for 21%, 39%, and 31%, respectively, of gross product sales for the three months ended March 31, 2022, and represented 29%, 37%, and 28%, respectively, of the gross accounts receivable balance as of March 31, 2022. Customers A, B, and C accounted for 27%, 35%, and 31%, respectively, of gross product sales for the three months ended March 31, 2021, and represented 35%, 36%, and 24%, respectively, of the gross accounts receivable balance as of March 31, 2021. We expect that we may have customer concentration risk as we enter additional countries. 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 sustained profitability. For the fiscal years ended December 31, 2021, we reported net income of approximately $7.7 million. For the fiscal years ended December 31, 2020 and 2019, we reported net losses of approximately $18.0 million and $22.6 million, and we had an accumulated deficit as of December 31, 2021 of $1.4 billion. For the three months ended March 31, 2022 and 2021, we reported losses of approximately $31.6 million and $1.6 million, respectively, and we had an accumulated deficit as of March 31, 2022 of $1.5 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 consistently profitable for a full year.

Our ability to become profitable on a sustained basis 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 achieve a steady state of 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 U.S. FDA for marketing in the United States for two important indications, received marketing authorization in Europe and is approved in smaller jurisdictions, it may not gain enough market acceptance to support consistent profitability. We anticipate continuing to incur significant costs associated with expanding the commercialization of VASCEPA. We may not achieve profitability on a sustained basis in the near term due to high costs associated with, for example, our expanded commercialization efforts in the United States and our expected commercialization efforts in Europe. If we are unable to continue to generate robust product revenues, we will not become profitable on a sustained basis in the near term, if ever, and may be unable to continue operations without continued funding.

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 those risks and uncertainties described in this Part II, Item 1A and the following:

- the recent and potential launches of additional generic versions of VASCEPA;
- continued and prolonged disruption to our business, or delays in resuming normal business activities, or reinstating restrictions after protocols have been lifted, from the COVID-19 pandemic;
- 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 payors 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, including our implemented Go-to-Market strategy, and the resulting effectiveness of those efforts;
- disruptions or delays in our or our partners' commercial or development activities, including as a result of political instability, civil unrest, terrorism, pandemics or other natural disasters, such as the coronavirus pandemic;
- the timing and ability of efforts outside the United States, to develop, register and commercialize VASCEPA in Europe, the China Territory, several Middle Eastern and North African countries, and Canada, for example, including obtaining necessary regulatory approvals, favorable pricing 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 ongoing regulatory dialogue.

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 $219.2 million and short-term investment balance of $143.4 million as of March 31, 2022 will be sufficient to fund our projected operations for at least 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could deplete our capital resources sooner

than we expect or fail to achieve positive cash flow. Depending on the level of cash generated from operations, and depending in part on the rate of prescription growth for VASCEPA, additional capital may be required to support planned VASCEPA promotion and potential VASCEPA promotion beyond which we are currently executing and for commercialization of VAZKEPA in Europe. If additional capital is required and we are unable to obtain additional capital on satisfactory terms, or at all, 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 as a result of the timing of certain items, including our purchases of API, VASCEPA promotional and educational activities, including launch activities in Europe and the impact from COVID-19 on our operations and those of our customers and any current or potential generic competition.

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 commercializing VAZKEPA in Europe, including hiring experienced professionals, and for additional regulatory approvals internationally, 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 and governmental inquiries;
- the time and costs involved in obtaining additional regulatory approvals for VASCEPA based on REDUCE-IT results internationally;
- 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, and our business generally, may suffer materially.

Changes in tax laws could have a material adverse effect on our business, financial condition and results of operations.

Tax law and policies in the United States and Ireland are unsettled and may be subject to significant change, including based on adjustments in political perspectives and administration shifts. In the United States and internationally, how to tax entities with international operations, like Amarin, has been subject to significant re-evaluation. We believe we developed VASCEPA in and from Ireland based on understanding of applicable requirements. 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 of 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 under applicable requirements. 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 that 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 and maintain profitability, if otherwise achievable. 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.

Changes in tax laws (including in response to the COVID-19 pandemic) or tax rulings, or changes in interpretations of existing laws, could cause us to be subject to additional income-based taxes and non-income taxes (such as payroll, sales, use, value-added, digital tax, net worth, property, and goods and services taxes), which in turn could materially affect our financial position and results of operations. In particular, there have been a number of significant changes to the U.S. federal income tax rules in recent years and additional tax reform proposed by the Biden administration may be enacted. The effect of any such tax reform is uncertain. As we continue to expand internationally, we will be subject to varied and complex tax regimes, and the tax laws of one jurisdiction may impact our expansion to or operations in other jurisdictions. Additionally, new, changed, modified, or newly interpreted or applied tax laws could increase our partners' and our compliance, operating and other costs, as well as the costs of our products. As we expand the scale of our business activities, any changes in the taxation of such activities may increase our effective tax rate and harm our business, financial condition, and results of operations.

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 29, 2022, we had 397,008,153 common shares outstanding including 396,811,326 shares held as ADSs and 196,827 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.

Further, the effects of Brexit are uncertain and may have a negative effect on global economic conditions, financial markets and our business, which could reduce the price of our ADSs and common shares. In particular, Brexit could lead to a period of considerable uncertainty in relation to the UK financial and banking markets, as well as on the regulatory process in Europe, which could cause the broader global financial markets to experience significant volatility. Asset valuations, currency exchange rates and credit ratings may also be subject to increased market volatility due to the ongoing uncertainty. Lack of clarity about future UK laws and regulations as the United Kingdom determines which EU rules and regulations to replace or replicate could decrease foreign direct investment in the UK, increase costs, disrupt our business, depress economic activity and restrict our access to capital, any of which could negatively impact the price of our ADSs and common shares.

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 under the Exchange Act 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.

If we were to be characterized as a passive foreign investment company there could be adverse consequences to U.S. investors.

A non-U.S. corporation will be classified as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes for any taxable year, if either (i) 75% or more of its gross income for such year consists of certain types of "passive" income or (ii) 50% or more of the value of its assets (determined on the basis of a quarterly average) during such year produce or are held for the production of passive income. Passive income generally includes dividends, interest, royalties, rents, annuities, net gains from the sale or exchange of property producing such income and net foreign currency gains. In addition, a non-U.S. corporation will be treated as owning its proportionate share of the assets and earning its proportionate share of the income of any other corporation in which it owns, directly or indirectly, no more than 25% (by value) of the stock.

Based on certain estimates of our gross income and gross assets, the latter determined by reference to the expected value of our ADSs and shares, we believe that we will not be classified as a PFIC for the taxable year ended December 31, 2021 and we do not

expect to be treated as a PFIC in any future taxable year for the foreseeable future. However, because PFIC status is based on our income, assets and activities for the entire taxable year, which we expect may vary substantially over time, it is not possible to determine whether we will be characterized as a PFIC for any taxable year until after the close of the taxable year. Moreover, we must determine our PFIC status annually based on tests that are factual in nature, and our status in future years will depend on our income, assets and activities in each of those years. There can be no assurance that we will not be considered a PFIC for any taxable year.

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 (although the marketplace rules of the Nasdaq Stock Market require that shareholders holding at least one-third of our outstanding shares of voting stock are present at the meeting or by proxy). 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 UK 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 the potential offer.
- When a person or group of persons who are treated as "acting in concert" with each other (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 of any class representing 10% of shares of that class have been acquired for cash by an offeror (i.e., a bidder) during the offer period (i.e., broadly speaking, the period after the potential offer has been made public) and within 12 months prior to commencement of the offer period, 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 for cash 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.
- The directors of those parties 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 (or even before if the board of the offeree company is aware that an offer is imminent) by the offeree company, which might frustrate the offer are generally prohibited unless shareholders approve these plans (or the bidder consents to the proposed course of action). Frustrating actions would include, for example, issuing new shares, 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 and pension schemes 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.

General Risk Factors

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

The pharmaceutical industry in which we operate 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.

Legal, political and economic uncertainty surrounding the exit of the UK from the EU may be a source of instability in international markets, create significant currency fluctuations, adversely affect our operations in the UK and pose additional risks to our business, revenue, financial condition, and results of operations.

The continued uncertainty concerning the UK's legal, political and economic relationship with the EU after Brexit may be a source of instability in the international markets, create significant currency fluctuations, and/or otherwise adversely affect trading agreements or similar cross-border co-operation arrangements whether economic, tax, fiscal, legal, regulatory or otherwise.

These developments, or the perception that any of them could occur, may have a significant adverse effect on global economic conditions and the stability of global financial markets, and could significantly reduce global market liquidity and limit the ability of key market participants to operate in certain financial markets. In particular, it could also lead to a period of considerable uncertainty in relation to the UK financial and banking markets, as well as on the regulatory process in Europe. Asset valuations, currency exchange rates and credit ratings may also be subject to increased market volatility.

If the UK and the EU are unable to implement acceptable agreements or if other EU member states pursue withdrawal, barrier-free access between the UK and other EU member states or among the European Economic Area, or EEA, overall could be diminished or eliminated. The long-term effects of Brexit will depend on any agreements (or lack thereof) between the UK and the EU.

Such a withdrawal from the EU is unprecedented, and it is unclear how the UK's access to the European single market for goods, capital, services and labor within the EU, or single market, and the wider commercial, legal and regulatory environment, will impact our current and future operations (including business activities conducted by third parties and contract manufacturers on our behalf) and clinical activities in the UK. In addition to the foregoing, our UK operations support our current and future operations and clinical activities in other countries in the EU and EEA and these operations and clinical activities could be disrupted by the ongoing effects of Brexit.

We may also face new regulatory costs and challenges that could have an adverse effect on our operations. The impact of the terms of the recent trade deal between the UK and EU are uncertain. Since the regulatory framework in the UK covering quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from EU directives and regulations, Brexit could materially impact the future regulatory regime with respect to the commercialization of our products in the UK. Any delay in commercializing our products in the UK and/or the EU

could restrict our ability to generate revenue and achieve and sustain profitability. The uncertainty around the UK's future relationship with the EU continues to cause economic uncertainty which could adversely impact customer confidence resulting in customers reducing their spending budgets on our solutions, which could adversely affect our business, revenue, financial condition, results of operations and could adversely affect the market price of our ADSs.

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 deterioration in financial markets and confidence in economies, particularly in light of the continued volatility attributed to COVID-19. 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.

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 burdensome 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. 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.

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

Issuer Purchases of Equity Securities

Shares purchased in the first quarter of 2022 are as follows:

Period	Total Number of Shares Purchased [1]	Average Price Paid per Share
January 1 - 31, 2022	61,599	$ 3.36
February 1 - 28, 2022	80,893	3.29
March 1 - 31, 2022	18,591	3.31
Total	161,083	$ 3.32

(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 5. Other Information

None.

Item 6. Exhibits

The following exhibits are filed or furnished as part of this report.

Exhibit Number	Description	Incorporated by Reference Herein	Form	Date
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.SCH	Inline XBRL Taxonomy Extension Schema Document	Filed herewith		
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	Filed herewith		
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	Filed herewith		
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	Filed herewith		
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	Filed herewith		
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibit 101)	Filed herewith		

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/ Karim Mikhail
Karim Mikhail

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

Date: May 4, 2022

Exhibit 31.1

CERTIFICATION

I, Karim Mikhail, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Amarin Corporation plc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 4, 2022

/s/ Karim Mikhail
Karim Mikhail
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Michael W. Kalb, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Amarin Corporation plc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 4, 2022

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

Exhibit 32.1

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

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

(1) The Company's Quarterly Report on Form 10-Q for the period ended March 31, 2022, to which this Certification is attached as Exhibit 32.1 (the "Quarterly Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Quarterly Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Karim Mikhail

Date: May 4, 2022

Karim Mikhail
President and Chief Executive Officer
(Principal Executive Officer)

/s/ Michael W. Kalb

Date: May 4, 2022

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

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