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, 2023
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.)**
Iconic Offices, The Greenway, Block C Ardilaun Court, 112 – 114 St Stephens Green	**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 Act). YES ☐ NO ☒

407,687,476 common shares were outstanding as of April 30, 2023, including 387,307,491 shares held as American Depositary Shares (ADSs), each representing one Ordinary Share, 50 pence par value per share and 20,379,985 Ordinary Shares.

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PART I

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

	March 31, 2023	December 31, 2022
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 191,412	$ 217,666
Restricted cash	523	523
Short-term investments	112,959	91,695
Accounts receivable, net	133,236	130,990
Inventory	225,813	228,732
Prepaid and other current assets	19,878	19,492
Total current assets	683,821	689,098
Property, plant and equipment, net	187	874
Long-term investments	544	1,275
Long-term inventory	143,730	163,620
Operating lease right-of-use asset	9,190	9,074
Other long-term assets	1,638	458
Intangible asset, net	21,078	21,780
TOTAL ASSETS	$ 860,188	$ 886,179
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 58,779	$ 64,602
Accrued expenses and other current liabilities	183,264	192,678
Current deferred revenue	2,199	2,199
Total current liabilities	244,242	259,479
Long-Term Liabilities:		
Long-term deferred revenue	12,702	13,147
Long-term operating lease liability	9,841	10,015
Other long-term liabilities	8,610	8,205
Total liabilities	275,395	290,846
Commitments and contingencies (Note 5)		
Stockholders' Equity:		
Common stock, £0.50 par, unlimited authorized; 416,080,298 shares issued, 407,265,944 shares outstanding as of March 31, 2023; 412,333,087 shares issued, 404,346,256 shares outstanding as of December 31, 2022	301,285	299,002
Additional paid-in capital	1,890,496	1,885,352
Treasury stock; 8,814,354 shares as of March 31, 2023; 7,986,831 shares as of December 31, 2022	(63,277)	(61,770)
Accumulated deficit	(1,543,711)	(1,527,251)
Total stockholders' equity	584,793	595,333
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 860,188	$ 886,179

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,	
	2023	2022
Product revenue, net	$ 84,654	$ 93,986
Licensing and royalty revenue	1,321	644
Total revenue, net	85,975	94,630
Less: Cost of goods sold	25,794	22,239
Less: Cost of goods sold - restructuring inventory	12,254	—
Gross margin	47,927	72,391
Operating expenses:		
Selling, general and administrative	59,587	90,647
Research and development	5,681	10,051
Total operating expenses	65,268	100,698
Operating loss	(17,341)	(28,307)
Interest income, net	2,221	203
Other income (expense), net	624	(246)
Loss from operations before taxes	(14,496)	(28,350)
Income tax provision	(1,964)	(3,213)
Net loss	$ (16,460)	$ (31,563)
Loss per share:		
Basic	$ (0.04)	$ (0.08)
Diluted	$ (0.04)	$ (0.08)
Weighted average shares:		
Basic	406,177	397,805
Diluted	406,177	397,805

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, 2022	**412,333,087**	**(7,986,831)**	**$ 299,002**	**$ 1,885,352**	**$ (61,770)**	**$ (1,527,251)**	**$ 595,333**
Exercise of stock options	1,232,263	—	744	1,127	—	—	1,871
Vesting of restricted stock units	2,514,948	(827,523)	1,539	(1,539)	(1,507)	—	(1,507)
Stock-based compensation	—	—	—	5,556	—	—	5,556
Loss for the period	—	—	—	—	—	(16,460)	(16,460)
March 31, 2023	**416,080,298**	**(8,814,354)**	**$ 301,285**	**$ 1,890,496**	**$ (63,277)**	**$ (1,543,711)**	**$ 584,793**

	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**

See notes to condensed consolidated financial statements.

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

	Three months ended March 31,	
	2023	**2022**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (16,460)	$ (31,563)
Adjustments to reconcile loss to net cash used in operating activities:		
Depreciation and amortization	63	144
(Accretion) amortization of investments	(907)	374
Stock-based compensation	5,556	6,078
Amortization of intangible asset	702	636
Changes in assets and liabilities:		
Accounts receivable, net	(2,246)	53,419
Inventory	22,809	(52,940)
Prepaid and other current assets	(386)	(5,740)
Other long-term assets	(556)	—
Interest receivable	(16)	140
Deferred revenue	(445)	(372)
Accounts payable and other current liabilities	(15,237)	(69,658)
Other long-term liabilities	115	635
Net cash used in operating activities	(7,008)	(98,847)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Maturities of securities	32,913	113,220
Purchases of securities	(52,523)	(14,171)
Net cash (used in) provided by investing activities	(19,610)	99,049
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of stock options, net of transaction costs	1,871	30
Taxes paid related to stock-based awards	(1,507)	(535)
Net cash provided by (used in) financing activities	364	(505)
NET DECREASE IN CASH AND CASH EQUIVALENTS AND RESTRICTED CASH	(26,254)	(303)
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH, BEGINNING OF PERIOD	218,189	223,372
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH, END OF PERIOD	$ 191,935	$ 223,069
Supplemental disclosure of cash flow information:		
Cash (paid) received during the year for:		
Income taxes	$ (38)	$ 51
Supplemental disclosure of non-cash transactions:		
Initial recognition of operating lease right-of-use asset	$ 446	$ 1,036
Initial recognition of furniture, fixtures and equipment lease	$ 624	$ —

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. The Company has launched commercial operations in certain European countries, such as the United Kingdom, or the UK, and 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 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. On June 18, 2021, the Company was notified that its petition for writ of certiorari to the United States Supreme Court was denied. As a result, the following generic versions of VASCEPA have obtained U.S. FDA approval with labeling consistent with the MARINE indication of VASCEPA and have entered the U.S. market:

Company	FDA MARINE Indication Approval	Launch Date
Hikma Pharmaceuticals USA Inc.	May 2020	November 2020 (1)
Dr. Reddy's Laboratories, Inc.	August 2020	June 2021
Teva Pharmaceuticals USA, Inc.	September 2020	September 2022 (2)
Apotex, Inc.	June 2021	January 2022
Zydus Lifesciences	April 2023	N/A

(1) Hikma launched a 1-gram capsule in November 2020 and a 0.5-gram capsule in March 2023.

(2) Teva launched a 0.5-gram capsule in September 2022 and a 1-gram capsule in January 2023.

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 European Union, or 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 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. 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 had 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 Europe, 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, 2022, 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, 2023 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.

At March 31, 2023, the Company had total assets of $860.2 million, of which $304.9 million consisted of cash and liquid short-term and long-term investments. More specifically, the Company had current assets of $683.8 million, including cash and cash equivalents of $191.4 million, short-term investments of $113.0 million, accounts receivable, net, of $133.2 million and current inventory of $225.8 million. In addition, as of March 31, 2023, the Company had long-term investments of $0.5 million and long-term inventory of $143.7 million. As of March 31, 2023, 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 7—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 45 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.

The following table summarizes the impact of accounts receivable reserves on the gross trade accounts receivable balances as of March 31, 2023 and December 31, 2022:

In thousands	March 31, 2023	December 31, 2022
Gross trade accounts receivable	$ 164,010	$ 187,418
Trade allowances	(18,920)	(44,626)
Chargebacks	(11,854)	(11,802)
Accounts receivable, net	$ 133,236	$ 130,990

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 classifies inventory as long-term inventory when consumption of the inventory is expected beyond the operating cycle. The Company classifies finished goods expected to be consumed within a normal operating cycle and all of VASCEPA's active pharmaceutical ingredient, or API, as current inventory. 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 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 stock-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 tax authorities. The Company is currently under audit by the IRS for its 2018 and 2019 U.S. income tax returns. The audit by the New Jersey Department of Treasury for the years 2012 to 2015 was closed in April 2023. 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 condensed 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. In periods with reported net operating losses, all stock options and restricted stock units 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, 2023 and 2022 are as follows:

	For the Three Months Ended March 31,	
In thousands	2023	2022
Net loss—basic and diluted	$ (16,460)	$ (31,563)
Weighted average shares outstanding—basic and diluted	406,177	397,805
Net loss per share—basic and diluted	$ (0.04)	$ (0.08)

For the three months ended March 31, 2023 and 2022, 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	2023	2022
Stock options	19,639	19,639
Restricted stock and restricted stock units	18,568	15,369
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 29%, 38%, and 27%, respectively, of gross product sales for the three months ended March 31, 2023, and represented 36%, 40%, and 20%, respectively, of the gross accounts receivable balance as of March 31, 2023. 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. 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.

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 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, 2023 and December 31, 2022 and indicate the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value:

	March 31, 2023			
In thousands	Total	Level 1	Level 2	Level 3
Asset:				
Agency Securities	$ 3,999	$ 3,999	$ —	$ —
Money Market Fund	80,105	80,105	—	—
U.S. Treasury Securities	3,153	3,153	—	—
Corporate Bonds	16,035	—	16,035	—
Commercial Paper	79,440	—	79,440	—
Repo Securities	3,250	—	3,250	—
Asset-Backed Securities	546	—	546	—
Certificate of Deposit	8,490	—	8,490	—
Non-US Government Securities	1,399	—	1,399	—
Total	$ 196,417	$ 87,257	$ 109,160	$ -

	December 31, 2022			
In thousands	Total	Level 1	Level 2	Level 3
Asset:				
Money Market Fund	$ 81,870	$ 81,870	$ —	$ —
U.S. Treasury Securities	3,117	3,117	—	—
Agency Securities	1,554	1,554	—	—
Corporate Bonds	28,416	—	28,416	—
Commercial Paper	62,347	—	62,347	—
Repo Securities	3,250	—	3,250	—
Asset-Backed Securities	1,260	—	1,260	—
Certificate of Deposit	9,100	—	9,100	—
Non-US Government Securities	1,393	—	1,393	—
Total	$ 192,307	$ 86,541	$ 105,766	$ —

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 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 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, 2023 and 2022 were losses of $0.2 million and $0.9 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 June 6, 2022, the Company announced a Comprehensive Cost Reduction Plan which includes an organizational restructuring plan to address current shifts within the Company's U.S. business. As part of the plan, the Company completed a reduction of its U.S. field force from approximately 300 sales representatives to approximately 75 sales representatives. During the three months ended March 31, 2023 the Company continued to assess its contractual supplier purchase obligations and has taken steps to amend supplier agreements to align supply arrangements with current and future market demand resulting in charges of $12.3 million recognized within cost of goods sold - restructuring inventory on the condensed consolidated statement of operations. The Company continues to negotiate with other contract suppliers to align its supply arrangements with current and future global demand which may result in additional costs to the Company.

On August 19, 2022, the Company announced that after the conclusion of the fourth and final round of negotiations in Germany with the National Association of Statutory Health Insurance Funds, or GKV-SV, a viable agreement on the reimbursement price of VAZKEPA in Germany could not be reached. As a result, the Company discontinued its German business operations effective September 1, 2022. During the year ended December 31, 2022, the Company recognized approximately $4.2 million within restructuring expense on the condensed consolidated statement of operations, substantially all of which were cash expenditures.

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

In thousands	Restructuring Liability
Balance at December 31, 2022	$ 192
Costs incurred	12,254
Payments	(10,323)
Balance at March 31, 2023	$ 2,123

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 website development costs and 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. 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, 2023, the intangible asset has an estimated weighted-average remaining life of 7.8 years. The carrying value as of March 31, 2023 and December 31, 2022 is as follows:

In thousands	March 31, 2023	December 31, 2022
Technology rights	$ 32,859	$ 32,859
Accumulated amortization	(11,781)	(11,079)
Intangible asset, net	$ 21,078	$ 21,780

(4) Inventory

The Company capitalizes its purchases of saleable inventory of VASCEPA from suppliers that have been qualified by regulatory authorities. Inventories as of March 31, 2023 and December 31, 2022 consist of the following:

In thousands	March 31, 2023	December 31, 2022
Raw materials	$ 127,025	$ 126,391
Work in process	7,085	52,297
Finished goods	235,433	213,664
Total inventory [(1)]	$ 369,543	$ 392,352

(1) Total inventory consists of both current inventory and long-term inventory. During the three months ended March 31, 2023, approximately $2.3 million of inventory was expensed through cost of goods sold for both product dating and non-product dating unsellable inventory.

As of March 31, 2023 and December 31, 2022, the Company had $143.7 million and $163.6 million of long-term inventory, respectively, as consumption is expected beyond the Company's operating cycle.

(5) Commitments and Contingencies

Amarin accrues a liability for legal contingencies when it believes that it is both probable that a liability has been incurred and that it can reasonably estimate the amount of the loss. Amarin reviews these accruals and adjusts them to reflect ongoing negotiations, settlements, rulings, advice of legal counsel and other relevant information. To the extent new information is obtained and Amarin's views on the probable outcomes of claims, suits, assessments, investigations or legal proceedings change, changes in Amarin's accrued liabilities would be recorded in the period in which such determination is made. For the matters referenced below, the amount of liability is not probable nor can the amount be reasonably estimated; therefore, accruals have not been made. In addition, in accordance with the relevant authoritative guidance, for matters in which the likelihood of material loss is at least reasonably possible, Amarin provides disclosure of the possible loss or range of loss. If a reasonable estimate cannot be made, however, Amarin will provide disclosure to that effect.

Amarin intends to vigorously enforce its intellectual property rights relating to VASCEPA, but cannot predict the outcome of these lawsuits described below, those lawsuits described in the Company's Form 10-K for the year ended December 31, 2022 or any subsequently filed lawsuits.

Litigation Updates

In April 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. In addition, in February 2023, Hikma filed a complaint against us in the United States District Court District of New Jersey (case no. 3:23-cv-01016) with consistent allegations as the Dr. Reddy's complaint. Amarin believes it has valid defenses and will vigorously defend against the claims. Such litigation can be lengthy, costly and could materially affect and disrupt our business.

Amarin is also named as a defendant in six 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 antitrust 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.

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 former 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). 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 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 related to the MARINE indication 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. On January 13, 2023, Lead Plaintiff filed an amended complaint that also named the former general counsel, and again alleged that the Company made false statements regarding the ANDA Litigation as well as about the REDUCE-IT indication and Vascepa's financial prospects resulting from REDUCE-IT. All Defendants have moved to dismiss the amended complaint. 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 March 29, 2023, purported investors in the Company's publicly traded securities filed a derivative lawsuit, naming as defendants the Company's former general counsel, the Company's trial counsel for the ANDA litigation, and the Company as nominal defendant, in the Superior Court of New Jersey, Law Division, Monmouth County, captioned *Anne Abramson, John Lissandrello, Georgette Appiano, and Andrew Bondarowicz v. Amarin Corporation plc, Covington & Burling, LLP, Joseph T. Kennedy, and John Does A-Z*, No. MON-L-000984-23 (N.J. Super. Ct. Law Div. Mar. 29, 2023). The complaint alleges that the defendants failed to exercise appropriate diligence and due care in their conduct of the ANDA litigation. Based on those allegations, the complaint alleges that the defendants committed legal malpractice and seeks monetary damages and attorneys' fees and costs. On April 8, 2023, the plaintiffs voluntarily dismissed this case without prejudice.

On March 31, 2023, the Company's former chief executive officer, Karim Mikhail, filed a complaint against the Company and certain of its affiliates in the Superior Court of New Jersey, Law Division – Somerset County, captioned *Mikhail v. Amarin Corporation, plc* (Docket No. SOM-L-000366-23), concerning Mr. Mikhail's alleged "constructive termination" from the Company. The complaint seeks unspecified damages arising from claims for breaches of Employment Agreement, Executive Severance and Change of Control Plan, and the implied covenant of good faith and fair dealing. On April 3, 2023, the case moved to the United States District Court for the District of New Jersey (Civ. No. 3:23-cv-01856).

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 currently has 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.

On June 6, 2022, the Company announced a Comprehensive Cost Reduction Plan which includes a comprehensive cost and organizational restructuring plan to address current shifts within the Company's U.S. business as a result of the generic competition. As part of this plan, the Company has reviewed its contractual supplier purchase obligations and has entered into agreements with suppliers to amend supplier agreements to align supply arrangements with current and future market demand. The Company continues

to negotiate with other contract suppliers to align its supply arrangements with current and future global demand which may result in additional costs to the Company. As of March 31, 2023, the Company has a total of approximately $81.7 million in future contractual purchase obligations without consideration to ongoing discussions with other suppliers. In addition, the Company has total obligations of $39.8 million contingent on either certain suppliers obtaining regulatory approval in Europe or pricing reimbursement in certain European countries not occurring by June 30, 2024.

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 such former shareholder) of £5 million (approximately $5.5 million as of March 31, 2023) 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, 2023.

(6) Equity

Common Stock

There was no common stock activity during the three months ended March 31, 2023 and 2022 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, 2023:

	March 31, 2023
Outstanding stock options	19,638,850
% of outstanding shares on a fully-diluted basis	4%
Outstanding RSUs	18,203,692
% of outstanding shares on a fully-diluted basis	4%

The following table represents equity awards activity during the three months ended March 31, 2023 and 2022:

	Three months ended March 31,	
	2023	2022
Common shares issued for stock option exercises	1,232,263	10,602
Gross and net proceeds from stock option exercises	$ 1,871,758	$ 30,000
Common shares issued in settlement of vested RSUs	2,270,674	493,381
Shares retained for settlement of employee tax obligations ─ RSUs	716,438	161,083
Common shares issued in settlement of vested Performance-based RSUs [(1)]	244,274	—
Shares retained for settlement of employee tax obligations ─ Performance-based RSUs	111,085	—

(1) Performance-based RSUs vested in connection with the achievement of certain sales performance conditions on February 21, 2023. These performance-based RSUs will vest over a three-year period based on continuous service from the grant date.

In February 2023, the Company granted a total of 7,775,850 RSUs and 4,297,500 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 in February 2023, the Company granted a total of 1,368,800 RSUs to employees under the 2020 Plan that vest upon the achievement of specified sales and operational performance conditions.

In February 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 in February 2022, the Company granted a total of 1,089,500 RSUs to employees under the 2020 Plan that vest upon the achievement of specified sales and operational performance conditions.

In January 2022, the Company granted a total of 81,082 RSUs and 103,569 stock options to newly appointed 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 anniversary of the grant date, and are subject to deferred settlement upon the Director's separation of service with the Company. The stock options vested 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, 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.

(7) 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 Europe 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, 2023 and 2022:

In thousands	Trade Allowances	Rebates, Chargebacks and Discounts	Product Returns	Other Incentives	Total
Balance as of December 31, 2022	**$ 44,626**	**$ 136,093**	**$ 8,746**	**$ 2,056**	**$ 191,521**
Provision related to current period sales	22,313	162,858	532	5,008	190,711
Provision related to prior period sales	—	(5,589)	—	107	(5,482)
Credits/payments made for current period sales	(11,534)	(105,542)	—	(3,925)	(121,001)
Credits/payments made for prior period sales	(36,485)	(51,460)	(577)	(839)	(89,361)
Balance as of March 31, 2023	**$ 18,920**	**$ 136,360**	**$ 8,701**	**$ 2,407**	**$ 166,388**

In thousands	Trade Allowances	Rebates, Chargebacks and Discounts	Product Returns	Other Incentives	Total
Balance as of December 31, 2021	**$ 86,636**	**$ 184,756**	**$ 8,089**	**$ 2,745**	**$ 282,226**
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**	**$ 141,859**	**$ 8,288**	**$ 2,061**	**$ 245,252**

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.

(8) 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 2023 and 2022, the Company exercised certain rights under the agreement, resulting in payments of $1.0 million in each of such periods 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 collectively 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 has 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, 2023 and 2022, the Company recognized $0.3 million and $0.2 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, 2023 and December 31, 2022, the Company recognized $8.0 million and $7.7 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 $9.0 million and $9.3 million is recorded in deferred revenue as of March 31, 2023 and December 31, 2022, respectively, on the condensed consolidated balance sheets and will be recognized as revenue over the remaining period of 11 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	April 2022	—
Kuwait	December 2021	March 2023	—
Saudi Arabia	March 2022	—	—

The Company recognized net product revenue of $0.3 million and nil for the three months ended March 31, 2023 and 2022, respectively, 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, 2023 and 2022, the Company recognized $0.1 million and $0.1 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, 2023 and December 31, 2022, the Company has recognized $8.3 million and $8.2 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 $5.4 million and $5.6 million is recorded in deferred revenue as of March 31, 2023 and December 31, 2022, respectively, on the condensed consolidated balance sheets and will be recognized as revenue over the remaining period of 7 years.

The Company recognized net product revenue of $1.6 million and nil for the three months ended March 31, 2023 and 2022, respectively, related to sales to HLS.

CSL Seqirus

In February 2023, the Company entered into an agreement with CSL Seqirus, or CSL, to secure pricing and reimbursement, commercialize and distribute VAZKEPA in Australia and New Zealand. The Company received an upfront payment of $0.5 million which was fully recognized during the first quarter of 2023. In addition to the upfront payment the Company will be eligible to receive event-related milestone payments of approximately $8.0 million and additional product-related milestone payments of approximately $4.0 million. The Company will be responsible for supplying finished product to CSL Seqirus at a price that is the greater of (i) a fixed transfer price, or (ii) a fixed percentage of the net selling price, as defined in the CSL agreement.

The Company assessed this arrangement in accordance with Topic 606 and concluded that the contract counterparty, CSL, is a customer. The Company identified the following distinct performance obligations at the inception of the contract: an exclusive license to use its trademarks in connection with the importation, distribution, promotion, marketing and sale of VASCEPA in the Australia and New Zealand territories.

The transaction price includes the $0.5 million upfront consideration. Any consideration related to event-based or product-based milestones will be recognized when the related milestone events 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, 2023, the Company recognized $0.5 million as licensing revenue related to the upfront payment received in connection with the CSL agreement (none in 2022).

The following table presents changes in the balances of the Company's contract assets and liabilities during the three months ended March 31, 2023 and 2022:

In thousands	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
Three months ended March 31, 2023:				
Contract assets	$ —	$ —	$ —	$ —
Contract liabilities:				
Deferred revenue	$ 15,346	$ —	$ (445)	$ 14,901
Three months ended March 31, 2022:				
Contract assets	$ —	$ —	$ —	$ —
Contract liabilities:				
Deferred revenue	$ 16,709	$ —	$ (372)	$ 16,337

During the three months ended March 31, 2023 and 2022, 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:	2023	2022
Amounts included in contract liability at the beginning of the period	$ 445	$ 372

(9) Leases

Lessee

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 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, the Company 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 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.

On September 13, 2022, the Company entered into a lease agreement for new office space in Dublin, Ireland, or the Dublin Lease. The Dublin Lease commenced on October 1, 2022, or the Dublin Commencement Date, for a 2-year period. Under the Dublin Lease, the Company will pay annual rent of approximately $0.4 million during the duration of the lease term.

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, 2023 and December 31, 2022, the total operating lease liability is $11.7 million and $11.6 million, respectively, and the total operating lease right-of-use asset is $9.2 million and $9.1 million, respectively.

The lease expense for the three months ended March 31, 2023 is approximately $0.9 million. The lease expense for the three months ended March 31, 2022 is approximately $0.6 million.

The table below depicts a maturity analysis of the Company's undiscounted payments for its operating lease liabilities and their reconciliation with the carrying amount of lease liability presented in the statement of financial position as of March 31, 2023:

	Undiscounted lease payments ($000s)
Remainder of 2023	$ 2,284
2024	2,827
2025	2,136
2026	2,135
2027	1,962
2028 and thereafter	5,251
Total undiscounted payments	$ 16,595
Discount Adjustments	$ (4,945)
Current operating lease liability	$ 1,809
Long-term operating lease liability	$ 9,841

Lessor

The Company classifies contractual lease arrangements entered as a lessor as a sales-type, direct financing or operating lease as described in ASC 842. For sales-type leases, the Company derecognizes the leased asset and recognizes the lease investment on the balance sheet.

On January 20, 2023 the Company entered into a sublease agreement for 50,000 square feet of the 67,747 square foot New Jersey Lease and included within the sublease are furniture, fixtures and equipment, collectively the Sublease. The Sublease commenced on February 1, 2023, or the Sublease Commencement Date, for a 7.5 year period. Under the Sublease, the Company will be paid monthly rent of approximately $0.1 million for the first year following the Sublease Commencement Date, and such rent increases by a nominal percentage every year following the first anniversary of the Sublease Commencement Date. In addition, Amarin will provide certain abatements subject to the limitations in the Lease.

The components of lease income are as follows:

	For the Three Months Ended March 31,
	2023
Interest income from sales-type leases	$ 11
Operating lease income	166
Loss recognized at commencement date of sales type lease	(61)
Total	$ 116

Future minimum sales type lease and operating lease receivables as of March 31, 2023 are as follows:

	Sales-Type Leases	Operating Leases
Remainder of 2023	$ 48	$ 411
2024	117	1,006
2025	119	1,029
2026	122	1,051
2027	125	1,073
2028 and thereafter	345	2,974
Total	$ 876	$ 7,544

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, 2022, 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 commercialized product, VASCEPA® (icosapent ethyl) was first approved by the United States, or U.S., 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 and we commercially launched in 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 European Union, or 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 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.

VASCEPA is currently available by prescription in the U.S. and certain other countries throughout the world, as described below. We are responsible for the supply of VASCEPA to all markets in which the branded product is sold, either to and through our collaborations with third-party companies or by us. 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 and no similar litigation is pending outside of the United States.

United States

VASCEPA is sold principally to a limited number of major wholesalers, as well as selected regional wholesalers and retail 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. Since VASCEPA was made commercially available in 2013, more than 20 million estimated normalized total prescriptions of VASCEPA have been reported by Symphony Health. In 2020, following our unsuccessful appeals of a court 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, several of our patents covering the MARINE indication were declared invalid. As a result, the following generic versions of VASCEPA have obtained U.S. FDA approval with labeling consistent with the MARINE indication and have entered the U.S. market with a 1-gram capsule:

Company	FDA MARINE Indication Approval	Launch Date
Hikma Pharmaceuticals USA Inc.	May 2020	November 2020 (1)
Dr. Reddy's Laboratories, Inc.	August 2020	June 2021
Teva Pharmaceuticals USA, Inc.	September 2020	September 2022 (2)
Apotex, Inc.	June 2021	January 2022
Zydus Lifesciences	April 2023	N/A

(1) Hikma launched a 1-gram capsule in November 2020 and a 0.5-gram capsule in March 2023.

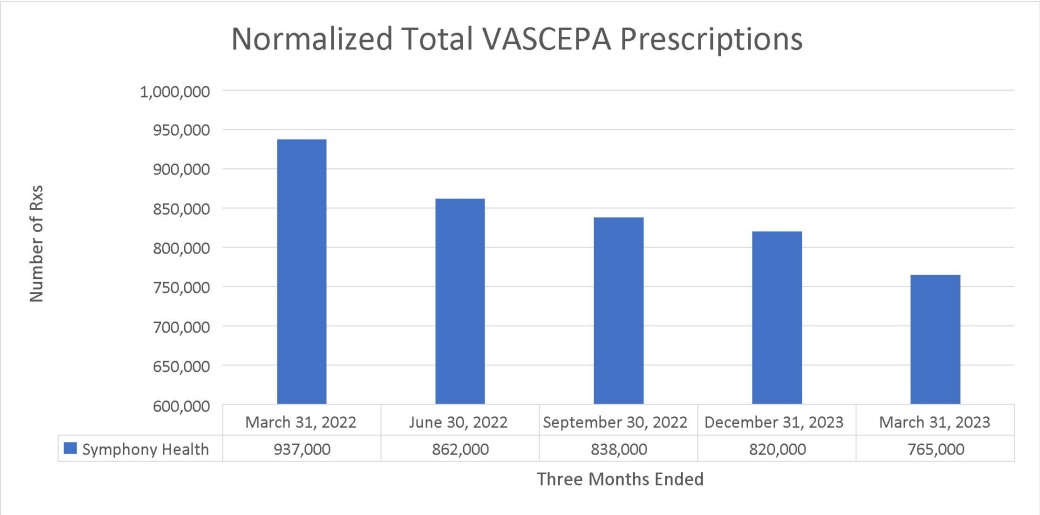
(2) Teva launched a 0.5-gram capsule in September 2022 and a 1-gram capsule in January 2023.

In June 2022, to address shifts within our U.S. business due to these generic competitors, we announced a comprehensive cost and organizational restructuring plan which would result in savings of $100.0 million over the subsequent 12 months compared to 2021 operating expenses. We expect to exceed the $100.0 million in savings during this 12 month period. Our U.S. cost reduction plan included:

- *U.S. workforce reduction:* The reduction of our U.S. field force and corporate positions. Our U.S. field force was reduced from approximately 300 sales representatives to approximately 75 sales representatives.
- *Streamlined operational expenditures:* Includes reductions and reallocations in overall selling, general and administrative expenses as well as savings related to refining our research and development strategy to a more focused, stepwise approach for our fixed-dose combination, or FDC, program.

In alignment with our U.S. cost reduction plan, our focus is primarily on engaging with our top VASCEPA brand prescribers, maintaining our exclusive formulary coverage with specific payers and implementing targeted promotional initiatives amid the continued pressure from generic competitors.

We obtain data from a third party, Symphony Health, who collects and reports 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 products like VASCEPA during such periods. The vendor's estimate utilizes a proprietary projection methodology and are based on a combination of data received from pharmacies and other distributors, as well as historical data when actual data is unavailable. Based on data from Symphony Health, the below chart represents the estimated number of normalized total VASCEPA prescriptions.



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 previous calculations of prescription levels by this vendor 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 this vendor's information and we do not receive prescription data directly from retail pharmacies.

Europe

In 2021, we received marketing authorization and regulatory approval in the EU, England, Wales and Scotland.

Launch of VAZKEPA in individual countries depends on the timing of achieving product reimbursement on a country-by-country basis. To date we have filed 15 dossiers to gain market access in European countries, including in all of the largest countries in Europe. 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 countries where individual price reimbursement is allowed prior to national reimbursement, product can be made available on a patient-by-patient basis, while the national reimbursements negotiations are ongoing. 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. While we believe that we have strong arguments regarding the cost effectiveness of VAZKEPA, the success of such reimbursement negotiations have a significant impact on the assessment of the commercial opportunity of VAZKEPA in Europe. Through the date of this Quarterly Report, we have received and made VAZKEPA available under individual reimbursement or received national reimbursement and launched commercial operations in the following countries, respectively.

Country	Individual Reimbursement	National Reimbursement	Product Availability	Launch Date
Sweden	NA	March 2022	March 2022	March 2022
Finland	NA	October 2022	December 2022	December 2022
United Kingdom/Wales	NA	July 2022	October 2022	October 2022
Austria	September 2022	NA	September 2022	NA
Denmark	June 2022	NA	June 2022	NA

In order to launch impactfully in targeted major markets in Europe we are building a core team of experienced professionals and highly capable local commercial teams involved with pre-launch planning and commercial launch activities and we are leveraging third-party relationships for various support activities. We are implementing an impactful and cost-effective hybrid commercial model balancing optimally digital and face-to-face approach for more impact and cost efficiency, which is or will be utilized throughout Europe as launches are rolled out.

Patients at high risk for cardiovascular disease tend to be treated more often by specialists, such as cardiologists, rather than by 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 than in the United States. However, this greater concentration of at-risk patients being treated by specialists in Europe should allow for more efficient promotion than in the United States. In Europe, VAZKEPA has the benefit of 10 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 entered into 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. 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. 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 had commenced. In Mainland China, the National Medical Products Administration, or NMPA, 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. On February 23, 2022 the Hong Kong Department of Health completed their regulatory evaluation and approved the use of VASCEPA under the REDUCE-IT indication. In China, on October 10, 2022, following the completion of product testing by the China National Institutes for Food and Drug Control, or NIFDC, the final NMPA review of the VASCEPA NDA was initiated with Edding expecting approval by the end of 2022. Due to delays in the regulatory review as a result of the resurgence of COVID-19 in the Beijing area at the end of 2022, Edding has communicated that an approval in Mainland China could be achieved by midyear of 2023.

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	April 2022	—
Kuwait	December 2021	March 2023	—
Saudi Arabia	March 2022	—	—

VASCEPA is under registration in additional countries in the MENA region.

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 had granted priority review status for the upcoming New Drug Submission, which was filed in April 2019. 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 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 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. HLS has obtained reimbursement from all major private and public payors gaining access to a majority of eligible patients in Canada. 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 have completed the first year of a three-year plan to submit and obtain regulatory approval in 20 additional countries in order to ensure that patients in the top 50 cardiometabolic markets worldwide can benefit from VASCEPA. Through the date of this Quarterly Report, we have filed for regulatory review in 10 countries and have received approval in eight countries outside of the United States and European Medicines Agency, or EMA, regulatory approval authority, including in Switzerland, Australia, New Zealand and Israel, under the REDUCE-IT indication. In addition, VAZKEPA has been made available under individual pricing reimbursement in Switzerland.

In February 2023, the Company entered into an agreement with CSL Seqirus, or CSL, to secure pricing and reimbursement, commercialize and distribute VAZKEPA in Australia and New Zealand. The Company will be responsible for supplying finished product to CSL Seqirus. We continue to assess other potential partnership opportunities for VASCEPA with companies outside of the United States and Europe with the intention of partnering in all other international markets where VASCEPA receives local regulatory approval.

Research and Development

Based on REDUCE-IT results, as of the date of the filing of this Quarterly Report, more than 30 clinical treatment guidelines, consensus statements or scientific statements from medical societies, scientific bodies, 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 or statements which were newly received during the first quarter of 2023 through the filing date of this Quarterly Report with recent examples as listed below:

- American Society of Preventive Cardiology published a clinical practice statement including that REDUCE-IT established that IPE reduced CV events among patients with fasting TG 135 to 499 mg/dL. Patients in this trial were already receiving background statin therapy with a median LDL-C of 75 mg/dL. In addition, this statement noted that results from REDUCE-IT have not been replicated in trials using mixed omega-3 fatty acids, suggesting that the CV benefit is attributed to EPA, not DHA.
- NICE released its guidelines on lipid management, which included that IPE is recommended for patients with established cardiovascular disease, or CVD, and elevated fasting TG (≥1.7 mmol/L) and who are taking statins with LDL-C levels between 1.04 and 2.60 mmol/L, as per the REDUCE-IT criteria.

- The Finnish Medical Association and the Finnish Association of Internists published updated guidelines on dyslipidemia treatment, which included that IPE is indicated for patients on statin therapy who have elevated TG levels and are at particularly high risk for arterial disease.
- The National Society of Cardiometabolic Medicine released its consensus statement on the role of omega-3 fatty acids in the prevention and treatment of CVD in Chinese patients. The consensus statement reviewed current knowledge about omega-3 fatty acids and their use in managing CVD in the Chinese population. The following key recommendation was included on use of IPE:
    - High-dose IPE can confer CV benefits in patients with high TG levels at high risk for atherosclerotic cardiovascular disease, or ASCVD, and who have additional CV risk factors (e.g., diabetes mellitus); therefore, IPE may be considered in the primary and secondary prevention settings in patients with high CV risk
    - EPA levels may be the driving force behind CV benefit reported with IPE, a concept supported by JELIS and REDUCE-IT trials in which serum EPA levels were inversely associated with CV risk in a dose-response relationship as well as in a subanalysis of REDUCE-IT, which showed that the CV reduction reported with IPE was attributed to changes in EPA levels rather than lipid biomarkers
    - IPE is the only omega-3 fatty acid approved by the FDA, Health Canada, and the European Medicines Agency for CV risk reduction in patients with CVD or diabetes with other ASCVD risk factors

In March 2023, we added to our growing body of knowledge on VASCEPA as a result of our continued analysis of the REDUCE-IT trial results presented at the American College of Cardiology scientific session. New prespecified and post hoc exploratory analyses of REDUCE-IT found VASCEPA significantly reduced the risk of first cardiovascular death, strokes, heart attacks, coronary revascularization or unstable angina in a subgroup of patients with recent (<12 months) acute coronary syndrome by 37% (HR 0.63; 95% CI, 0.48-0.84, p=0.002).

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 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. In 2022, we reviewed our contractual supplier purchase obligations and began taking steps to amend supplier agreements to align supply arrangements with current and future market demand, while we decrease our current inventory levels primarily related to North America approved inventory. As of March 31, 2023, we had inventory of $369.5 million, of which 90% is inventory approved for use in North America. We continue to negotiate with our contract suppliers to align our supply arrangements with current and future global market demand.

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, VASCEPA is sold to three major wholesalers, as well as several regional wholesalers along with mail order pharmacy providers, or collectively, our distributors or our customers. Most of these customers resell VASCEPA to retail pharmacies for purposes of dispensing VASCEPA to patients. Revenues from VASCEPA sales are recognized upon delivery to the distributor or 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 may differ from period to period. During the quarters ended March 31, 2023 and 2022, our product revenue, net, included adjustment for co-pay mitigation rebates provided by us to commercially insured patients 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 sales to our international commercial partners are recognized when the commercial partners obtain control of our product 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. In the three months ended March 31, 2023, we incurred costs of $12.3 million in *Cost of goods sold - restructuring inventory* related to steps taken to amend supplier agreements to align supply arrangements with current and future market demand.

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. We expense research and development costs as incurred.

Interest income, net and other income (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 income (expense), net, consists primarily of foreign exchange losses and gains as well as sublease income.

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 2023 and 2022 are not more likely than not to be realized.

Critical Accounting Policies and Significant Judgments and Estimates

Our 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 requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expenses. On an ongoing basis, estimates are assessed and adjusted based on historical experience and on current market-specific indicators, environments and assumptions. Actual results may differ from these estimates under different assumptions or conditions. 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 in the accompanying Notes 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.

Comparison of Three Months Ended March 31, 2023 and March 31, 2022

Total revenue, net. We recorded total revenue, net, of $86.0 million and $94.6 million during the three months ended March 31, 2023 and 2022, respectively, a decrease of $8.7 million, or 9%. Total revenue, net consists primarily of revenue from the sale of VASCEPA in the United States. In addition to the United States, during the three months ended March 31, 2023, we also sold VASCEPA by prescription in certain countries in Europe. VASCEPA is also 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 $11.2 million decrease in U.S. net product revenue, offset by a $1.8 million increase in net product revenue outside of the United States and a $0.7 million increase in licensing and royalty revenue.

Product revenue, net. We recorded product revenue, net, of $84.7 million and $94.0 million during the three months ended March 31, 2023 and 2022, respectively, a decrease of $9.3 million, or 10%. This decrease was driven primarily by a 12% decrease in VASCEPA sales in the United States.

We recorded U.S. product revenue, net, of $82.3 million and $93.5 million during the three months ended March 31, 2023 and 2022, respectively. This decrease was driven by a decline in volume and net selling price as a result of the impact from an increase in generic competition in the market. During the three months ended March 31, 2023 there were four generics in the market. During the three months ended March 31, 2022 there were three generics in the market.

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, 2023 by 4% as compared to the three months ended March 31, 2022. Our share of the icosapent ethyl market has decreased to approximately 57% in the three months ended March 31, 2023 compared to approximately 72% in the three months ended March 31, 2022. Additionally, based on prescription levels reported by Symphony Health, VASCEPA-branded prescriptions decreased by 18% in the three months ended March 31, 2023 compared to the three months ended March 31, 2022.

In Europe, we recorded product revenue, net, of $0.4 million and $0.5 million during the three months ended March 31, 2023 and March 31, 2022, respectively.

For the three months ended March 31, 2023 we recorded $1.9 million of product revenue, net, from our collaboration partners and recorded nil product revenue, net during the three months ended March 31, 2022.

Despite the generic competition in the U.S., we remain confident that the global patient need for VASCEPA is high. In 2023, we continue to focus on obtaining pricing reimbursement and launching commercial operations in all remaining European markets as well as progressing regulatory filings and supporting approval processes in up to nine countries throughout the rest of the world.

Licensing and royalty revenue. Licensing and royalty revenue during the three months ended March 31, 2023 and 2022 was $1.3 million and $0.6 million, respectively, an increase of $0.7 million, or 105%. 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 a new 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.
- CSL – a $0.5 million up-front payment which was received upon closing of the agreement in January 2023.

The up-front and milestone payments for Edding and HLS are being recognized over the estimated period in which we are required to provide regulatory and development support pursuant to the agreements. The up-front payment for CSL is recognized upon closing the agreement as no regulatory and development support is required pursuant to the agreement. 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 with 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, 2023 and 2022 was $38.0 million and $22.2 million, respectively, an increase of $15.8 million, or 71%. 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. During the three months ended March 31, 2023, as part of our cost reduction plan we have taken steps to amend supplier agreements to align supply arrangements with current and future demand resulting in a $12.3 million charge which was recorded as cost of goods sold - restructuring inventory. In addition, during the three months ended March 31, 2023, approximately $2.3 million of inventory was expensed through cost of goods sold for both product dating and non-product dating unsellable inventory.

The API included in the calculation of the average cost of goods sold during the three months ended March 31, 2023 and 2022 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. 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 each of the three months ended March 31, 2023 and 2022 was 55% and 76%, respectively. Excluding the restructuring inventory charge, gross margin was 70% for the three months ended March 31, 2023. The remaining decrease in gross margin is primarily 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, 2023 and 2022 was $59.6 million and $90.6 million, respectively, a decrease of $31.1 million, or 34%. Selling, general and administrative expenses for the three months ended March 31, 2023 and 2022 are summarized in the table below:

	Three months ended March 31,	
In thousands	**2023**	**2022**
Selling expense [(1)]	$ 32,154	$ 62,252
General and administrative expense [(2)]	23,090	23,766
Non-cash stock-based compensation expense [(3)]	4,343	4,629
Total selling, general and administrative expense	$ 59,587	$ 90,647

(1) Selling expense for the three months ended March 31, 2023 and 2022 was $32.2 million and $62.3 million, respectively, a decrease of $30.1 million, or 48%. This decrease is primarily due to a reduction in costs associated with our cost reduction plans resulting in decreased promotional initiatives, reduced travel and a decrease in our U.S. sales force as well as our commercial withdrawal from Germany in the third quarter of 2022.

(2) General and administrative expense for the three months ended March 31, 2023 and 2022 was $23.1 million and $23.8 million, respectively, a decrease of $0.7 million, or 3%. This decrease is primarily due to a decrease in employee-related costs as a result of the reduction in force from the cost reduction plans as well as a decrease in branded pharma fees as a result of lower sales due to additional generic entrants in the market. The decrease in general and administrative expense was offset by advisory fees related to the shareholder's special meeting.

(3) Non-cash stock-based compensation expense for the three months ended March 31, 2023 and 2022 was $4.3 million and $4.6 million, respectively, a decrease of $0.3 million, or 6%. 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.

We are investing in building an appropriate foundation for the successful launch of VAZKEPA throughout Europe, advancing regulatory filings internationally and navigating the dynamic U.S. environment. 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 U.S. generic competition as well as timing of pricing reimbursements throughout Europe.

Research and development expense. Research and development expense for the three months ended March 31, 2023 and 2022 was $5.7 million and $10.1 million, respectively, a decrease of $4.4 million, or 43%. Research and development expenses for the three months ended March 31, 2023 and 2022 are summarized in the table below:

	Three months ended March 31,	
In thousands	**2023**	**2022**
REDUCE-IT study [(1)]	$ 270	$ 730
Fixed-dose combination [(2)]	274	1,355
Regulatory filing fees and expenses [(3)]	356	739
Internal staffing, overhead and other [(4)]	3,568	5,778
Research and development expense, excluding non-cash expense	4,468	8,602
Non-cash stock-based compensation expense [(5)]	1,213	1,449
Total research and development expense	$ 5,681	$ 10,051

(1) The decrease in expenses for the REDUCE-IT study is primarily driven by incremental efficiencies applied to ongoing analyses performed on the REDUCE-IT cardiovascular outcomes trial data, further leveraging existing internal resources compared to outsourced support.

(2) Fixed-dose combination expenses relate to the initial start-up and ongoing costs associated with planning and development of the fixed-dose combination of VASCEPA and a statin, which began in 2022.

(3) The decrease in regulatory filing fees is primarily related to higher spend in 2022 relating to the preparation, submission, and review defense of regulatory filings for several countries. The Company has not prepared nor submitted as many regulatory filings in 2023 as in the previous year.

(4) 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 and maintaining regulatory approvals for VAZKEPA in Europe as originally achieved in 2021 as well as further regulatory expansion in other countries throughout 2023. Also included are costs related to qualifying suppliers and costs associated with various other activities, including other costs in collaboration with Mochida and pilot studies regarding VASCEPA.

(5) 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 various factors, including the impact of U.S. generic competition as well as timing of pricing reimbursements throughout Europe.

Interest income, net. Interest income, net for the three months ended March 31, 2023 and 2022 was $2.2 million and $0.2 million, respectively, an increase of $2.0 million, or 994%. Interest income, net represents income earned on cash and investment balances. The increase is primarily due to higher interest rates in the current year compared to the prior year.

Other income (expense), net. Other income (expense), net, for the three months ended March 31, 2023 and 2022 was income of $0.6 million and expense of $0.2 million, respectively, an increase of $0.9 million, or 354%. Other income (expense), net, primarily consists of gains and losses on foreign exchange transactions. The increase in other income (expense), net is due to the continued global expansion and related activity in foreign currencies as well as sublease income relating to the sublease agreement commencing during the current year.

Income tax provision. Income tax provision for the three months ended March 31, 2023 and 2022 was $2.0 million and $3.2 million, respectively. The provision for the three months ended March 31, 2023 is the result of income generated by our U.S. and foreign operations for which tax expense has been recognized based on a full year estimated U.S. and foreign income tax liability.

Liquidity and Capital Resources

As of March 31, 2023, our aggregate sources of liquidity include cash and cash equivalents and restricted cash of $191.9 million, short-term investments of $113.0 million and long-term investments of $0.5 million. We have no indebtedness. Our cash and cash equivalents primarily include checking accounts and money market funds with original maturities of less than 90 days. Our short-term investments consist of securities that will be due in one year or less. Our long-term investments consist of securities that will mature between one and two years. 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	**2023**	**2022**
Cash (used in) provided by:		
Operating activities	$ (7.0)	$ (98.8)
Investing activities	(19.6)	99.0
Financing activities	0.4	(0.5)
Decrease in cash and cash equivalents and restricted cash	$ (26.2)	$ (0.3)

Net cash used in operating activities decreased during the three months ended March 31, 2023 as compared to the same period in 2022 . This is primarily as a result of a decrease in U.S. product revenue in 2023, increased costs associated with commercial and pre-launch operations in Europe, as well as an increase in inventory purchases in the first half of 2022.

Net cash used in investing activities during the three months ended March 31, 2023 increased due primarily to $52.5 million in purchases of investment-grade interest bearing instruments, partially offset by the proceeds from the maturity of $32.9 million in investment-grade interest bearing instruments as compared to the same period in 2022 where proceeds from the maturity of investment-grade interest bearing instruments was $113.2 million, partially offset by $14.2 million in purchases of investment-grade interest bearing instruments.

Net cash provided by financing activities during the three months ended March 31, 2023 as compared to net cash used in financing activities during the same period in 2022 was primarily as a result of an increase in stock option exercises, offset by taxes paid related to stock-based awards.

As of March 31, 2023, we had net accounts receivable of $133.2 million, current inventory of $225.8 million and long-term inventory of $143.7 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, 2023. 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 generic competition in the United States and pricing and reimbursement of VAZKEPA in Europe. In addition, in June 2022 we announced our Comprehensive Cost Reduction Plan to address shifts within our U.S. business which would result in savings of $100.0 million over 12 months compared to 2021 operating expenses. We expect to exceed the $100.0 million in savings during this 12 month period. For Europe, VAZKEPA is available in five countries, including the UK, 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.

As of March 31, 2023, we had cash and cash equivalents of $191.4 million and short-term investments of $113.0 million. In accordance with ASC 205-40, management is required to evaluate our ability to continue as a going concern for at least one year after the date the financial statements are issued. We believe that our cash and cash equivalents and our short-term investments will be sufficient to fund our projected operations for at least one year from the issuance date of our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report and are 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.

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 of 1934, as amended, 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 interim 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 interim principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2023. Based on such evaluation, our interim principal executive officer and principal financial officer have concluded that as of March 31, 2023, 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, 2023, 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 in this Quarterly Report for further details on our current legal proceedings.

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.

Except where denoted with an “”, these risk factors have not been materially updated from our Annual Report on 10-K for the year ended December 31, 2022 filed with the SEC on March 1, 2023, 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, launch and commercialization in Europe and other major markets.
- In the United States, we face increasing competition from generic drug companies in the near term and our revenues and results could continue to be materially and adversely affected.
- In Europe, we are seeking 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.
- The commercial value of VASCEPA outside the United States may be smaller than we anticipate, including if we are unable to secure favorable product reimbursement levels, 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.
- Factors outside of our control make it more difficult for VASCEPA to achieve a level of market acceptance by physicians, patients, healthcare payors and others in the medical community at levels sufficient to achieve commercial success.
- Our previous cost reduction and organizational restructuring plans, and any similar efforts we may undertake in the future, may not be successful in mitigating risks and challenges associated with our U.S. business and establishing a more significant international footprint.
- The manufacture, supply and commercialization, including promotional activities, of VASCEPA is subject to regulatory scrutiny.
- We may not be able to compete effectively against our competitors’ pharmaceutical products, including generic products. In addition, we face competition from omega-3 fatty acids that are marketed by other companies as non-prescription dietary supplements, subjecting us to non-prescription competition and consumer substitution.
- Our supply of product for the commercial market and clinical trials is dependent upon relationships with third-party manufacturers and suppliers, including manufacturers and suppliers who may require us to comply with burdensome minimum purchase commitments, which may be greater than our supply needs.
- Our dependence on third parties in the distribution channel from our manufacturers to patients subjects us to risks that limit our profitability and could limit our ability to supply VASCEPA to large market segments.
- We have limited experience commercializing VASCEPA outside the United States, and we may not be successful in building an infrastructure, including a sales force, that can navigate the regulatory and other dynamics outside of the United States. We are currently, and may continue to be, substantially dependent on third parties for our international efforts, and

we may not be successful in negotiating or establishing relationships with business partners to support and maintain control over our international activities.

- We are dependent on patents, proprietary rights and confidentiality obligations of our employees, agents, business partners and third parties to protect the commercial value and potential of VASCEPA. Enforcing our patent rights is challenging and costly and, even if we are able to successfully enforce our patent rights, our issued patents may not prevent competitors from competing with VASCEPA.
- We have pending patent applications relating to VASCEPA and its use. There can be no assurance that any of these applications will issue patents, and even if patent protection is obtained, it may be insufficient to minimize competition or support our commercialization efforts.

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.

We currently derive substantially all of our revenue from sales of VASCEPA. We may be substantially dependent on sales of VASCEPA for many years. Our financial condition and the success of our company will be materially adversely affected, we may have to further restructure our current operations, and our business prospects will be limited, if we experience any negative developments relating to VASCEPA. For example, in the first quarter of 2020, the U.S. District Court for the District of Nevada 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, that declared as invalid several patents of ours protecting the first U.S. FDA-approved use of our drug, to reduce severely high triglyceride levels, or the MARINE indication. We were unsuccessful in our appeals and our stock price was adversely and materially impacted by the ruling, the results of the appeals process and the introduction of generic competition. If other proprietary rights protecting VASCEPA or its use are challenged, our stock price could further decline, particularly if such challenges, which are costly to defend, are successful.

Although we are exploring ways to broaden our development and commercial pipeline, such efforts are likely to be time consuming, costly and may utilize resources that could otherwise be focused on commercializing VASCEPA. It took over a decade of preceding product development before we received marketing approval for VAZKEPA in March 2021 from the European Commission, or 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 may be initially 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 continue to be materially and adversely affected.

Following the patent litigation rulings against us, generic versions of VASCEPA began launching in the United States in November 2020, and several generic versions are currently available including for both the 0.5-gram and 1-gram capsules, and we expect that VASCEPA could face more competition from generic companies in the United States. 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.

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 substitution laws. Although, we intend to vigorously defend our intellectual property rights related to VASCEPA, 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.

Given the changing dynamic in the U.S. market, we initiated cost and organizational restructuring plans which reduced our U.S. commercial team from approximately 300 sales representatives to approximately 75 sales representatives by the end of 2022. Although this streamlining has resulted in an improved expense structure, such efforts could impact employee morale and make hiring and retaining talented personnel more challenging, may not result in all of the cost-savings or other benefits we anticipate and are costly to implement.

In Europe, we are seeking 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.

We continue our development efforts to support commercialization of VASCEPA in major markets outside the United States, particularly in light of the level of competition, including from generic products, in the United States. This process is conducted on a country-by-country basis and is time consuming and complex, and, even though the EC approved the marketing authorization for VAZKEPA in March 2021, and we have received positive national pricing and reimbursement decisions in England and Wales, Sweden and Finland, there is no guarantee that we will be able to negotiate and obtain further reimbursement and pricing terms on favorable terms, or at all, in the countries where we are pursuing commercialization. Further, successful progress or pricing terms in one country may not be indicative of our outcomes in other jurisdictions. For example, although the UK's National Institute for Health and Care Excellence, or NICE, announced final guidance for reimbursement for VAZKEPA® and use across the National Health Service, or NHS, in England and Wales, we decided to discontinue business operations in Germany following the conclusion of negotiations with the National Association of Statutory Health Insurance Funds during which a viable agreement on the reimbursement price of VAZKEPA could not be reached. The Arbitration Board process concluded without an agreement in November 2022 and although we plan to resubmit a pricing and reimbursement dossier with new data in Germany, we may be unable to resume commercial operations in Germany. We may not be successful in obtaining additional approvals in a timely manner with acceptable terms, or in additional countries, and if we are unable to do so, and continue to face increased competition in the United States, our financial position could be materially and adversely impacted.

We have been developing VAZKEPA on our own in Europe, where we have limited experience. We are exploring possible strategic collaborations in smaller markets within Europe and in other major markets, which will increase our reliance on third parties, over whom we have limited control. We currently have multiple partners for the development and commercialization of VASCEPA in select geographies and are assessing potential partners to commercialize VASCEPA in other parts of the world. We have strategic collaborations for the development and commercialization of VASCEPA in Canada, the Middle East, Australia, New Zealand 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, or that we will be able to rely upon these third parties; 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 commercial value of VASCEPA outside the United States may be smaller than we anticipate, including if we are unable to secure favorable product reimbursement levels, 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.

There can be no assurance as to the market for VASCEPA outside the United States, or we may face challenges in successfully achieving market opportunities available to us. Despite having received EC approval to commercialize VAZKEPA in Europe and approval elsewhere around the world, 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, any of which could limit the market opportunity, or our ability to capitalize on such opportunity, for VASCEPA.

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, and is not always successful. For example, after the conclusion of negotiations with the National Association of Statutory Health Insurance Funds, a viable agreement on the reimbursement price of VAZKEPA in Germany could not be reached. As a result of the negotiation outcome, we discontinued our German operations as of September 1, 2022. In November 2022, the Arbitration Board process concluded without an agreement.

Further, 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. The time required to secure reimbursement tends to vary from country to country and cannot be reliably predicted at this time. 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 obtaining all necessary 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.

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

We may be unsuccessful in expanding our global footprint. We are launching VAZKEPA on our own in the most commercially significant markets in Europe. The commercial launch of a new pharmaceutical product is a complex and resource heavy undertaking for a company to manage and may be impacted by decisions by and interactions with local regulators. We have no prior experience as a company operating a commercial-stage pharmaceutical business in Europe. As noted above, a viable agreement on the reimbursement price of VAZKEPA in Germany could not be reached with German regulators and we have discontinued our Germany business operations. 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 and senior management, particularly in light of our recent reductions in force and turnover on the management team;
- 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 sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe or patients to use VASCEPA;
- overestimating the addressable market for VASCEPA;
- 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;
- 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
- any continued or resumed impact from COVID-19 on healthcare providers, patients and personnel.

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. 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 of the United States have affected and will continue to affect access to and sales of our products.

Outside of 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 of 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. We as an organization have limited experience in navigating the pricing and reimbursement regimes outside of the United States. The foreign regimes are varied and complex, and this 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 achieve 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 CV 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 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, or our REDUCE-IT indication.

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 generic competition. If VASCEPA does not achieve an adequate level of acceptance, we may not generate product revenues sufficient to become profitable, or, even if we do achieve profitability, we may not be able to generate consistent profitability. 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 adjudicated, settled and 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;
- the prevalence and severity of any side effects and warnings in VASCEPA's approved labeling internationally;
- peer review of different elements of data supporting our REDUCE-IT indication over time;
- continued review and analysis of the results of our clinical data supporting our REDUCE-IT indication 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 our 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 teams;
- publicity concerning VASCEPA or competing products;
- our ability to continually promote VASCEPA in the United States consistent with 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 the COVID-19 pandemic, international conflicts and political unrest, all of which could inhibit our ability to promote VASCEPA regionally and which 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.

Any one or more of the above factors could have a negative impact on our ability to successfully commercialize VASCEPA, which would in turn have a negative impact on our financial condition.

Additional data or related interpretations that are generated or arise over time related to REDUCE-IT might not meet expectations, and the perception of REDUCE-IT results and VASCEPA revenue potential may suffer and our stock price may decline.

While the U.S. FDA approved the expanded label for VASCEPA for the REDUCE-IT indication in 2019, additional data assessment by international regulatory authorities or otherwise could yield additional information to inform greater understanding of study outcome, which information could impact the perception of VASCEPA. Such data or interpretations may not be favorable for us. 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 our REDUCE-IT trial 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 adversely impact 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 render new or adverse 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. Results from this study were presented during the 2022 American Heart Association Scientific Sessions in November 2022 and were consistent with the evidence from the REDUCE-IT study.

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. Even though such results from these trials were positive, additional clinical development efforts may be necessary in these markets to demonstrate the effectiveness of VASCEPA, which may be costly to pursue, or may not produce the desired or expected results.

If the outcomes of any study involving VASCEPA and icosapent ethyl is unfavorable, 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, or perceptions about the potential for VASCEPA, including as a treatment for broader indications, may suffer. If this occurs our revenue and business could suffer and our stock price could significantly decline.

Our previous cost reduction and organizational restructuring plans, and any similar efforts we may undertake in the future, may not be successful in mitigating risks and challenges associated with our Company's U.S. business and establishing a more significant international footprint.

If we are not successful in our efforts to continue to market and sell VASCEPA in the United States, including following the implementation of our cost reduction and organizational restructuring plan, our anticipated revenues or our expenses could be materially adversely affected, and we may not maintain profitability in the United States or obtain profitability internationally. Further, we may need to cut back on research and development activities or we may need to 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.

Our promotional initiatives have had to adjust over the last several years, given the impact of COVID-19 and international instability, which efforts have been costly and require considerable resources. Shifts from traditional face-to-face interactions to mostly virtual outreach, specifically, access to healthcare professionals through digital or other channels, were not as productive as in-person interactions in promoting use of VASCEPA and we have been pursuing increased face-to-face interactions with targeted health care professionals as protocols have eased and travel has resumed to more stable levels. 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.

The manufacture, supply and commercialization, including promotional activities, of VASCEPA is subject to regulatory scrutiny.

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 the U.S. government, 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.

As a result of a lawsuit that we and a group of independent physicians filed against the U.S. FDA in 2015, we were granted preliminary relief 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. The U.S. FDA did not appeal the court's ruling and ultimately 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.

Promotional activities in the biotechnology and pharmaceutical industries generally are subject to considerable regulatory scrutiny and, may be subject to enhanced scrutiny to ensure that our promotion remains within the scope covered by the settlement. 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. Although 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 product, including generic products. In addition, we face competition from omega-3 fatty acids that are marketed by other companies as non-prescription dietary supplements, subjecting us to non-prescription competition and consumer substitution.

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. We expect 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 companies such as Hikma, Dr. Reddy's, Apotex and Teva, all of which have greater resources than us, 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.

We also face considerable competition in the United States from branded products and generic versions of competing branded products and formulations, including Lovaza®, Tricor,® Trilipix®and Niaspan®, all of which have multiple generic competing versions. We compete with 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.

Further, drugs in development that are expected to compete with VASCEPA if they are ultimately approved and commercialized, and the perceived safety and efficacy of such commercialized drugs or drug products, could have a negative impact on the perceived safety and efficacy of VASCEPA.

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 CV 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 CV risk reduction indication without the need in advance to conduct a long and expensive CV 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 and other regulators. 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.

Consistent with the competitive landscape in the United States, our competitors outside of the United States 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 competitors seek to compete with 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 precluded 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 such protection expired on December 13, 2022, three years from the date of U.S. FDA approval of the REDUCE-IT sNDA.

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 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, 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 Hikma, Dr. Reddy's, Apotex and Teva have done. 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.

The generic market entries beginning in 2020 have limited our U.S. sales, and had an adverse impact on our business and results of operations. 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. It often requires considerable advanced planning and long-term financial commitments to ensure sufficient capacity is available when needed. Certain generic competitors filed lawsuits against us claiming we have engaged in anticompetitive practices related to our building of adequate supply for our needs, and 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 and resulting regulatory scrutiny could be costly for us and could negatively and materially interfere with our business plans.

The active pharmaceutical ingredient in VASCEPA is difficult and time consuming to manufacture, and often requires considerable advanced planning and necessitates long-term financial commitments to ensure sufficient capacity is available when needed. We have invested over a decade of resources and expenses to develop active pharmaceutical ingredient, or API, with our third-party supplier, and to otherwise build our supply chain, improve our technical knowhow, establish manufacturing processes and obtain related regulatory approvals to help enable our suppliers to supply our clinical and commercial needs globally. Despite such efforts, the stability of the supply chain is largely out of our control and is subject to market and supply volatility and the actions of third parties. Any disruption to the supply chain, including the manufacturing processes and availability of API, would be disruptive to our business and would have a negative impact on our results of operations.

In April 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 API 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 that such alleged violations resulted in higher prices to consumers. In addition, in February 2023, Hikma filed a complaint against us in the United States District Court District of New Jersey (case no. 3:23-cv-01016) making allegations consistent with the Dr. Reddy's complaint. Such litigation can be lengthy, costly and could materially affect and disrupt our business.

In addition, as noted above, we have also received a CID from the U.S. FTC and a subpoena from the New York Attorney General with respect to practices relating to our supply of the API in VASCEPA. 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.

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 CV 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. We may not be successful in such efforts, or such efforts may prove too costly to be effective.

In addition, the net price of VASCEPA to patients even after insurance reimbursement and offered discounts could be 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. VASCEPA 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.

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 litigation and settlement with the U.S. FDA, as discussed above, 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. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are also subject to periodic unannounced inspections by the U.S. FDA and state agencies for compliance with cGMP requirements. In addition, under the Food and Drug Omnibus Reform Act of 2022, or FDORA, sponsors of approved drugs and biologics must provide 6 months' notice to the FDA of any changes in marketing status, such as the withdrawal of a drug, and failure to do so could result in the FDA placing the product on a list of discontinued products, which would revoke the product's ability to be marketed.

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 cannot predict when these investigations will be resolved, the outcome of the investigations or their potential impact on 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, and our reputation may be harmed. 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.

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. 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 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 in 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 which may not be favorable to us.

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.

In the U.S. and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any products for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

There has been increasing legislative and enforcement interest in the United States with respect to 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. The Inflation Reduction Act of 2022, or IRA, includes several provisions that may impact our business to varying degrees, including provisions that that reduce the out-of-pocket spending cap for Medicare Part D beneficiaries from $7,050 to $2,000 starting in 2025, thereby effectively eliminating the coverage gap, impose new manufacturer financial liability on all drugs in Medicare Part D, allow the U.S. government to negotiate Medicare Part B and Part D pricing for certain high-cost drugs and biologics without generic or biosimilar competition, require companies to pay rebates to Medicare for drug prices that increase faster than inflation, and delay until January 1, 2032 the implementation of the HHS rebate rule that that would have limited the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one rare disease designation and for which the only approved indication is for that disease or condition. If a product receives multiple rare disease designations or has multiple approved indications, it may not qualify for the orphan drug exemption. The effect of IRA on our business and the healthcare industry in general is not yet known.

In addition, President Biden has issued multiple executive orders that have sought to reduce prescription drug costs. In February 2023, HHS also issued a proposal in response to an October 2022 executive order from President Biden that includes a proposed prescription drug pricing model that will test whether targeted Medicare payment adjustments will sufficiently incentivize manufacturers to complete confirmatory trials for drugs approved through FDA's accelerated approval pathway. 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.

The continuing efforts of the government, insurance companies, managed care organizations and other payers of healthcare services to contain or reduce costs of healthcare may adversely affect:

- the demand for any of our product candidates, if approved;
- the ability to set a price that we believe is fair for any of our product candidates, if approved;

- our ability to generate revenues and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

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 operating results and 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 third countries, including 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. They require a case-by-case assessment of the law in the recipient country to ensure it provides "essentially equivalent" protections to safeguard the transferred personal data as the EEA, and require businesses to adopt supplementary measures if such standard is not met. The new SCCs do not apply to the UK, but the UK Information Commissioner's Office has published its own transfer mechanism, the International Data Transfer Agreement, or UK IDTA, which entered into force on March 21, 2022, and enables data transfers originating from the UK. It requires a similar assessment of the data protection provided in the importer's country. We will be required to transition to the new forms of transfer mechanisms and doing so will require significant effort and cost. The new transfer

mechanisms 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 or the UK GDPR, and the related national data protection laws of the EEA Member States or the UK may result in substantial fines. 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 costly, 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 the REDUCE-IT indication, 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.

For example, the June 2020 CIDs from the DOJ informing us that the DOJ is investigating whether aspects of our promotional speaker programs and copayment waiver program violated the U.S. Anti-Kickback Statute and from the FCA relating to the sale and marketing of VASCEPA by us and our previous co-marketing partner, Kowa America, as well as the March 2021 CID from the FTC 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 require us to produce documents and answer written questions, or interrogatories, relevant to specified time periods. The subpoena from the New York State attorney general covers the same subject matter on which the FTC CID is focused. 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.

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 scale our infrastructure for commercializing VASCEPA based on market dynamics for VASCEPA in the United States and commercial initiatives and plans for VAZKEPA in Europe and other parts of the world, we may encounter difficulties in managing the size and adaptability of our operations successfully.

The process of establishing, maintaining, expanding and streamlining a commercial infrastructure is difficult, expensive and time consuming, particularly when such efforts need to adapt to changing market and business dynamics. We implemented cost and organizational restructuring plans, which included a reduction to our U.S. commercial team to approximately 75 sales representatives by the end of 2022. Our sales team promotes VASCEPA to a targeted group of physicians and other healthcare professionals in select geographies in the United States who recognize the potential benefit to patients, and this team is not large enough to call upon a sufficient number of physicians.

In addition to sales force reductions 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. If we are successful in obtaining sufficient

approvals and adequate pricing and reimbursement levels in major markets in Europe and elsewhere, we will need to ensure that our operations are adequate to support a commercial launch and continued promotion. Although we are preparing for growth in Europe and elsewhere by expanding our infrastructure, we are operating with streamlined teams and will need to expand internally and 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. 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. 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.

Our life-cycle management is substantially dependent on our ability to develop, obtain regulatory approval and commercialize a fixed-dose combination of VASCEPA and yet to be disclosed statins. 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, 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 a 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.

****The continued scale, scope and duration of business interruptions caused by the COVID-19 pandemic and related recovery efforts remain uncertain.***

Despite recent improvements, the ongoing presence 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, including resurgences, and the efficacy of recovery efforts;
- governmental, business and individuals' actions taken in response to the pandemic;
- the impact of the pandemic on economic and political activity and our supply chain;
- 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;
- the impact that changes in patients' and healthcare providers' behavior and practices regarding face to face visits may have on our commercialization efforts, including whether virtual interactions will be as impactful as traditional, in-person interactions;
- 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; 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.

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, including manufacturers and suppliers who may require us to comply with burdensome minimum purchase commitments, which may be greater than our supply needs.

We have no in-house manufacturing capacity and rely entirely 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, or if they insist on burdensome terms, such as excessive minimum supply commitments, we may not be able to obtain adequate quantities of product in a timely manner, at cost efficient levels 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 potentially 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 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. We continue to take steps to negotiate our contract supply agreements to align supply arrangements with current and future global market demand.

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 and indirect commercialization of VASCEPA. We are also committed to providing supply to our commercial partners and distributors in Australia and New Zealand, 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 of commercial launch, including in China and various European countries. 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, and the ability to qualify any new suppliers. 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. For example, the EMA has not yet approved use of each of our suppliers used for VASCEPA in the United States for supply of VAZKEPA in the EU.

Further, 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.

If our third-party manufacturing capacity is not appropriately qualified 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, or any minimum purchase requirements, may exceed actual demand for VASCEPA.

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.

If our minimum purchase commitments exceed our supply needs for VASCEPA, we may have to renegotiate with partners in our supply chain who may not be incentivized to renegotiate terms that are favorable to us, or at all. If we are unable to secure adequate levels of supply to meet demand, our financial condition could be negatively and materially impacted.

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 on us 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 past 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. Since March 2020 when foreign and domestic inspections of facilities were largely placed on hold, the U.S. FDA has been working to resume pre-pandemic levels of inspection activities, including routine surveillance, bioresearch monitoring and pre-approval inspections. 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 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.

We have limited experience commercializing VASCEPA outside the United States, and we may not be successful in building an infrastructure, including a sales force, that can navigate the regulatory and other dynamics outside of the United States. We are currently, and may continue to be, substantially dependent on third parties for our international efforts, and we may not be successful in negotiating or establishing relationships with business partners to support and maintain control over our international activities.

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, Canada and most recently Australia and New Zealand. We continue to assess other opportunities to develop VASCEPA commercialization outside of the United States through similar arrangements.

For example, Edding is responsible for development and commercialization activities in the China Territory and associated expenses under our development, commercialization and supply agreement with them. Additionally, Edding is required to conduct clinical trials in the China Territory to secure regulatory approval in certain territories. Edding has successfully undertaken clinical trials and approval initiatives under our arrangement with them, including the announcement of statistically significant positive topline results from Edding's Phase 3 clinical trial of VASCEPA and has obtained approval for VASCEPA in Hong Kong under the REDUCE-IT indication with anticipated approval in Mainland China expected by midyear 2023. However, Edding may be required to undertake clinical development efforts in these markets, or Edding may face challenges or be unsuccessful in pursuing commercial launch. Further, any development and regulatory efforts in the China Territory may be negatively impacted if the coronavirus pandemic worsens, 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.

We are party to arrangements with Biologix FZCo, or Biologix, to register and commercialize VASCEPA in several Middle Eastern and North African countries, with HLS Therapeutics Inc., or HLS, to register, commercialize and distribute VASCEPA in Canada and with CSL Seqirus, or CSL, to commercialize and distribute VASCEPA in Australia and New Zealand. Although Biologix is currently actively commercializing VASCEPA in the United Arab Emirates and Lebanon, and HLS is currently commercializing VASCEPA in Canada, we are completely reliant on these third parties to secure approval and successfully commercialize the product in those markets, which markets can be complex and challenging. Further, development and 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.

If Edding, Biologix, HLS or CSL, or other third parties who we rely on for development and commercialization of VASCEPA, do not successfully carry out their contractual obligations or meet expected deadlines, our recourse and remedies against these parties is limited.

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 launch of VAZKEPA in Germany in September 2021 (where operations were subsequently discontinued) and the launch of VAZKEPA in certain countries in the fourth quarter of 2022, including the UK in October 2022, 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.

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 us 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. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. Refer to "*Item 1. Business - Government Regulation - Fraud and Abuse Laws and Data Regulation*" for further details.

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, the June 2020 CIDs from the DOJ informing us that the DOJ is investigating whether aspects of our promotional speaker programs and copayment waiver program violated the U.S. Anti-Kickback Statute, and from the FCA relating to the sale and marketing of VASCEPA by us and our previous co-marketing partner, Kowa America, as well as the March 2021 CID from the FTC 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 require us to produce documents and answer written questions, or interrogatories, relevant to specified time periods; as does the subpoena from the New York State attorney general regarding the same subject matter on which the FTC CID is focused. As noted, we are cooperating with the government, but 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.

It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations.

In addition, 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 obligations of our employees, agents, business partners and third parties to protect the commercial value and potential of VASCEPA. Enforcing our patent rights is challenging and costly and, even if we are able to successfully enforce our patent rights, our issued patents may not prevent competitors from competing with 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.

We plan to vigorously defend our rights under issued patents, however such defense activities can be costly to pursue and may not have the desired results. 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 CV 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. On October 13, 2022, the district court granted final judgement and the Company is appealing (Fed. Cir. No. 23-1169 filed November 21, 2022) the decision of the district court but cannot predict the outcome or the impact on its business. We entered into a settlement agreement with Health Net, LLC on December 26, 2022. 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.

Patent litigation is a time-consuming and costly process. There can be no assurance that we will be successful in enforcing any 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.

We have pending patent applications relating to VASCEPA and its use. There can be no assurance that any of these applications will issue patents, and even if patent protection is obtained, it may be insufficient to minimize competition or support our commercialization efforts.

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/VAZKEPA. 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.

However, our pending patent applications may not 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 2023, we disclosed our 2023 financial outlook. Such outlook and estimates are based on estimates, assumptions and the judgment of management. Because of the inherent nature of estimates, including during the uncertainty of our European launch and the impact from U.S. generic competition, we have suspended providing net revenue guidance, as 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 and initiative 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 recent senior management changes.***

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 and the changes to our Board and the recently announced departure of our Chief Executive Officer, 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 continued or 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 expand commercialization efforts 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 remains focused on continued promotion of VASCEPA in the United States, and expansion in Europe, the current and potential threat of generic competition and our recent reductions in force 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 or 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. 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, a more material breach could 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 state tax authorities. 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 29%, 38%, and 27%, respectively, of gross product sales for the three months ended March 31, 2023, and represented 36%, 40%, and 20%, respectively, of the gross accounts receivable balance as of March 31, 2023. 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. 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 year ended December 31, 2022 and 2020, we reported net losses of approximately $105.8 million and $18.0 million, respectively. For the fiscal year ended December 31, 2021, we reported net income of approximately $7.7 million. We had an accumulated deficit as of December 31, 2022 of $1.5 billion. For the three months ended March 31, 2023 and 2022, we reported losses of approximately $16.5 million and $31.6 million, respectively, and we had an accumulated deficit as of March 31, 2023 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 commercialization and research and development, 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.

We may never generate sufficient revenue to achieve a steady state of profitability.

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 consistently 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 future potential launches of additional generic versions of VASCEPA;
- 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;
- 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, and our cost and reorganization efforts, including our recent cost reduction plan, 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;
- additional developments regarding our intellectual property portfolio and regulatory exclusivity protections, if any;
- outcomes of litigation and other legal proceedings;
- 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; 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 $191.4 million and short-term investment balance of $113.0 million as of March 31, 2023 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. 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 and VASCEPA promotional and educational activities, including launch activities in Europe 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 and 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 us, 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 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.

The IRA was enacted into law on August 16, 2022. Included in the IRA was a provision to implement a 15% corporate alternative minimum tax on corporations whose average annual adjusted financial statement income during the most recently-completed three-year period exceeds $1.0 billion. This provision is effective for tax years beginning after December 31, 2022. We are in the process of evaluating the provisions of the IRA.

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 30, 2023, we had 407,687,476 common shares outstanding including 387,307,491 shares held as ADSs and 20,379,985 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 long-term effects of the UK's departure from the EU, or Brexit, remain 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, ongoing uncertainty related to Brexit and the long-term relationship between the UK and the EU could lead to a period of disruption in 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 that they beneficially own. 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. 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, 2022 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 UK left the EU on January 31, 2020, but remained in the EU's customs union and single market for a transitional period that expired on December 31, 2020. Although the UK entered into a trade and cooperation agreement with the EU, which was provisionally applicable since January 1, 2021 and formally applicable since May 1, 2021, the UK-EU TCA, that provides for, among other things, the free movement of goods between the United Kingdom and the EU, continued legal uncertainty and potentially divergent national laws and regulations in areas not specifically addressed in the UK-EU TCA may continue to affect trade and other interactions between the UK and the EU. In addition, UK service suppliers no longer benefit from automatic access to the entire EU single market and free movement of goods is subject to increased bureaucracy. The loss of these benefits could impact the attractiveness of the UK as a global business and financial center, which may have an adverse effect on the rate of economic growth in the UK and the EU.

On a greater macroeconomic level, ongoing uncertainty related to Brexit and the UK's legal, political and economic relationship with the EU 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 cooperation arrangements whether economic, tax, fiscal, legal, regulatory or otherwise.

These developments 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.

The long-term effects of Brexit are currently unknown and will depend on the evolution of any agreements (or lack thereof) that the UK makes to retain access to the EU markets.

Such a withdrawal from the EU is unprecedented, and it remains 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 long-term 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 and other global instability. We may also have to scale back or further restructure our operations. If we are unable to obtain additional funding when needed , 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.

We are currently operating in a period of economic uncertainty and capital markets disruption, which has been significantly impacted by geopolitical instability, including in Europe, and record inflation. Our business, financial condition and results of operations could be materially and adversely affected by any negative impact on the global economy and capital markets resulting from these global economic conditions, particularly if such conditions are prolonged or worsen.

Economic uncertainty in various global markets, including the U.S. and Europe, caused by political instability and conflict, such as Russia's invasion of Ukraine, and economic challenges caused by the COVID-19 pandemic, have led to market disruptions, including significant volatility in commodity prices, credit and capital market instability and supply chain interruptions, which have caused record inflation globally.

Although, to date, our business has not been materially impacted by these global economic and geopolitical conditions, it is impossible to predict the extent to which our operations will be impacted in the short and long term, or the ways in which such instability could impact our business and results of operations. The extent and duration of these market disruptions, whether as a result

of the military conflict between Russia and Ukraine, geopolitical tensions, record inflation or otherwise, are impossible to predict, but could be substantial. Any such disruptions may also magnify the impact of other risks described in this report.

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

Issuer Purchases of Equity Securities

Shares purchased in the first quarter of 2023 are as follows:

Period	Total Number of Shares Purchased [1]	Average Price Paid per Share
January 1 - 31, 2023	485,433	$ 1.81
February 1 - 28, 2023	218,374	1.82
March 1 - 31, 2023	123,716	1.87
Total	827,523	$ 1.82

[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 incorporated by reference or filed or furnished as part of this report.

Exhibit Number	Description	Incorporated by Reference Herein	
		Form	Date
10.1	Consent of Landlord to Sublease dated as of January 20, 2023, among Amarin Pharma, Inc. ST Shared Services LLC and Liberty Denver Wood LLC	Annual Report on Form 10-K for the year ended December 31, 2022, as Exhibit 10.44	March 1, 2023
10.2	Guaranty dated January 20, 2023, issued by MEH, Inc.	Annual Report on Form 10-K for the year ended December 31, 2022, as Exhibit 10.45	March 1, 2023
10.3	Sublease Agreement dated January 20, 2023, by and between Amarin Pharma, Inc. and ST Shared Services LLC	Annual Report on Form 10-K for the year ended December 31, 2022, as Exhibit 10.46	March 1, 2023
31.1	Certification of Interim President and Chief Executive Officer (Interim 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 Interim President and Chief Executive Officer (Interim 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 Exhibits 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/ Aaron Berg
Aaron Berg

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

Date: May 3, 2023

AMARIN CORPORATION PLC

By: /s/ Tom Reilly
Tom Reilly

Senior Vice President, Chief Financial Officer
(Principal Financial and Accounting Officer)
(On behalf of the Registrant)

Date: May 3, 2023

Exhibit 31.1

CERTIFICATION

I, Aaron Berg, 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 3, 2023

/s/ Aaron Berg

Aaron Berg
Interim President and Chief Executive Officer
(Interim Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Tom Reilly, 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 3, 2023

/s/ Tom Reilly

Tom Reilly
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), Aaron Berg, Interim President and Chief Executive Officer (Interim Principal Executive Officer) of Amarin Corporation plc (the "Company"), and Tom Reilly, 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, 2023, 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/ Aaron Berg

Date: May 3, 2023

Aaron Berg
Interim President and Chief Executive Officer
(Interim Principal Executive Officer)

/s/ Tom Reilly

Date: May 3, 2023

Tom Reilly
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.