UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

☑ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 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. 0-21392

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)

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

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

Securities registered pursuant to section 12(g) of the Act: None.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☑ NO ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. YES ☐ NO ☑

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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☑

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2023 was approximately $484.7 million, based upon the closing price on the NASDAQ Global Market reported for such date.

410,671,800 shares were outstanding as of February 23, 2024, including 401,870,067 shares held as American Depositary Shares (ADSs), each representing one Ordinary Share, 50 pence par value per share, and 8,801,733 Ordinary Shares.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information required to be disclosed in Part III of this Annual Report on Form 10-K is incorporated by reference from the registrant's definitive proxy statement to be filed not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

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PART I

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This Annual Report on Form 10-K contains forward-looking statements. All statements other than statements of historical fact contained in this Annual Report on Form 10-K are forward-looking statements, including statements regarding the progress and timing of our clinical programs, regulatory filings and commercialization activities, and the potential clinical benefits, safety and market potential of our product candidates, as well as more general statements regarding our expectations for future financial and operational performance, regulatory environment, and market trends. In some cases, you can identify forward-looking statements by terminology such as "may," "would," "should," "could," "expects," "aims," "plans," "anticipates," "believes," "estimates," "predicts," "projects," "potential," or "continue"; the negative of these terms; or other comparable terminology. These statements include but are not limited to statements regarding the commercial success of and benefits and market opportunity for VASCEPA (brand name VAZKEPA in Europe but predominately referenced in this document by its brand name in the United States and other countries where it is approved, VASCEPA or icosapent ethyl) and factors that can affect such success; plans to obtain regulatory approvals and favorable market access and pricing in several jurisdictions, to expand promotion of VASCEPA and statements regarding cost and pricing of VASCEPA and other treatments; interpretation of court decisions; plans with respect to litigation; expectation on determinations and policy positions of the United States Food and Drug Administration, or U.S. FDA; the safety and efficacy of our product and product candidates; expectation regarding the potential for VASCEPA to be partnered, developed and commercialized outside of the United States; expectation on the scope and strength of our intellectual property protection and the likelihood of securing additional patent protection; estimates of the potential markets for our product candidates; estimates of the capacity of manufacturing and other facilities to support our products; our operating and growth strategies; our industry; our projected cash needs, liquidity and capital resources; and our expected future revenues, operations and expenditures.

Forward-looking statements are only current predictions and are subject to known and unknown risks, uncertainties, and other factors that may cause our or our industry's actual results, levels of activity, performance, or achievements to be materially different from those anticipated by such statements. These factors include, among other things, those listed under "Risk Factors" in Item 1A of Part I of this Annual Report on Form 10-K and elsewhere in this Annual Report on Form 10-K. These and other factors could cause results to differ materially from those expressed in these forward-looking statements.

Although we believe that the expectations reflected in the forward-looking statements contained in this Annual Report on Form 10-K are reasonable, we cannot guarantee future results, performance, or achievements. Except as required by law, we are under no duty to update or revise any of such forward-looking statements, whether as a result of new information, future events or otherwise, after the date of this Annual Report on Form 10-K.

Unless otherwise indicated, information contained in this Annual Report on Form 10-K concerning our product candidates, the number of patients that may benefit from these product candidates and the potential commercial opportunity for our product candidates, is based on information from independent industry analysts and third-party sources (including industry publications, surveys, and forecasts), our internal research, and management estimates. Management estimates are derived from publicly available information released by independent industry analysts and third-party sources, as well as data from our internal research, and based on assumptions made by us based on such data and our knowledge of such industry, which we believe to be reasonable. None of the sources cited in this Annual Report on Form 10-K has consented to the inclusion of any data from its reports, nor have we sought their consent. Our internal research has not been verified by any independent source, and we have not independently verified any third-party information. While we believe that such information included in this Annual Report on Form 10-K is generally reliable, such information is inherently imprecise. In addition, projections, assumptions, and estimates of our future performance are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in "Risk Factors" in Item 1A of Part I of this Annual Report on Form 10-K and elsewhere in this Annual Report on Form 10-K. These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

Item 1. ***Business***

References in this Annual Report on Form 10-K to "Amarin," the "Company," "we," "our" and "us" refer to Amarin Corporation plc and its subsidiaries, on a consolidated basis, unless otherwise indicated.

This Annual Report on Form 10-K, or Annual Report, includes the registered and unregistered trademarks and service marks of other parties.

Amarin Corporation plc is a public limited company incorporated under the laws of England and Wales. Amarin Corporation plc was originally incorporated in England as a private limited company on March 1, 1989 under the Companies Act 1985, and re-registered in England as a public limited company on March 19, 1993.

Our principal office is located at Iconic Offices, The Greenway, Block C Ardilaun Court, 112-114 St Stephens Green, Dublin 2 Ireland. Our registered office is located at One New Change, London EC4M 9AF, England. Our primary office for our European market access team is located at Überbauung Metalli, Gotthardstrasse 2, Zug CH-6300, Switzerland. Our primary office in the United States is located at 440 Route 22, Bridgewater, NJ 08807, USA. Our telephone number at that location is (908) 719-1315.

For purposes of this Annual Report, our ordinary shares may also be referred to as "common shares" or "common stock."

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. On June 1, 2023, we announced that regulatory approval from the National Medical Products Administration, or NMPA, for VASCEPA in Mainland China was received by our partner for the MARINE indication.

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.

Organizational Restructuring Program

On July 18, 2023, we announced that we were implementing a new Organizational Restructuring Program, or the ORP, resulting in the elimination and consolidation of certain roles across our organization, both in the U.S. and abroad, representing a reduction of our total employee base by approximately 30%. The ORP was implemented following a review of our business and to better position the organization for a new strategic focus. We expect the ORP will reduce operating costs by approximately $40.0 million annually. Our refocused strategic priorities and restructuring plan focuses on three core areas:

- *Maximizing U.S. Cash Flow Through Streamlined Model:* We have maintained VASCEPA as a cost-competitive option to generics despite an elimination of all U.S. sales force positions and approximately 30% of non-sales positions. We maintained our managed care and trade organization to support these efforts. We continue to explore innovative approaches to drive revenue to maintain our leadership position in the icosapent ethyl, or IPE, market.
- *European Redesign:* We redesigned our commercial infrastructure in Europe to better align with pricing and reimbursement status, commercial potential and progress to date, as well as streamline certain cross-geographic functions and better leverage learnings across countries. In addition, we will continue to advance our pricing and reimbursement activities to drive access in remaining geographies, including those where progress has been delayed.

- *Expanding Upon International Partnerships:* We continue to work on generating revenue from our partnerships in key international markets, including Canada, Middle East and North Africa, or MENA, China, South Korea, Australia and New Zealand and will continue to explore additional partnerships.

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, approximately 25 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:

Company	FDA MARINE Indication Approval	1-gram Launch Date	0.5-gram Launch Date
Hikma Pharmaceuticals USA Inc.	May 2020	November 2020	March 2023
Dr. Reddy's Laboratories, Inc.	August 2020	June 2021	June 2023
Teva Pharmaceuticals USA, Inc.	September 2020	January 2023	September 2022
Apotex, Inc.	June 2021	January 2022	N/A
Zydus Lifesciences	April 2023	N/A	N/A
Strides Pharma	September 2023	N/A	N/A
Epic Pharma	December 2023	N/A	N/A

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 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 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 reimbursement 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 Annual 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	N/A	March 2022	March 2022	March 2022
Finland	N/A	October 2022	December 2022	December 2022
England/Wales	N/A	July 2022	October 2022	October 2022
Spain	N/A	July 2023	September 2023	September 2023
Netherlands	N/A	August 2023	September 2023	September 2023
Scotland	N/A	August 2023	August 2023	September 2023
Austria	September 2022	N/A	September 2022	N/A
Denmark	June 2022	N/A	June 2022	N/A

We continue to advance our pricing and reimbursement activities to drive access in remaining geographies, including those where progress has been delayed. We are leveraging third-party relationships for various support activities and 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

As discussed above, one of the core areas of focus from our ORP is continuing to work on generating revenue from our partnerships in key international markets, including Canada, MENA, China, Australia and New Zealand and we will continue to explore additional partnerships.

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 Mainland 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. 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 Mainland China, the 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. 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. The Company announced on June 1, 2023 that Edding received approval from NMPA for VASCEPA in Mainland China under the MARINE indication and launched commercially in October 2023. In October 2023, Edding's submission of a regulatory filing to the NMPA for VASCEPA under the REDUCE-IT indication was accepted.

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	N/A
Bahrain	April 2021	April 2022	N/A
Kuwait	December 2021	March 2023	September 2023
Saudi Arabia	March 2022	June 2023	September 2023

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 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 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. 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 completed the second year of a three-year plan to submit and obtain regulatory approval in 20 or more additional countries and regions in order to ensure that patients in the top 50 cardiometabolic markets worldwide can benefit from VASCEPA. Through

the date of this Annual Report, we have filed for regulatory review in 20 countries and regions and have received approval in 13 countries and regions outside of the United States, the European Medicines Agency, or EMA, and the MHRA 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. In July 2023, the Company entered into an agreement with Lotus Pharmaceuticals to commercialize and distribute VAZKEPA in South Korea and nine countries in Southeast Asia. In August 2023, the Company entered into an agreement with Neopharm (Israel) 1996 Ltd., or Neopharm, to distribute VAZKEPA in Israel, Gaza, West Bank, and the territories of the Palestinian Authority. The Company will be responsible for supplying finished product to these partners. 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.

Clinical Trials

The REDUCE-IT Study (basis for expanded U.S. FDA approved indication and label expansion in December 2019; basis for EU EC approved indication and label in March 2021))

The REDUCE-IT study was designed to evaluate the efficacy of VASCEPA in reducing major cardiovascular events in an at-risk patient population also receiving statin therapy. REDUCE-IT was a multinational, prospective, randomized, double-blind, placebo-controlled, parallel-group study to evaluate the effectiveness of VASCEPA, as an add-on to statin therapy, in reducing first major cardiovascular events in an at-risk patient population compared to statin therapy alone. The control arm of the study was comprised of patients on optimized statin therapy plus placebo. The active arm of the study was comprised of patients on optimized statin therapy plus VASCEPA. All subjects enrolled in the study had elevated triglyceride levels and either established coronary heart disease or risk factors for coronary heart disease.

It is believed that the effects of the omega-3 acid eicosapentaenoic acid, or EPA, are not due to a single mode of action, such as triglyceride lowering, but rather to multiple mechanisms working together. Studies in the scientific literature explore potentially beneficial effects of EPA on multiple atherosclerosis processes, including endothelial function, oxidative stress, foam cell formation, inflammation/cytokines, plaque formation/progression, platelet aggregation, thrombus formation, and plaque rupture. With respect to triglyceride levels, our scientific rationale for the REDUCE-IT study was supported by (i) epidemiological data that suggests elevated triglyceride levels correlate with increased cardiovascular disease risk, (ii) genetic data that suggest triglyceride and/or triglyceride-rich lipoproteins (as well as LDL-C, known as bad cholesterol) are independently in the causal pathway for cardiovascular disease and (iii) clinical data that suggest substantial triglyceride reduction in patients with elevated baseline triglyceride levels correlates with reduced cardiovascular risk. The REDUCE-IT study was designed to determine the clinical benefit, if any, of stable EPA therapy in statin-treated patients with elevated triglyceride levels.

In 2016, we completed patient enrollment and randomization of 8,179 individual patients into the REDUCE-IT study. Our personnel remained blinded to the efficacy and safety data from the REDUCE-IT study until after the study was completed and the database was locked in 2018.

On November 10, 2018, we announced primary results from our REDUCE-IT study as late-breaking clinical results at the 2018 Scientific Sessions of the American Heart Association, or AHA, and the results were concurrently published in *The New England Journal of Medicine*. REDUCE-IT met its primary endpoint demonstrating a 25% RRR, to a high degree of statistical significance ($p<0.001$), in first occurrence of major adverse cardiovascular event, or MACE, in the intent-to-treat patient population with use of VASCEPA 4 grams/day as compared to placebo. Patients qualified to enroll in REDUCE-IT had LDL-C between 41-100 mg/dL (median baseline LDL-C 75 mg/dL) controlled by statin therapy and various cardiovascular risk factors including persistent elevated TG between 135-499 mg/dL (median baseline 216 mg/dL) and either established cardiovascular disease (secondary prevention cohort) or age 50 or more with diabetes mellitus and at least one other CV risk factor (primary prevention cohort). Approximately 59% of the patients had diabetes at baseline, approximately 71% of the patients had established cardiovascular disease at time of enrollment and approximately 29% were primary prevention subjects at high risk for cardiovascular disease. REDUCE-IT also showed a 26% RRR in its key secondary composite endpoint of cardiovascular death, heart attacks and stroke ($p<0.001$). We expended more than $300.0 million to fund completion of the REDUCE-IT study.

VASCEPA in the REDUCE-IT study demonstrated a number needed to treat, or NNT, of 21 for the first occurrence of MACE in the five-point primary composite endpoint. NNT is a statistical concept intended to provide a measurement of the impact of a medicine or therapy by estimating the number of patients that need to be treated in order to have an impact on one person.

An additional seven secondary endpoints were achieved below the key secondary endpoint, in order of sequential statistical testing within the prespecified hierarchy:

- Cardiovascular death or nonfatal heart attack: 25% RRR ($p<0.001$)
- Fatal or nonfatal heart attack: 31% RRR ($p<0.001$)
- Urgent or emergent revascularization: 35% RRR ($p<0.001$)
- Cardiovascular death: 20% RRR ($p=0.03$)
- Hospitalization for unstable angina: 32% RRR ($p=0.002$)
- Fatal or nonfatal stroke: 28% RRR ($p=0.01$)
- Total mortality, nonfatal heart attack or nonfatal stroke: 23% RRR ($p<0.001$)

The next prespecified secondary endpoint in the hierarchy was the only such endpoint that did not achieve statistical significance although it trended positively:

- Total mortality, which includes mortality from non-cardiovascular and cardiovascular events: 13% RRR ($p=0.09$)

Positive REDUCE-IT results were consistent across various patient subgroups, including female/male, diabetic/non-diabetic and secondary/primary prevention.

Overall adverse event rates in REDUCE-IT were similar across treatment groups and VASCEPA was well tolerated. VASCEPA was associated with an increase (3% vs 2%) in the reported rate of atrial fibrillation or atrial flutter requiring hospitalization in a double-blind, placebo-controlled trial. The incidence of atrial fibrillation was greater in patients with a previous history of atrial fibrillation or atrial flutter. It is not known whether patients with allergies to fish and/or shellfish are at an increased risk of an allergic reaction to VASCEPA. VASCEPA was associated with an increase (12% vs 10%) in the reported rate of bleeding in a double-blind, placebo-controlled trial. The reported incidence of bleeding was greater in patients receiving concomitant antithrombotic medications, such as aspirin, clopidogrel or warfarin.

Common adverse reactions in the cardiovascular outcomes trial (incidence ≥3% and ≥1% more frequent than placebo) were: musculoskeletal pain (4% vs 3%), peripheral edema (7% vs 5%), constipation (5% vs 4%), gout (4% vs 3%), and atrial fibrillation (5% vs 4%). Common adverse reactions in the hypertriglyceridemia trials (incidence >1% more frequent than placebo) were: arthralgia (2% vs 1%) and oropharyngeal pain (1% vs 0.3%). Patients receiving VASCEPA and concomitant anticoagulants and/or anti-platelet agents for bleeding are to be monitored. In the REDUCE-IT trial, cardiovascular benefits appeared not to be influenced significantly by TG levels at baseline (above or below 150 mg/dL baseline range) or as achieved at one year, potentially suggesting mechanisms at work with use of VASCEPA that are independent of baseline TG levels or therapy-driven reduction in TG levels. Determining the mechanisms responsible for the benefit shown in REDUCE-IT was not the focus of REDUCE-IT. As summarized from the primary results of REDUCE-IT in *The New England Journal of Medicine,* potential VASCEPA mechanisms of action at work in REDUCE-IT may include TG reduction, anti-thrombotic effects, antiplatelet or anticoagulant effects, membrane-stabilizing effects, effects on stabilization and/or regression of coronary plaque and inflammation reduction, each as supported by earlier stage mechanistic studies.

On December 13, 2019, the U.S. FDA approved a new indication and label expansion for VASCEPA capsules. VASCEPA is the first and only drug approved by the U.S. FDA as an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated TG levels (≥150 mg/dL) and either established cardiovascular disease or diabetes mellitus and two or more additional risk factors for cardiovascular disease.

Based on REDUCE-IT results, as of the date of the filing of this Annual Report, more than 40 clinical treatment guidelines, consensus statements or scientific statements from medical societies or journals have been updated recommending the use of icosapent ethyl in appropriate at-risk patients, including those statements which we were informed of by our global partners in Canada, China and the Middle East as well as guidelines which were newly received during the fourth quarter of 2023 as listed below:

- In December 2023, the Hellenic Atherosclerosis Society published guidelines for the diagnosis and treatment of dyslipidemia. The publication stated that clinical trials and meta-analyses have not shown that increasing consumption of omega-3 PUFA decreases the risk of atherosclerotic cardiovascular disease, or ASCVD, except for IPE. Based on the findings of REDUCE-IT, IPE (at a dose of 2 g twice daily) should be added in combination with a statin (and fenofibrate if needed) for patients with type 2 diabetes and established ASCVD or with ≥1 major risk factor and TG >150 mg/dL.

- The Cardiological Society of India released clinical practice guidelines for dyslipidemia management in December 2023. The guidelines state that in patients with mild to moderate hypertriglyceridemia (TG 150–499 mg/dL), there is no role for fibric acid derivatives. In those with diabetes (≥40 years of age) or ASCVD, IPE may be considered if TG remains high after lifestyle changes and diabetes control have been achieved. In addition, the guidelines note that the REDUCE-IT randomized controlled trial of highly purified IPE showed significant reduction of MACE.

During 2023, we announced the following data which added to our growing body of knowledge on VASCEPA as a result of our continued analysis of the REDUCE-IT trial results:

- In March 2023, a new prespecified and post hoc exploratory analysis of REDUCE-IT, presented at the American College of Cardiology, 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).
- In April 2023, the EVAPORATE- FFRCT study was published online in the European Heart Journal - Cardiovascular Imaging. This subgroup analysis assessed the impact of VASCEPA on coronary physiology assessed by fractional flow reserve derived from coronary CTA data sets, or FFRCT, using imaging data from EVAPORATE. FFRCT has been associated with various clinical outcomes, such as the safe deferral of invasive coronary angiography, cardiovascular death or myocardial infarction, and revascularization. This study is the first assessment of FFRCT to determine drug effect, and there was significant improvement in the pre-specified primary endpoint of FFRCT value in the distal coronary segment from baseline to follow-up in the most diseased vessel per patient using VASCEPA compared with placebo. VASCEPA improved mean distal segment FFRCT at 9- and 18-months follow-up compared with placebo (P = 0.02, P = 0.03 respectively). The secondary endpoint, change in translesional FFRCT (change in FFRCT across the most severe (minimum 30%) diameter stenosis) coronary lesion per vessel was improved with VASCEPA treatment compared with placebo, although it was not statistically significant (P = 0.054).
- In August 2023, we supported research that was presented at the ESC Congress, both onsite and online in Amsterdam. This new research included, along with other topics, the REDUCE-IT mediation analysis report of the contribution of IPE and other biomarkers to MACE reduction.

In total, Amarin and global medical and scientific collaborators supported close to 50 publications inclusive of accepted abstracts, posters, and manuscripts.

The MARINE Trial (first U.S. FDA-approved label for VASCEPA approved in July 2012)

The MARINE trial was a Phase 3, multi-center, placebo-controlled, randomized, double-blind, 12-week study for patients with very high triglycerides which was completed in 2010.

In November 2010, we reported topline data for the MARINE trial. In the trial, VASCEPA met its primary endpoint at doses of 4 grams and 2 grams per day with median placebo-adjusted reductions in triglyceride levels of 33% ($p < 0.0001$) compared to placebo for 4 grams and 20% ($p = 0.0051$) compared to placebo for 2 grams. The median baseline triglyceride levels were 703 mg/dL, 680 mg/dL and 657 mg/dL for the patient groups treated with placebo, 4 grams of VASCEPA and 2 grams of VASCEPA, respectively. VASCEPA was well tolerated in the MARINE trial, with a safety profile comparable to placebo and there were no treatment-related serious adverse events observed.

Observed Clinical Safety of VASCEPA in MARINE, ANCHOR and Early Development

In the MARINE and ANCHOR trials, patients dosed with VASCEPA demonstrated a safety profile similar to placebo. There were no treatment-related serious adverse events in the MARINE study or in the ANCHOR study. In the MARINE and ANCHOR trials, the most commonly reported adverse reaction (incidence >2% and greater than placebo) in VASCEPA treated patients was arthralgia (joint pain) (2.3% for VASCEPA vs. 1.0% for placebo). There was no reported adverse reaction > 3% and greater than placebo.

Prior to commencing the REDUCE-IT, MARINE and ANCHOR trials, we conducted a pre-clinical program for VASCEPA, including toxicology and pharmacology studies. In addition, we previously investigated VASCEPA in central nervous system disorders in several double-blind, placebo-controlled studies, including Phase 3 trials in Huntington's disease. Over 1,000 patients were dosed with VASCEPA in these studies, with over 100 receiving continuous treatment for a year or more. In all studies performed to date, VASCEPA has shown a favorable safety and tolerability profile.

In addition to the REDUCE-IT, MARINE and ANCHOR trials, we completed a 28-day pharmacokinetic study in healthy volunteers, a 26-week study to evaluate the toxicity of VASCEPA in transgenic mice and multiple pharmacokinetic drug-drug

interaction studies in healthy subjects in which we evaluated the effect of VASCEPA on certain common prescription drugs. All findings from these studies were consistent with our expectations and confirmed the overall safety profile of VASCEPA.

Clinical Study in China

Edding completed a Phase 3 study of VASCEPA in China, the design of which was similar to, but larger than, our MARINE study. In November 2020, along with Edding, we announced statistically significant topline positive results. 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 23, 2022, the Hong Kong Department of Health completed their evaluation and approved the use of VASCEPA under the REDUCE-IT indication. The Company announced on June 1, 2023 that Edding received approval from NMPA for VASCEPA in Mainland China under the MARINE indication and launched commercially in October 2023. In October 2023, Edding's submission of a regulatory filing to the NMPA for VASCEPA under the REDUCE-IT indication was accepted.

Collaboration with Mochida

In Japan, ethyl-EPA is marketed under the product name of Epadel by Mochida Pharmaceutical Co., Ltd., or Mochida, and is indicated for hyperlipidemia and peripheral vascular disease. In an outcomes study called the Japan EPA Lipid Intervention Study, or JELIS study, which consisted of more than 18,000 patients followed over multiple years, Epadel, when used in conjunction with statins, was shown to reduce cardiovascular events by 19% compared to the use of statins alone. In this study, cardiovascular events decreased by approximately 53% compared to statins alone in the subset of primary prevention patients with triglyceride levels of 150 mg/dL (median of 272 mg/dL at entry) and HDL-C <40 mg/dL.

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

In November 2022, the data related to RESPECT-EPA was presented at the American Heart Association, or AHA, 2022 Scientific Sessions, A Randomized Trial for Evaluation in Secondary Prevention Efficacy of Combination Therapy - Statin and Eicosapentaenoic Acid, or RESPECT-EPA. The RESPECT-EPA clinical trial is an independent study funded by the Japanese Heart Foundation and is the third study to show CV benefit consistent with REDUCE-IT and JELIS. The study achieved a borderline statistical significance with a 21.5% reduction in the primary composite endpoint measuring cardiovascular risk and achieved a statistically significant 26.6% reduction in the secondary composite endpoint.

Fixed-Dose Combination

On January 10, 2022, we announced that we have initiated development of a fixed-dose combination product that has both icosapent ethyl and a statin. During 2023, it became clear that the fixed-dose combination product would not drive short-term value and has subsequently been deprioritized.

Potential Benefits and Market Opportunity for VASCEPA

VASCEPA, encapsulated in 1-gram capsules, is 1-gram of icosapent ethyl, or ethyl-EPA, and contains no docosahexaenoic acid, or DHA. Icosapent ethyl is the only active ingredient. We believe that icosapent ethyl, in the stable form as it is presented in VASCEPA, is more effective than if combined with other omega-3 molecules. In particular, based on clinical evidence, we believe that the removal of DHA mitigates against the LDL-C raising effect observed in omega-3 compositions that include DHA. Based on the results of the REDUCE-IT trial, VASCEPA was the first omega-3 based product, or any type of product, to demonstrate a statistically significant reduction in cardiovascular risk beyond cholesterol lowering therapy in high-risk patients approved for treatment. Prior to REDUCE-IT, based on the MARINE trial, VASCEPA was the first omega-3 based product to demonstrate statistically significant triglyceride reduction without a statistically significant increase in LDL-C in this very high triglyceride population.

Guidelines for the management of very high triglyceride levels (500 mg/dL) suggest that reducing triglyceride levels is the primary treatment goal in these patients to reduce the risk of acute pancreatitis. Treating LDL-C remains an important secondary goal.

Other important parameters to consider in patients with very high triglycerides include levels of apolipoprotein B, or apo B, non-HDL-C, and very low-density lipoprotein cholesterol, or VLDL-C. The effect of VASCEPA on the risk for pancreatitis in patients with hypertriglyceridemia has not been determined.

We believe that the results of the REDUCE-IT, ANCHOR and MARINE clinical trials of VASCEPA and VASCEPA's EPA only/DHA-free composition position VASCEPA to achieve a global "best-in-class" prescription therapy in studied patient populations. Potential mechanisms of action at work in the reduction of cardiovascular events seen in REDUCE-IT as discussed in *The New England Journal of Medicine* publication of REDUCE-IT primary results include TG reduction, anti-thrombotic effects, antiplatelet or anticoagulant effects, membrane-stabilizing effects, effects on stabilization and/or regression of coronary plaque and inflammation reduction. Mechanisms responsible for the benefit shown in REDUCE-IT were not studied in REDUCE-IT as that was not the purpose of an outcomes study. While the mechanisms of action of VASCEPA have been broadly studied and continue to be studied, similar to other drugs with multifactorial mechanisms of action, such as aspirin, statins and metformin, we may never fully determine to what extent, if any, each of these effects or others may be responsible for the CV risk reduction benefit demonstrated in REDUCE-IT.

United States

Heart attacks, strokes and other cardiovascular events represent the leading cause of death and disability among men and women in western societies. According to the *Heart Disease and Stroke Statistics—2023 Update* from the AHA, CVD is the underlying cause of death in approximately one out of every three deaths – one death approximately every 34 seconds. Approximately 130 million adults in the United States live with one or more types of cardiovascular disease with an estimated one million new or recurrent coronary events and 795,000 new or recurrent strokes occurring each year. An estimated 25 million adults 20 years of age have high total serum cholesterol levels (240 mg/dL), and an estimated 65 million adults 20 years of age have borderline high or high low-density lipoprotein ("bad") cholesterol, or LDL-C, levels (130 mg/dL). According to the Cardiovascular Disease: A Costly Burden for America Projections Through 2035 from the AHA, 45% of the United States population is projected to have some form of CVD by 2035 and total costs of CVD are expected to reach $1.1 trillion in 2035.

It is estimated that more than 50 million adults in the United States have elevated triglyceride levels ≥150 mg/dL. Additionally, approximately two to three million adults in the United States have very high triglyceride levels (500 mg/dL), the condition for which VASCEPA received its initial drug approval from the U.S. FDA in 2012 based on the MARINE clinical trial. There are approximately 5 to 15 million people in the United States that meet the specific REDUCE-IT inclusion criteria. Additionally, the U.S. FDA-approved label for VASCEPA mentions maximally tolerated statin therapy in the indication statement. Since 1976, mean triglyceride levels have increased, along with the growing epidemic of obesity, insulin resistance, and type 2 diabetes mellitus. In contrast, mean LDL-C levels have decreased. Multiple primary and secondary prevention trials have shown a significant RRR of 25% to 35% in the risk of cardiovascular events with statin therapy, leaving significant persistent residual CV risk despite the achievement of target LDL-C levels.

Europe and Rest of World

Cardiovascular diseases remain the leading cause of disease burden in the world. There are more than 500 million people reportedly living with cardiovascular diseases globally, with 290 million in China. In the European Union, there are approximately 60 million people reportedly living with cardiovascular disease, including approximately 38 million diagnosed with ischemic heart disease, stroke or peripheral heart disease. The proportion of patients dying from cardiovascular disease is reportedly higher in Europe than in the United States and there are more patients on statin therapy in Europe in aggregate compared to the United States. Caring for cardiovascular disease in Europe is expensive with annual spending estimated to currently exceed €200 billion annually.

Manufacturing and Supply for VASCEPA

We manage the manufacturing and supply of VASCEPA and 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. Similar to U.S. FDA, regulators in other countries in which we, or our

partners, sell or seek to sell VASCEPA, regulate manufacturer's quality control and manufacturing procedures. For Europe, various suppliers have been inspected and approved by European regulatory authorities and we do not anticipate supply availability limiting our continued launch in Europe.

The API material that constitutes ethyl-EPA is a chemical modification of a naturally occurring substance that is derived from specific fish sourced from qualified producers. The fishing from which the raw material for VASCEPA is derived is regulated by local government agencies under policies designed to ensure sustainability of the marine life supply. We have worked with our suppliers to build the required scale, quality and cost-efficiency needed to meet our current and anticipated future market requirements. Among the conditions for U.S. FDA approval of a pharmaceutical product is the requirement that the manufacturer's quality control and manufacturing procedures are validated and conform to pharmaceutical current Good Manufacturing Practice, or cGMP, which, under applicable regulations, must be followed at all times. The U.S. FDA typically inspects manufacturing facilities before regulatory approval of a product candidate, such as VASCEPA, and on a periodic basis after the initial approval. Consistent with cGMP regulations, pharmaceutical manufacturers must expend resources and time to ensure compliance with product specifications as well as production, record keeping, quality control, reporting, and other regulatory requirements.

Production of VASCEPA, from sourcing of raw materials through stocking of finished goods inventory requires significant coordination between companies and considerable lead-times. We are often making purchasing decisions for supply more than a year in advance of anticipated product sales. Planning for capacity expansion also requires significant lead-times as, for example, creation of new manufacturing facilities for API can require multiple years to construct, equip and qualify. 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.

Beginning 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 December 31, 2023, we had inventory of $336.2 million, of which approximately 80% 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.

Competition

General

The biotechnology and pharmaceutical industries are highly competitive. There are many pharmaceutical companies, biotechnology companies, public and private universities and research organizations actively engaged in the research and development of products that may be similar to our product. It is probable that the number of companies seeking to develop products and therapies similar to our product or within the same therapeutic category will increase. Many of these and other existing or potential competitors have substantially greater financial, technical and human resources than we do and may be better equipped to develop, manufacture and market products. These companies may develop and introduce products and processes competitive with, more efficient than or superior to ours. For example, agents with longer dosing intervals inhibiting proprotein convertase subtilisin/kexin type 9 ("PCSK9") have recently been approved. These agents include alirocumab (Praluent®), evolocumab (Repatha®), and inclisiran (Leqvio®). 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.

United States

Our competitors include large, well-established pharmaceutical and generic companies, specialty and generic pharmaceutical companies, and specialized cardiovascular treatment companies.

In 2020, following our unsuccessful appeals of a court ruling in favor of the Defendants, several of the Company's 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 of VASCEPA, have entered the U.S. market and represent our main competitors:

Company	FDA MARINE Indication Approval	1-gram Launch Date	0.5-gram Launch Date
Hikma Pharmaceuticals USA Inc.	May 2020	November 2020	March 2023
Dr. Reddy's Laboratories, Inc.	August 2020	June 2021	June 2023
Teva Pharmaceuticals USA, Inc.	September 2020	January 2023	September 2022
Apotex, Inc.	June 2021	January 2022	N/A
Zydus Lifesciences	April 2023	N/A	N/A
Strides Pharma	September 2023	N/A	N/A
Epic Pharma	December 2023	N/A	N/A

Woodward Pharma Services LLC currently sells Lovaza®, which it acquired from GlaxoSmithKline plc in the third quarter of 2021. Lovaza, a prescription-only omega-3 fatty acid indicated for patients with severe hypertriglyceridemia was approved by the U.S. FDA in 2004 and has been on the market in the United States since 2005. Multiple generic versions of Lovaza are available in the United States. Other large companies with competitive products include AbbVie, Inc., which currently sells Tricor® and Trilipix® for the treatment of severe hypertriglyceridemia and Niaspan®, which is primarily used to raise high-density lipoprotein cholesterol, or HDL-C, but is also used to lower triglycerides. Multiple generic versions of Tricor, Trilipix and Niaspan are also available in the United States. We compete with these drugs, and in particular, multiple low-cost generic versions of these drugs, in our U.S. FDA-approved indicated uses, even though such products do not have U.S. FDA approval to reduce CV risk on top of statin therapy.

AstraZeneca conducted a long-term outcomes study to assess Statin Residual Risk Reduction With EpaNova in HiGh Cardiovascular Risk PatienTs With Hypertriglyceridemia, or STRENGTH. The study was a randomized, double-blind, placebo-controlled (corn oil), parallel group design that is believed to have enrolled approximately 13,000 patients with hypertriglyceridemia and low HDL and high risk for cardiovascular disease randomized 1:1 to either corn oil plus statin or Epanova plus statin, once daily. On January 13, 2020, following the recommendation of an independent Data Monitoring Committee, AstraZeneca decided to close the STRENGTH trial due to its low likelihood of demonstrating benefit to patients with mixed dyslipidemia who are at increased risk of cardiovascular disease. Full data from the STRENGTH trial was presented at the AHA's Scientific Sessions in November 2020 confirming that Epanova failed to meet the primary endpoint of CV risk reduction, and published in Journal of the American Medical Association, or JAMA, in December 2020. In addition, in March 2017, Kowa Research Institute (a subsidiary of the Japanese company Kowa Co., Ltd) initiated a Phase 3 cardiovascular outcomes trial titled PROMINENT examining the effect of pemafibrate (experimental name K-877) in reducing cardiovascular events in Type II diabetic patients with hypertriglyceridemia. In April 2022, Kowa Research Institute announced the decision to not continue the PROMINENT study as the primary endpoint was unlikely to be met. Results of the PROMINENT trial were presented at the 2022 AHA Scientific Session in November 2022, confirming that pemafibrate did not lower the incidence of cardiovascular events among the studied population.

We are also aware of other pharmaceutical companies that are developing products that, if successfully developed, approved and marketed, would compete with VASCEPA.

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 as over-the-counter drugs, by the U.S. FDA in the United States. Most regulatory authorities outside the United States are similar in this regard. Some of the promoters of such products have greater resources than us and are not restricted to the same standards as are prescription drugs with respect to promotional claims or manufacturing quality, consistency and subsequent product stability. We have taken successful legal action against supplement manufacturers attempting to use the REDUCE-IT results to promote their products. Still, 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 the U.S. FDA's stringent regulatory oversight, as significant advantages versus omega-3 dietary supplements regardless of clinical study results and other scientific data.

Europe and Rest of World

On March 26, 2021, the EC granted approval of the marketing authorization application in the EU for VAZKEPA as an approved therapy to reduce cardiovascular risk in high-risk statin-treated patients with elevated TG levels, which is based on the REDUCE-IT indication. There is currently no other drug that is approved for cardiovascular risk reduction in at-risk patients in Europe. In addition, there is currently no other direct competition for Canada and the Middle East. However, consistent with the U.S., our competitors globally include large, well-established pharmaceutical companies, specialty and generic pharmaceutical companies, marketing companies, and specialized cardiovascular treatment companies.

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.

In addition, VASCEPA also faces competition from dietary supplement manufacturers marketing omega-3 productions as nutritional supplements. In Europe, such products are classified as food, not as prescription drugs or as over-the-counter drugs.

Limitations of Current Therapies

HTG is a prevalent lipid disorder in approximately 25% of the U.S. adult population. Both epidemiological and genetic data have shown associations between HTG and coronary heart disease. Many of those patients are taking statin therapy directed at lowering the risk of CVD by lowering their LDL-C levels, primarily. Recently, real world administrative database analyses have

reported an increased CVD risk as well as direct healthcare costs associated with HTG despite statin therapy and controlled LDL-C compared to those with TG<150 mg/dL.

Regulatory Matters

Government Regulation and Regulatory Matters

Any product development activities related to VASCEPA or products that we may develop or acquire in the future will be subject to extensive regulation by various government authorities, including the U.S. FDA and comparable regulatory authorities in other countries, which regulate the design, research, clinical and nonclinical development, testing, manufacturing, storage, distribution, import, export, labeling, advertising and marketing of pharmaceutical products. Generally, before a new drug can be sold, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific to each regulatory authority, submitted for review and approved by the regulatory authority. The data are generated in two distinct development stages: preclinical and clinical. Drugs must be approved by regulatory authorities before they are first marketed for example, by the U.S. FDA through the new drug application, or NDA, process in the United States or the marketing authorization application, or MAA, process under the EMA in the EU. For new chemical entities, the preclinical development stage generally involves synthesizing the active component, developing the formulation, determining the manufacturing process and controls, as well as carrying out non-human toxicology, pharmacology and drug metabolism studies which support subsequent clinical testing.

The clinical stage of development can generally be divided into Phase 1, Phase 2 and Phase 3 clinical trials. In Phase 1, generally, a small number of healthy volunteers are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these studies is to assess the metabolism, pharmacologic action, side effect tolerability and safety of the drug. Phase 2 trials typically involve studies in disease-affected patients to determine the dose required to produce the desired benefits. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected. Phase 3 trials generally involve large numbers of patients at multiple sites, in multiple countries and are designed to provide the pivotal data necessary to demonstrate the effectiveness of the product for its intended use and its safety in use, provide an adequate basis for physician labeling and may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a product during marketing.

United States Drug Development and Approval

In the United States, the process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable United States requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include the U.S. FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Prior to the start of human clinical studies for a new drug in the United States, preclinical laboratory and animal tests are often performed under the U.S. FDA's Good Laboratory Practices regulations, or GLP, and an IND is filed with the U.S. FDA. Similar filings are required in other countries; however, data requirements and other information needed for a complete submission may differ in other countries. The amount of data that must be supplied in the IND depends on the phase of the study. Phase 1 studies typically require less data than larger Phase 3 studies. A clinical plan must be submitted to the U.S. FDA prior to commencement of a clinical trial. If the U.S. FDA has concerns about the clinical plan or the safety of the proposed studies, it may suspend or terminate the study at any time. Studies must be conducted in accordance with Good Clinical Practice, or GCP, including the requirement that subjects provide their informed consent, and regular reporting of study progress and any adverse experiences is required. Studies are also subject to review by independent institutional review boards, or IRBs, responsible for overseeing studies at particular sites and protecting human research study subjects. An independent IRB may also suspend or terminate a study once initiated.

U.S. FDA Review Process

The results of nonclinical studies and clinical trials, together with other information, including manufacturing information and information on the composition of the drug and proposed labeling, are submitted to the U.S. FDA in an NDA requesting approval to market the drug for one or more specified indications. Each NDA is typically accompanied by a user fee and there is also an annual prescription drug product program fee for human drugs. The U.S. FDA reviews an NDA to determine, among other things, whether a drug is safe and effective for its intended use and whether the product is being manufactured in accordance with cGMP requirements to assure and preserve the product's identity, strength, quality and purity. The U.S. FDA will conduct a pre-approval inspection of the manufacturing facilities for the new drug and may audit data from clinical trials to ensure compliance with GCP requirements. Additionally, the U.S. FDA may refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The U.S. FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

After the U.S. FDA evaluates an NDA, it will issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A complete response letter indicates that the review cycle of the application is complete and the application will not be approved in its present form, and usually describes all the specific deficiencies in the NDA identified by the U.S. FDA. The complete response letter may require additional clinical data and/or additional clinical trial(s), and/or other information. If a complete response letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, withdraw the application, or request a hearing. Even if such data and information is submitted, the U.S. FDA may ultimately decide that the NDA does not satisfy the criteria for approval.

Following the approval process of any drug product, the U.S. FDA may require post-marketing testing and surveillance to monitor the effects of approved products or it may place conditions on approvals including potential requirements or risk management plans that could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory requirements or if problems occur following initial marketing.

Off-label Promotion in the United States

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, or off-label promotion. Companies that market drugs for unapproved uses or indications have been subject to related costly litigation, criminal penalties and civil liability under the FDCA and the False Claims Act. However, recent case law has called into question the extent to which government in the United States, including 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.

If our promotional activities or other operations are found to be in violation of any law or governmental regulation through existing or new interpretations, we may be subject to prolonged litigation, penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Also, if governmental parties or our competitors view our claims as misleading or false, we could also be subject to liability based on fair competition-based statutes, such as the Lanham Act. Any of such negative circumstances could adversely affect our ability to operate our business and our results of operations.

Post-Marketing Requirements in the United States

Following approval of a new product, a pharmaceutical company generally must engage in numerous specific monitoring and recordkeeping activities, such as routine safety surveillance, and must continue to submit periodic and other reports to the applicable regulatory agencies, including any cases of adverse events and appropriate quality control records. Such reports submitted to the U.S. FDA may result in changes to the label and/or other post-marketing requirements or actions, including product withdrawal. Additionally, under the Food and Drug Omnibus Reform Act of 2022, or FDORA, sponsors of approved drugs must provide six 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. These are viable risks once a product is on the market. Additionally, modifications or enhancements to the products or labeling or changes of site of manufacture are often subject to the approval of the U.S. FDA and other regulators, which may or may not be received or may result in a lengthy review process.

Prescription drug advertising is subject to federal, state and foreign regulations. In the United States, the U.S. FDA regulates prescription drug promotion, including direct-to-consumer advertising. Prescription drug promotional materials must be submitted to the U.S. FDA in conjunction with their first use. Any distribution of prescription drug products and pharmaceutical samples must comply with the U.S. Prescription Drug Marketing Act, or the PDMA, a part of the FDCA.

In the United States, once a product is approved, its manufacture is subject to comprehensive and continuing regulation by the U.S. FDA. U.S. FDA regulations require that products be manufactured in specific approved facilities and in accordance with pharmaceutical cGMPs, and NDA holders must list their products and register their manufacturing establishments with the U.S. FDA and certain state agencies. Third-party manufacturers and other entities involved in the manufacture and distribution of approved drugs, and those supplying products, ingredients, and components of them, are also required to register their establishments with the U.S. FDA and certain state agencies. These regulations also impose certain organizational, procedural and documentation requirements with respect to manufacturing and quality assurance activities. NDA holders using contract manufacturers, laboratories or packagers are responsible for the selection and monitoring of qualified firms, and, in certain circumstances, qualified suppliers to these firms. These firms and, where applicable, their suppliers are subject to inspections by the U.S. FDA at any time, and the discovery of violative conditions, including failure to conform to cGMPs, could result in enforcement actions that interrupt the operation of any such facilities or the ability to distribute products manufactured, processed or tested by them. 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 the U.S. FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are otherwise unfit for distribution in the United States.

U.S. FDA Marketing Exclusivity and Generic Competition

The FDCA, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, as amended, or the Hatch-Waxman Amendments, provides for market exclusivity provisions that can help protect the exclusivity of new drugs by delaying the acceptance and final approval of certain competitive drug applications. New chemical entity, or NCE, marketing exclusivity precludes approval during the five-year exclusivity period of certain 505(b)(2) applications and ANDAs submitted by another company for another version of the drug. The timelines and conditions under the ANDA process that permit the start of patent litigation and allow the U.S. FDA to approve generic versions of brand name drugs like VASCEPA differ based on whether a drug receives three-year, or five-year, NCE marketing exclusivity.

NCE marketing exclusivity precludes approval during the five-year exclusivity period of certain 505(b)(2) applications and ANDAs submitted by another company for another version of the drug. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. In such case, the pioneer drug company is afforded the benefit of a 30-month stay against the launch of such a competitive product that extends from the end of the five-year exclusivity period. A pioneer company could also be afforded extensions to the stay under applicable regulations, including a six-month pediatric exclusivity extension or a judicial extension if applicable requirements are met. In May 2016, after litigation, the U.S. FDA determined that VASCEPA was entitled to NCE marketing exclusivity. The related 30-month stay expired on January 26, 2020, seven-and-a-half years after U.S. FDA approval of VASCEPA.

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, when the application contains reports of new clinical investigations (other than bioavailability studies) conducted by the sponsor that were essential to approval of the application. Accordingly, we expect to receive three-year exclusivity in connection with any future regulatory approvals of VASCEPA. We received such three-year regulatory exclusivity in connection with the approval based on the REDUCE-IT outcomes study results. Such three-year exclusivity protection precludes 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, for a period of three years from the date of U.S. FDA approval. The U.S. FDA may accept and commence review of such applications during the three-year exclusivity period. Such three-year exclusivity grant does not prevent a company from challenging the validity of patents at any time, subject to any prior four-year period pending from a grant of five-year exclusivity. This three-year form of exclusivity may also not prevent the U.S. FDA from approving an NDA that relies only on its own data to support the change or innovation.

Foreign Regulation of New Drug Compounds

In addition to regulations in the United States, we may be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products.

Whether or not we obtain U.S. FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in all or most foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application, or CTA, much like the IND prior to the commencement of human clinical trials. In Europe, for example, a CTA must be submitted to each country's national health authority and an independent ethics committee, much like the U.S. FDA and IRB, respectively. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed. Similarly, clinical trials conducted in countries such as Australia, Canada, and New Zealand, require review and approval of clinical trial proposals by an ethics committee,

which provides a combined ethical and scientific review process. Most countries in which clinical studies are conducted require the approval of the clinical trial proposals by both the national regulatory body and an ethics committee.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials must be conducted in accordance with GCP, which have their origin in the World Medical Association's Declaration of Helsinki, the applicable regulatory requirements, and guidelines developed by the International Conference on Harmonization, or ICH, for GCP practices in clinical trials.

European Union Drug Development and Approval

The below EU rules relating to drug development, approval and post-approval are generally applicable in the European Economic Area, or EEA, which consists of the EU Member States, Norway, Liechtenstein and Iceland.

Clinical Trials Regulation

In April 2014, the EU adopted Clinical Trials Regulation (EU) No 536/2014, which replaced the Clinical Trials Directive 2001/20/EC on January 31, 2022 and overhauled the system of approvals for clinical trials. Specifically, the new Regulation, which is directly applicable in all EU Member States, such that no national implementing legislation in each EU Member State is required, aims to simplify and streamline the approval of clinical trials in the EU. For example, the Regulation provides for a streamlined application procedure through a single entry point and strictly defined deadlines for the assessment of clinical trial applications.

Drug Review and Approval

Medicinal products can only be commercialized after obtaining a marketing authorization. To obtain regulatory approval of a medicinal product in the EU, a company must submit a marketing authorization application, or MAA. Centralized marketing authorizations are issued by the EC through the centralized procedure based on the opinion of the CHMP of the EMA and are valid throughout the EU as well as Iceland, Norway and Lichtenstein. The centralized procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, advanced-therapy medicinal products such as gene-therapy, somatic cell-therapy or tissue-engineered medicines, and medicinal products containing a new active substance indicated for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions, and viral diseases. The centralized procedure is optional for products containing a new active substance not yet authorized in the EU, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.

Under the centralized procedure, the maximum timeframe for the evaluation of an MAA by the EMA is 210 days, excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP. Clock stops may extend the timeframe of evaluation of an MAA considerably beyond 210 days. Where the CHMP gives a positive opinion, it provides the opinion together with supporting documentation to the EC, who makes the final decision to grant a marketing authorization, which is issued within 67 days of receipt of the EMA's recommendation. Accelerated assessments may be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of major public health interest, particularly from the point of view of therapeutic innovation. The timeframe for the evaluation of an MAA under the accelerated assessment procedure is 150 days, excluding clock stops, but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that the application is no longer appropriate to conduct an accelerated assessment.

National marketing authorizations, which are issued by the competent authorities of the Member States of the EU and only cover their respective territory, are available for products not falling within the mandatory scope of the centralized procedure. Where a product has already been authorized for marketing in a Member State of the EU, this national marketing authorization can be recognized in other EU Member States through the mutual recognition procedure. If the product has not received a national marketing authorization in any EU Member State at the time of application, it can be approved simultaneously in various Member States through the decentralized procedure.

Now that the UK, which comprises Great Britain and Northern Ireland, has left the EU, Great Britain is no longer covered by centralized marketing authorizations, while under the Northern Ireland Protocol centralized marketing authorizations currently continue to be recognized in Northern Ireland. A separate marketing authorization is therefore required to market products in Great Britain. On January 1, 2024, a new international recognition framework was put in place by the MHRA under which the MHRA may have regard to decisions on the approval of a marketing authorization made by the EMA and certain other regulators when considering whether to grant a UK marketing authorization. The MHRA also has the power to have regard to marketing authorizations approved in

EU Member States through decentralized or mutual recognition procedures with a view to more quickly granting a marketing authorization in the UK or Great Britain.

Periods of Authorization and Renewals

A marketing authorization in the EU is valid for five years, in principle, and it may be renewed after five years on the basis of a re-evaluation of the risk benefit balance by the EMA for a centrally authorized product, or by the competent authority of the authorizing Member State for a nationally authorized product. Once renewed, the marketing authorization is valid for an unlimited period, unless the EC or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal period. Any authorization that is not followed by the placement of the product on the EU market, in the case of the centralized procedure, or on the market of the authorizing Member State for a nationally authorized product, within three years after authorization, or if the product is removed from the market for three consecutive years, ceases to be valid.

Data and Market Exclusivity

In the EU, upon receiving marketing authorization, innovative medicinal products generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents generic or biosimilar applicants from referencing the innovator's pre-clinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization in the EU, during a period of eight years from the date on which the reference product was first authorized in the EU. During the additional two year period of market exclusivity, a generic or biosimilar marketing authorization application can be submitted, and the innovator's data may be referenced, but no generic or biosimilar product can be marketed until the expiration of the market exclusivity. The overall ten year period will be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to authorization, is held to bring a significant clinical benefit in comparison to the existing therapies. There is no guarantee that a product will be considered by the EMA to be an innovative medicinal product and products may not qualify for data exclusivity. Even if a product is considered to be an innovative medicinal product so that the innovator gains the prescribed period of data exclusivity, another company may market another version of the product if such company obtained a marketing authorization based on an MAA with a complete and independent data package of pharmaceutical tests, preclinical tests and clinical trials. Following the expiry of regulatory exclusivity for a product (or if a product does not qualify for regulatory exclusivity), a generic or biosimilar of the applicable product may be authorized and marketed in the EU and we would therefore need to rely upon enforcement of any surviving European patents covering the applicable product to protect against generic competition in the EU.

Regulatory Requirements after obtaining Marketing Authorization

Where a marketing authorization for a medicinal product in the EU is obtained, the holder of the marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products. These include:

- Compliance with the EU's stringent pharmacovigilance or safety reporting rules must be ensured. These rules can impose post-authorization studies and additional monitoring obligations.
- The manufacturing of authorized medicinal products, for which a separate manufacturer's license is mandatory, must also be conducted in strict compliance with the applicable EU laws, regulations and guidance, including Directive 2001/83/EC, Directive (EU) 2017/1572, Regulation (EC) No 726/2004 and the European Commission Guidelines Manufacturing Practice. These requirements include compliance with EU cGMP standards when manufacturing medicinal products and active pharmaceutical ingredients, including the manufacture of active pharmaceutical ingredients outside of the EU with the intention to import the active pharmaceutical ingredients into the EU.
- The marketing and promotion of authorized medical products, including industry-sponsored continuing medical education and advertising directed toward the prescribers of medical products and/or the general public, are strictly regulated in the EU. Direct-to-consumer advertising of prescription medicines is prohibited across the EU.

The aforementioned European Union rules are generally applicable in the EEA.

Reform of the Regulatory Framework in the European Union

The EC introduced legislative proposals in April 2023 that, if implemented will replace the current regulatory framework in the EU for all medicines (including those for rare diseases and for children). The EC has provided the legislative proposals to the European Parliament and the European Council for their review and approval. In October 2023, the European Parliament published

draft reports proposing amendments to the legislative proposals, which will be debated by the European Parliament. Once the EC's legislative proposals are approved (with or without amendment), they will be adopted into EU law.

Brexit and the Regulatory Framework in the United Kingdom

The UK formally left the EU on January 31, 2020, and the EU and the UK have concluded a trade and cooperation agreement, or TCA, which was provisionally applicable since January 1, 2021 and has been formally applicable since May 1, 2021. The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition of GMP, inspections of manufacturing facilities for medicinal products and GMP documents issued, but does not provide for wholesale mutual recognition of UK and EU pharmaceutical regulations. At present, Great Britain has implemented EU legislation on the marketing, promotion and sale of medicinal products through the Human Medicines Regulations 2012 (as amended) (under the Northern Ireland Protocol, the EU regulatory framework currently continues to apply in Northern Ireland). Except in respect of the EU Clinical Trials Regulation, the regulatory regime in Great Britain therefore currently largely aligns with EU regulations, however it is possible that these regimes will diverge more significantly in future now that Great Britain's regulatory system is independent from the EU and the TCA does not provide for mutual recognition of UK and EU pharmaceutical legislation. However, notwithstanding that there is no wholesale recognition of EU pharmaceutical legislation under the TCA, under a new international recognition procedure which was put in place by the MHRA, on January 1, 2024, the MHRA may take into account decisions on the approval of a marketing authorization from the EMA (and certain other regulators) when considering an application for a Great Britain marketing authorization.

On February 27, 2023, the UK government and the EC announced a political agreement in principle to replace the Northern Ireland Protocol with a new set of arrangements, known as the "Windsor Framework". This new framework fundamentally changes the existing system under the Northern Ireland Protocol, including with respect to the regulation of medicinal products in the UK. In particular, the MHRA will be responsible for approving all medicinal products destined for the UK market (i.e., Great Britain and Northern Ireland), and the EMA will no longer have any role in approving medicinal products destined for Northern Ireland. A single UK-wide marketing authorization will be granted by the MHRA for all medicinal products to be sold in the UK, enabling products to be sold in a single pack and under a single authorization throughout the UK. The Windsor Framework was approved by the EU-UK Joint Committee on March 24, 2023, so the UK government and the EU will enact legislative measures to bring it into law. On June 9, 2023, the MHRA announced that the medicines aspects of the Windsor Framework will apply from January 1, 2025.

Fraud and Abuse Laws and Data Regulation

In addition to U.S. FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws restrict certain marketing practices in the biopharmaceutical industry. These laws include Anti-Kickback Statutes and false claims statutes.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity knowingly and willfully offering, paying, soliciting, or receiving remuneration, directly or indirectly, in cash or in kind, to induce or in return for a referral or the purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order of any healthcare facility, item or service reimbursable under Medicare, Medicaid, or other federal healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. Liability may be established without a person or entity having actual knowledge of the federal anti-kickback statute or specific intent to violate it. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability. Moreover, there are no safe harbors for many common practices, such as educational and research grants or patient or product support programs. On November 20, 2020, the United States Department of Health and Human Services, or HHS, Office of Inspector General, or OIG, finalized further modifications to the federal Anti-Kickback Statute. Under the final rules, OIG added safe harbor protections under the Anti-Kickback Statute for certain coordinated care and value-based arrangements among clinicians, providers, and others. We continue to evaluate what effect, if any, these rules will have on our business.

The federal civil and criminal false claim laws, including the civil monetary penalty laws and the civil False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds, or knowingly making or using, or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly concealing, or knowingly and improperly avoiding, decreasing, or concealing an obligation to pay money or transmit properly to the federal government. Manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The False Claims Act also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the statute and to share in any monetary recovery. Recently, several pharmaceutical and other healthcare companies have been investigated or faced enforcement actions under the federal civil False Claims Act for a variety of alleged improper marketing activities, including allegations that they caused false claims to be submitted because of the company's marketing of the product for unapproved, and thus allegedly non-reimbursable, uses. Federal enforcement agencies also have showed increased interest in pharmaceutical companies' product and patient assistance programs, including reimbursement and co-pay support services, and a number of investigations into these programs have resulted in significant civil and criminal settlements. Pharmaceutical and other healthcare companies also are subject to other federal false claims laws, including, among others, federal criminal healthcare fraud and false statement statutes that extend to non-government health benefit programs.

The Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, including the Final Omnibus Rule published in January 2013, collectively referred to herein as HIPAA, among other things, imposes criminal and civil liability for knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payor and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. In addition, HITECH imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information. It requires certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

The federal Physician Payment Sunshine Act, implemented as the Open Payments Program, requires manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare and Medicaid Services, or CMS, information related to direct or indirect payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other licensed healthcare practitioners and teaching hospitals, as well as ownership and investment interests held in the company by physicians and their immediate family members.

The federal government price reporting laws require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs. Additionally, federal consumer protection and unfair competition laws broadly regulate marketplace activities and activities that potentially harm consumers.

Many foreign countries and the majority of states also have statutes or regulations similar to the federal Anti-Kickback Statute and False Claims Act, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers. Other states or localities may have laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; restrict the ability of manufacturers to offer co-pay support to patients for certain prescription drugs; require drug manufacturers to report information related to clinical trials, or information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; relate to insurance fraud in the case of claims involving private insurers; and/or require identification or licensing of sales representatives.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring manufacturers to report information related to payments to physicians and other healthcare providers, marketing expenditures, and drug pricing information. Certain state and local laws require the registration of pharmaceutical sales representatives. State and foreign laws, including for example the California Consumer Privacy Act, or CCPA, and the European Union General Data Protection Regulation, or EU GDPR, and the UK equivalent of the same, or the UK GDPR, also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

The CCPA creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA will require covered companies to provide certain disclosures to consumers about its data collection, use and sharing practices, and to provide affected California residents with ways to opt-out of certain sales or transfers of personal information. The CCPA went into effect on January 1, 2020, and the California Attorney General has commenced enforcement against violators as of July 1, 2020. While there is currently an exception for protected health information that is subject to HIPAA and clinical trial regulations, as currently written, the CCPA may impact our business activities.

With respect to Europe, the EU GDPR and UK GDPR (collectively referred to as the GDPR in this Annual Report on Form 10-K), as well as other national data protection legislation in force in relevant EU and European Economic Area, or EEA member states and the UK (including the UK Data Protection Act 2018 in the UK) govern the collection, use, storage, disclosure, transfer, or other processing of personal data, including personal health data (i) regarding individuals in the EU, EEA and UK; and/or (ii) carried out in the context of the activities of our establishment in any EU and EEA member state or the UK. Currently, the EU GDPR and UK GDPR remain largely aligned. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, legal basis for processing personal data which may include obtaining consent of the individuals to whom the personal data relates, providing detailed information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, ensuring certain accountability measures are in place and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EU, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million (£17.5 million for the UK GDPR) or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities. The GDPR and other applicable data protection laws, impose restrictions in relation to the international transfer of personal data. For example, in order to transfer data outside of the EEA or the UK to a non-adequate country, the GDPR requires us to enter into an appropriate transfer mechanism, and may require us to take additional steps to ensure an essentially equivalent level of data protection, including carrying out transfer impact assessments. These transfer mechanisms are subject to change, and implementing new or revised transfer mechanisms or ensuring an essentially equivalent protection may involve additional expense and potentially increased compliance risk. In the event a legislator, government, regulator or court imposes additional restrictions on international transfers, there may be operational interruption in the performance of services for customers and internal processing of employee information. Such restrictions may also increase our obligations in relation to carrying out international transfers of personal data, and incur additional expense and increased regulatory liabilities. On June 28, 2021, the EC adopted an adequacy decision in respect of transfers of personal data to the UK for a four year period until June 27, 2025. Similarly, the UK has determined that it considers all of the EEA to be adequate for the purposes of data protection. This ensures that data flows between the UK and the EEA remain unaffected.

The EU GDPR and UK GDPR remain largely aligned. Currently, the most impactful point of divergence between the GDPR and the UK GDPR relates to these transfer mechanisms as explained above. There may be further divergence in the future, including with regard to administrative burdens. The UK has announced plans to reform the country's data protection legal framework in its Data Reform Bill, which will introduce significant changes from the EU GDPR. This may lead to additional compliance costs and could increase our overall risk exposure as we may no longer be able to take a unified approach across the EEA and the UK, and we will need to amend our processes and procedures to align with the new framework.

Because of the breadth of these laws and the narrowness of the exceptions or safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Such a challenge could have a material adverse effect on our business, financial condition and results of operations. These laws may impact, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business.

If our promotional activities or other operations are found to be in violation of any of the laws described above or any other governmental regulations or guidance that apply to us through existing or new interpretations, we may be subject to prolonged litigation, penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, the exclusion from participation in federal and state healthcare programs, individual imprisonment, reputational harm 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. Also, if governmental parties or our competitors view our claims as misleading or false, we could also be subject to liability based on fair competition-based statutes, such as the Lanham Act. Any of such negative circumstances could adversely affect our ability to operate our business and our results of operations.

In the U.S., to help patients afford our approved product, we may utilize programs to assist them, including patient assistance programs, or PAPs and co-pay coupon programs for eligible patients. PAPs are regulated by and subject to guidance from HHS OIG. In addition, at least one insurer has directed its network pharmacies to no longer accept co-pay coupons for certain specialty drugs identified by the insurer. Our co-pay coupon programs could become the target of similar insurer actions. In addition, in November 2013, the CMS issued guidance to the issuers of qualified health plans sold through the ACA's, as defined herein, marketplaces encouraging such plans to reject patient cost-sharing support from third parties and indicating that the CMS intends to monitor the provision of such support and may take regulatory action to limit it in the future. The CMS subsequently issued a rule requiring individual market qualified health plans to accept third-party premium and cost-sharing payments from certain government-related entities. In September 2014, the OIG of the HHS issued a Special Advisory Bulletin warning manufacturers that they may be subject to sanctions under the federal anti-kickback statute and/or civil monetary penalty laws if they do not take appropriate steps to exclude Part D beneficiaries from using co-pay coupons. Accordingly, companies exclude these Part D beneficiaries from using co-pay coupons.

United States Healthcare Reform and Legislation

In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system that could affect our future results of operations.

On March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. Due to the Statutory Pay-As-You-Go Act of 2010, estimated budget deficit increases resulting from the American Rescue Plan Act of 2021, and subsequent legislation, Medicare payments to providers will be further reduced starting in 2025 absent further legislation. These laws and regulations may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

In August 2022, the Inflation Reduction Act of 2022, or the IRA, was signed into law. The IRA includes several provisions that may impact our business, depending on how various aspects of the IRA are implemented. Provisions that may impact our business include a $2,000 out-of-pocket cap for Medicare Part D beneficiaries, the imposition of new manufacturer financial liability on most drugs in Medicare Part D, permitting 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, requiring 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 would have limited the fees that pharmacy benefit managers can charge. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA's Medicare drug price negotiation program. The effects of the IRA on our business and the healthcare industry in general is not yet known.

Political, economic and regulatory influences are subjecting the healthcare industry in the United States to fundamental changes. There have been, and we expect there will continue to be, legislative and regulatory proposals to change the healthcare system in ways that could impact our ability to sell our products profitably. We anticipate that the United States Congress, state legislatures and the private sector will continue to consider and may adopt healthcare policies intended to curb rising healthcare costs. These cost containment measures include: controls on government funded reimbursement for drugs; new or increased requirements to pay prescription drug rebates to government healthcare programs; controls on healthcare providers; challenges to the pricing of drugs or limits or prohibitions on reimbursement for specific products through other means; requirements to try less expensive products or generics before a more expensive branded product; changes in drug importation laws; expansion of use of managed care systems in which healthcare providers contract to provide comprehensive healthcare for a fixed cost per person; and public funding for cost effectiveness research, which may be used by government and private third-party payors to make coverage and payment decisions. Further, federal budgetary concerns could result in the implementation of significant federal spending cuts, including cuts in Medicare and other health related spending in the near term.

Pharmaceutical Pricing and Reimbursement

In the United States and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Our ability to successfully commercialize our product therefore depends significantly on the availability of adequate financial coverage and reimbursement from third-party payors, including, in the United States, governmental payors such as Medicare and Medicaid, as well as managed care organizations, private health insurers and other organizations. Third-party payors decide which drugs they will pay for and establish reimbursement and copayment levels. Third-party payors are increasingly challenging the prices charged for medicines and examining their cost effectiveness, in addition to their safety and efficacy. In the United States, the principal decisions about reimbursement for new medicines are typically made by CMS, an agency within the HHS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree.

In the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Coverage and reimbursement for drug products can differ significantly from payor to payor. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved.

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of products have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue generated from the sale of any approved products. Coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which a company or its collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Payors also are increasingly considering new metrics as the basis for reimbursement rates, such as average sales price, average manufacturer price and actual acquisition cost. CMS surveys and publishes retail community pharmacy acquisition cost information in the form of National Average Drug Acquisition Cost files to provide state Medicaid agencies with a basis of comparison for their own reimbursement and pricing methodologies and rates. It is difficult to project the impact of these evolving reimbursement mechanics on the willingness of payors to cover our products. We participate in the Medicaid Drug Rebate program, the 340B drug pricing program, and the U.S. Department of Veterans Affairs, or VA, Federal Supply Schedule, or FSS, pricing program. Under the Medicaid Drug Rebate program, we are required to pay a rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid and Part B of the Medicare program.

Federal law requires that any company that participates in the Medicaid Drug Rebate program also participate in the 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. There have been several changes to the 340B drug pricing program. On November 3, 2023, the U.S. District Court of South Carolina issued an opinion in Genesis Healthcare Inc. v. Becerra et al. that may lead to an expansion of the scope of patients eligible to access prescriptions at 340B pricing. The outcome of this judicial proceeding is uncertain. We continue to review developments impacting the 340B program. It is unclear how these developments could affect covered hospitals who might purchase our future products and affect the rates we may charge such facilities for our approved products in the future, if any.

In order to be eligible to have our products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies and grantees, we participate in the VA/FSS pricing program. Under this program, we are obligated to make our products available for procurement on an FSS contract and charge a price to four federal agencies - the VA, U.S. Department of Defense, Public Health Service and U.S. Coast Guard - that is no higher than the statutory Federal Ceiling Price, or FCP. 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. 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.

The Medicaid Drug Rebate program, 340B program, and VA/FSS pricing program, and the risks relating to price reporting and other obligations under these programs, are further discussed under the heading "*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*" in Part I, Item 1A of this Annual Report on Form 10-K.

Outside the United States, ensuring coverage and adequate payment for a product also involves challenges. Pricing of prescription pharmaceuticals is subject to government control in many countries. Pricing negotiations with government authorities can extend well beyond the receipt of regulatory approval for a product and may require a clinical trial that compares the cost-effectiveness of a product to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in commercialization.

In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. A Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, products launched in the European Union do not follow price structures of the U.S. and generally prices, particularly when for the same product and the same indication as in the U.S., tend to be significantly lower.

Price negotiations are conducted in the UK and each EU country for new medicines between the manufacturer and the national government pricing committee, or the parties. In many cases, there is no specific timeline for negotiation conclusion and the dynamics depends on the discussions between both parties. Analyzing a benchmark of innovative cardiovascular and metabolic products in recent years, the average time to price negotiation from marketing authorization ranged from 12 months in England to 52 months in countries like France. Recent macro-economic context has put additional pressure on EU authorities in their ability to allocate large budgets for innovative medicines. After this negotiation phase concludes between the parties, a confidential agreement is signed for usually 3 to 5 years with a specific public budget allocation and a price is published, or the list price. For retail products like VAZKEPA in the UK, Sweden or Finland there are no confidential deals with authorities impacting net prices.

Other Regulatory Matters

Manufacturing, sales, promotion, importation, and other activities related to approved products are also subject to regulation by numerous regulatory authorities, including, in the United States, the U.S. FDA, the Centers for Medicare & Medicaid Services, other divisions of the Department of Health and Human Services, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency, and state and local governments. Sales, marketing and scientific/educational programs must comply with the Food, Drug, and Cosmetic Act, the Anti-Kickback Statute, and the False Claims Act and similar state laws. Pricing and rebate programs must comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The failure to comply with regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory 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 product approvals, or refusal to allow a firm to enter into supply contracts, including government contracts. In addition, even if a firm complies 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. Prohibitions or restrictions on sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

Changes in regulations or 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.

Patents, Proprietary Technology, Trade Secrets

Our success depends in part on our ability to obtain and maintain intellectual property protection for our drug candidates, technology and know-how, and to operate without infringing the proprietary rights of others. While certain key patents related to our product based on the MARINE clinical study were determined to be invalid as obvious by a district court in the United States, it

remains the case that our ability to successfully implement our business plan and to protect our products with our intellectual property will depend in large part on our ability to:

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

We have prosecuted, and are currently prosecuting, multiple patent applications to protect the intellectual property developed during the VASCEPA development program. As of the date of this Annual Report on Form 10-K, we had more than 100 patent applications in the United States that have been either issued or allowed, most of which are listed in the FDA publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations also known as the FDA Orange Book.

Currently-issued U.S. patents will expire between 2027 and 2033 and contain claims directed to the methods of using icosapent ethyl to treat hypertriglyceridemia, severe hypertriglyceridemia and cardiovascular risk reduction. Our VASCEPA patent portfolio also includes many granted patents in foreign jurisdictions including pending foreign and Patent Cooperation Treaty, or PCT patent applications. Currently-granted European patents directed to the same subject matter as above will expire between 2027 and 2033, and may be subject to a potential further extension of a patent right. Granted patents in other foreign jurisdictions will expire between 2030 and 2033 and may be subject to a potential further patent term extension, depending on the country. Pending applications covering VASCEPA/VAZKEPA may, if granted, provide exclusivity for the drug until 2039.

Patents and applications described above are either owned by Amarin or exclusively licensed from others.

We have pending patent applications worldwide related to potential new uses of icosapent ethyl or other derivatives of EPA and potential new formulations thereof. Patents maturing from such pending applications would expire between 2030 and 2043.

No assurance can be given that, if and when issued, our patents will prevent competitors from competing with VASCEPA. For example, we may choose to not assert all issued patents in patent litigation and patents or claims within patents may be determined to be invalid.

Geographies outside the United States in which VASCEPA is sold or under regulatory review are not subject to the U.S. patent litigation and judgment. No litigation involving potential generic versions of VASCEPA is pending outside the United States. Outside the United States, VASCEPA is currently available by prescription in certain European countries, China, Canada, Lebanon, the United Arab Emirates, Kuwait and Saudi Arabia. In Canada, VASCEPA has the benefit of data protection afforded through Health Canada until the end of 2027, in addition to separate patent protection with expiration dates that could extend into 2039. We are pursuing additional regulatory approvals for VASCEPA in Europe, China and the Middle East. In China and the Middle East, we are pursuing such regulatory approvals and subsequent commercialization of VASCEPA with commercial partners. The EC approval provides 10 years of market protection in the EU. Furthermore, patent protection in Europe includes: one granted patent related to the use of a pharmaceutical composition comprised of 4g of 96% EPA ethyl ester to treat the REDUCE-IT population expiring 2033. In addition, pending patent applications in Europe, if granted, may have the potential to extend exclusivity into 2039.

Human Capital Management

Diversity and Inclusion

We believe that a diverse and inclusive workforce helps us better connect our work with the needs of our patients, physicians, partners and other stakeholders. In our hiring and recruiting of prospective candidates, we give priority to attitude, intelligence, competency for the position and assessment of what they can contribute to our company. We promote employees based on merit with emphasis on accomplishments over effort while supporting the benefits of diversity. While we acknowledge and support the benefits of diversity and seek ways to continually improve in this area, individual hiring, promotion, compensation, retention and other employment decisions are made irrespective of personal characteristics such as race, disability, gender, sexual orientation, religion, or age.

Attracting, developing and retaining key scientific, technical, research, marketing, sales and other personnel is critical to our ability to implement and execute our business plan and is key to our success. Our ability to recruit and retain such talent depends on a number of factors, including compensation and benefits, talent development, career opportunities and work environment. As of December 31, 2023, we had approximately 275 full-time employees located in fifteen countries, of which 25% are located in the

United States and 75% are located throughout Europe. For the 25% of our total employees located in the United States, our workforce diversity representation for gender and race is 39% and 32%, respectively.

Employee Development & Engagement

We believe in a direct management-employee engagement model by which managers and employees maintain a regular dialogue about working conditions, compensation, compliance, safety and advancement opportunities. We communicate frequently and transparently with our employees through a variety of communication methods, including written and video communications and quarterly town hall meetings. We believe these engagement efforts keep our employees informed about our strategy, purpose and priorities, which is consistent with our core values of integrity, operational excellence, collaboration and commitment to quality and we believe this engagement motivates our employees to do their best work. We also initiated a global employment engagement survey during 2023, which will be an annual survey going forward, to obtained feedback from our employees on our employment engagement and development practices, among other areas. The participation and results of this survey were positive and allows management to continuously focus on improvements in this area. Our core values promote an empowering, supportive atmosphere where we work together to put patients first and improve patient care through our actions and products. We encourage employees to share ideas and learn from each other, while expecting high standards of quality and continuous improvement.

Compensation and Benefits

We are committed to rewarding, supporting, and developing our employees who make it possible to deliver on our strategy. To that end, we offer a comprehensive rewards program aimed at the varying health and financial needs of our employees. Our program includes market-competitive salaries and wages, bonuses and broad-based stock grants, healthcare benefits, retirement plans with employer matching provisions, paid time off and family leave and a strong commitment to corporate wellness. In addition, we have implemented a hybrid workplace model for our offices throughout the world. We utilize independent consultants to help us ensure that our compensation and benefits are competitive with market practices and compliant with laws and regulations in the various geographies in which we operate.

Organizational Structure

At February 29, 2024, we had the following subsidiaries:

Subsidiary Name	Country of Incorporation or Registration	Proportion of Ownership Interest and Voting Power Held
Amarin Pharmaceuticals Ireland Limited	Ireland	100%
Amarin Pharma, Inc.	United States	100%
Ester Neurosciences Limited	Israel	100%
Amarin Switzerland GmbH	Switzerland	100%
Amarin Germany GmbH	Germany	100%
Amarin France SAS	France	100%
Amarin UK Limited	United Kingdom	100%
Amarin Italy S.r.l.	Italy	100%
Amarin Switzerland GmbH Sucursal Espana	Spain	100%
Amarin Switzerland GmbH Austrian branch	Austria	100%
Amarin Belgium, branch of Amarin Switzerland GmbH	Belgium	100%
Amarin Denmark, filial af Amarin Switzerland GmbH	Denmark	100%
Amarin Switzerland GmbH, Suomen sivuliike	Finland	100%
Amarin Switzerland GmbH Greek branch	Greece	100%
Amarin Switzerland GmbH Dutch branch	Netherlands	100%
Amarin Switzerland GmbH Norwegian branch	Norway	100%
Amarin Switzerland GmbH, Sucursal em Portugal	Portugal	100%
Amarin Switzerland GmbH Sweden filial	Sweden	100%

As of the date of this Annual Report on Form 10-K, our principal operating activities were being conducted by Amarin Corporation plc, together with Amarin Pharmaceuticals Ireland Limited and Amarin Pharma, Inc. Operating activity being conducted by the European subsidiaries were in support of Amarin Pharmaceuticals Ireland Limited. Ester Neurosciences Limited had no operating activities.

Available Information

Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K (including exhibits), and amendments to reports filed pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, are made available free of charge on or through our website at *www.amarincorp.com* as soon as reasonably practicable after such reports are filed with, or furnished to, the Securities and Exchange Commission, or SEC. The SEC also maintains a website, *www.sec.gov*, that contains reports and other information regarding issuers that file electronically with the SEC. We are not, however, including the information contained on our website, or information that may be accessed through links on our website, as part of, or incorporating such information by reference into, this Annual Report on Form 10-K.

Financial Information

The financial information required under this Item 1 is incorporated herein by reference to Item 8 of this Annual Report on Form 10-K.

Item 1A. ***Risk Factors***

This Annual Report on Form 10-K 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.

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 compete with, and may face increasing competition from, generic drug companies, 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, particularly if we are unable to secure favorable product pricing and reimbursement levels, which vary from country to country. If we are unable to realize product reimbursement rates at reasonable price 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 Organizational Restructuring Program, or ORP, effected in July 2023 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 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.
- 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 subject 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.
- Our efforts to return capital to our shareholders and increase shareholder value, including our share repurchase program (which is subject to shareholder and UK court approval), may not be implemented in a timely manner or at all, or may not have the expected results.
- If we are unable to meet the listing requirements of the NASDAQ Stock Market, our stock may be delisted.

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 this Annual Report on Form 10-K, 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. 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, or the ANDA litigation. 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 compete with, and may face increasing competition from, generic drug companies and our revenues and results of operations could continue to be materially and adversely affected.

Following the ANDA litigation rulings against the Company, 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 by pharmacies across the U.S. to fill prescriptions 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 the 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, in 2022 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, and in July 2023 all remaining sales force positions in the U.S. were eliminated and our overall headcount was reduced by 30% as part of our ORP. Although these initiatives are expected to result 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. Furthermore, such efforts may reduce our ability to expand use of VASCEPA.

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, and as part of our ORP, we redesigned our commercial infrastructure in Europe. 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 various countries, 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 other 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, Greater China, South Korea and many markets in Southeast Asia, and Israel. 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 pricing and reimbursement levels, which vary from country to country. If we are unable to realize product reimbursement rates at reasonable price 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, and 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 these negotiations are not always successful. 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 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.

Further, in countries outside the U.S., 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, and have redesigned our commercial infrastructure 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, including our ORP announced in July 2023, 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 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 may put us at a competitive disadvantage relative to companies with more extensive product lines;
- an inability by us or our partners to obtain regulatory and marketing approval or establish marketing channels in foreign jurisdictions; and
- unforeseen costs and expenses associated with operating a new independent sales and marketing organization outside of the United States.

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 generics. Refer to "*Item 1. Business - Government Regulation – Pharmaceutical Pricing and Reimbursement*" for further details.

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 products throughout the pharmaceutical industry, including VASCEPA. 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.

We may be unable to increase or maintain market acceptance by physicians, patients, healthcare payors and others in the medical community, 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, pandemics, international conflicts and political unrest, all of which could negatively impact our supply chain or 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.

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.

Any new clinical data or analysis of existing data from clinical trials 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.

Analysis of data from 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.

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. China's National Medical Products Administration, or NMPA, approved VASCEPA as an adjunct to diet to reduce the levels of triglyceride in adult patients suffering from severe hypertriglyceridemia (≥500mg/dL) and in October 2023 Edding submitted a regulatory filing to the NMPA which, if approved, would secure National Reimbursement Drug Listing for VASCEPA in Mainland China under the REDUCE-IT indication. 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 new studies involving VASCEPA and icosapent ethyl, or further analysis of existing trial data, 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 ORP effected in July 2023 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.

If we are not successful in our efforts to continue to market and sell VASCEPA in the United States, including following our ORP announced in July 2023 which eliminated all remaining sales force positions in the United States, with the managed care and trade organization remaining to support U.S. commercial efforts, and approximately 30% of non-sales positions, 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.

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. For example, we were recently the subject of two civil investigative demands, or CID, from the U.S. Federal Trade commission and a subpoena from the New York Attorney General, or the Investigations. Although we are cooperating with the government and completed document product in mid-2023, we cannot predict when these investigations will be resolved, the outcome of the investigations or their potential impact on our business.

In addition, we 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.

If our promotional activities or other operations are found to be in violation of any law or governmental regulation through existing or new interpretations or as a result of the findings of the Investigations, 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 may 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 possibly in the near term, 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.

For a more detailed discussion of our competitors, and potential competing drugs in development, in the United States and the rest of the world, see our discussion above in *Item 1. Business - Competition*.

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 limited 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.

We could face patent litigation related to the patents filed in the Orange Book related to the REDUCE-IT study, particularly given that the three-year period of exclusivity under the Hatch-Waxman Amendments expired on December 13, 2022, which exclusivity would have precluded the U.S. FDA from approving a marketing application for an ANDA for a product candidate that the U.S. FDA viewed as having the same conditions of approval as VASCEPA.

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

We cannot predict the outcome of the pending lawsuits, any appeals, or any subsequently filed lawsuits or inter partes review.

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 suppliers, 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.

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 omega-3 fatty acid dietary supplements, which are subject to less stringent regulatory oversight.

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.

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 dietary supplement 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 VASCEPA 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. For certain commercial prescription drug products, manufacturers and other parties involved in the supply chain must also meet chain of distribution requirements and build electronic, interoperable systems for product tracking and tracing and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or other products that are otherwise unfit for distribution in the United States. In addition, under the Food and Drug Omnibus Reform Act of 2022, or FDORA, sponsors of approved drugs and biologics must provide six 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, over whom we have limited or no control. 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.

The success of our product candidates, if approved, depends on the availability of coverage and adequate reimbursement from third-party payors. We cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, our product candidates or assure that coverage and reimbursement will be available for any product that we may develop.

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. For example, the IRA recently was enacted in the United States in an effort to manage certain drug prices, which includes provisions such as a $2,000 out-of-pocket cap for Medicare Part D beneficiaries, the imposition of new manufacturer financial liability on most drugs in Medicare Part D, permitting 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, requiring 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 would have limited the fees that pharmacy benefit managers can charge. This could have an adverse impact on our future revenues. Refer to *Item 1. Business - United States Healthcare Reform and Legislation* and *Item 1. Business - Pharmaceutical Pricing and Reimbursement* for further details.

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 D. 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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively 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 D 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 D 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, uses, 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. Refer to *Item 1. Business - Current and Future Legislation* and *Item 1. Business - United States Healthcare Reform and Legislation.*

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 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.

We are subject to European data protection regulations, where we collect and use personal data relating to Europe, including in relation to our personnel in the European Economic Area, or the EEA, or in the United Kingdom, or the UK. This regulatory regime includes the GDPR, as well as other national data protection legislation in force in relevant EU and EEA member states and the UK (including the UK Data Protection Act 2018 in the UK), which govern the collection, use, storage, disclosure, transfer, or other processing of personal data (including health data processed in the context of clinical trials): (i) regarding individuals in the EU, EEA and UK; and/or (ii) carried out in the context of the activities of our establishment in any EU and EEA member state or the UK. Currently, the EU GDPR and UK GDPR remain largely aligned. The GDPR imposes several requirements on companies that process personal data, including requirements relating to the processing of health and other sensitive data, legal basis for processing personal data which may include obtaining the consent of the individuals to whom the personal data relates, providing detailed information to individuals about how their personal data is used, notification of personal data breaches to data protection authorities and individuals, and implementing safeguards to protect the security and confidentiality of the personal data. The GDPR also imposes strict rules on the transfer of personal data out of the EEA and UK to third countries, including the United States in certain circumstances, unless a derogation exists or a valid GDPR transfer mechanism (e.g., the European Commission approved Standard Contractual Clauses, or SCCs, and the UK International Data Transfer Agreement/Addendum, or UK IDTA) have been put in place. Where relying on the SCCs /UK IDTA for data transfers, we may also be required to carry out transfer impact assessments to assess whether the recipient is subject to local laws which allow public authority access to personal data. Any inability to transfer personal data from the EEA and UK to the United States in compliance with data protection laws may impede our business operations and may adversely affect our business and financial position.

The UK Government has introduced a Data Protection and Digital Information Bill, or Data Reform Bill, into the UK legislative process to reform the UK's data protection regime, and if passed, the final version of the Data Reform Bill may have the effect of further altering the similarities between the UK and EEA data protection regimes and threaten the UK international transfers adequacy decision from the European Commission, which may lead to additional compliance costs for us and could increase our overall risk. It is unclear how UK data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the UK will be regulated in the long term.

Failure to comply with the requirements of the GDPR and related national data protection laws of the EEA Member States or the UK may result in substantial fines of up to €20 million or 4% of a company's global annual revenues for the preceding financial year, whichever is higher. Moreover, the GDPR grants data subjects and consumer associations the right to claim material and non-material damages resulting from infringement of the GDPR. The GDPR imposes additional responsibility and liability in relation to personal data that we process, where such processing is subject to the GDPR 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. Although the EU GDPR and the UK GDPR currently impose substantially similar obligations, it is possible that over time the UK GDPR could become less aligned with the EU GDPR. In addition, EEA Member States have adopted national laws to supplement the EU GDPR, which may partially deviate from the EU GDPR, and the competent authorities in the EEA Member States may interpret EU GDPR obligations slightly differently from country to country, such that we do not expect to operate in a uniform legal landscape in the EEA and UK with respect to data protection regulations. The potential of the respective provisions and enforcement of the EU GDPR and UK GDPR further diverging in the future creates additional regulatory challenges and uncertainties for us. The lack of clarity on future UK laws and regulations and their interaction with EU laws and regulations could add legal risk, uncertainty, complexity and compliance cost to the handling of European personal data and our privacy and data security compliance programs could require us to amend our processes and procedures to implement different compliance measures for the UK and the EEA.

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.

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. In 2022 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, and in July 2023 all remaining sales force positions in the U.S. were eliminated and our overall headcount was reduced by 30% as part of our ORP. As a result, we do not have a sales team to promote VASCEPA to physicians and other healthcare professionals in the United States, and will rely on only our managed care and trade organization to support sales of VASCEPA in the United States.

In addition to the elimination of our sales force 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. We redesigned our commercial infrastructure in Europe to better align with pricing and reimbursement status and commercial potential. We will be operating with

streamlined teams in Europe and elsewhere outside the United States; however, we will anticipate the need to expand internally and expect that we will need to manage additional relationships with various collaborative partners, suppliers and other third parties as we progress in Europe and outside the United States. 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 business is depending on successful life-cycle management efforts.

Our drug development efforts are subject to the risks and uncertainties inherent in any drug development program. Due to the risks and uncertainties involved in progressing through development and bioequivalence or even potential additional trials (as may be required by specific regulatory agencies), and the time and cost involved in obtaining regulatory approvals, 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 derivative, combination or next generation product candidate. The potential success of any derivative, combination or next generation product candidate will depend on a number of factors, including the scope of and our success with manufacturing, obtaining regulatory approvals and achieving sufficient (or any) levels of market acceptance if approved.

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, South Korea and Southeast Asia, and Israel, 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, 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 required 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 adversely 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 a 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.

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.

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.

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, New Zealand, South Korea and Southeast Asia, and Israel. We continue to assess other opportunities to develop VASCEPA commercialization outside of the United States through similar arrangements.

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 and in Mainland China under the MARINE indication. In October 2023, Edding submitted for the approval of the REDUCE-IT indication in Mainland China. However, Edding may be required to undertake pre- or post-approval clinical development efforts in these markets, or Edding may face challenges or be unsuccessful in commercial launch. Further, any development and regulatory efforts in the China Territory may be negatively impacted by the lingering effects of the 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 issues expressed between the countries regarding trade practices, tariffs and honoring

intellectual property rights. If Edding is not able to effectively commercialize VASCEPA in the China Territory, we may not be able to generate revenue from our agreement with Edding 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, with CSL Seqirus, or CSL, to commercialize and distribute VASCEPA in Australia and New Zealand, Lotus Pharmaceuticals, or Lotus, to commercialize and distribute VASCEPA in several countries in Southeast Asia and Neopharm (Israel) 1996 Ltd., or Neopharm, to distribute VASCEPA in Israel. Although Biologix is currently actively commercializing VASCEPA in the United Arab Emirates, Lebanon, Kuwait and Saudi Arabia, and HLS is currently commercializing VASCEPA in Canada, we are completely reliant on these third parties to successfully commercialize the product in those markets, which markets can be complex and challenging.

If Edding, Biologix, HLS, CSL, Lotus or Neopharm, 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 the launch of VAZKEPA in certain countries in the last two years, 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, including the Investigation referenced above. 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.

In the U.S., to help patients afford our approved product, we utilize programs to assist them, including patient assistance programs and co-pay coupon programs for eligible patients. Government enforcement agencies have shown increased interest in pharmaceutical companies' product and patient assistance programs, including reimbursement support services, and a number of investigations into these programs have resulted in significant civil and criminal settlements. It is possible that changes in insurer policies regarding co-pay coupons and/or the introduction and enactment of new legislation or regulatory action could restrict or otherwise negatively affect these patient support programs, which could result in fewer patients using affected products, and therefore could have a material adverse effect on our sales, business, and financial condition.

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.

In addition, investigator initiated trials, or IITs, which are scientific research that is initiated, sponsored, and conducted by an independent investigator(s) and/or institution(s) not affiliated with us, are being, and additional IITs, may be conducted involving potential product candidates. The investigator, sponsor, and/or investigator/sponsor remains responsible for conception, design, data analysis, publication, and compliance with applicable law. Investigator initiated trials can contribute towards enhancing the understanding of products (such as mechanism of action) and sparking new ideas for further research; however, IITs are generally not supported by pharmaceutical companies for the purposes of generating data that can lead to product labelling changes. Even if an IIT has positive results, additional studies, along with regulatory agency guidance and approval, would be required to advance a pharmaceutical product to the next stage of development and new potential labelling changes or indications. If we are unable to confirm or replicate the results from an IIT or if negative results are obtained, we would likely be further delayed or prevented from advancing further clinical development. Further, if the data proves to be inadequate compared to the firsthand knowledge we might have gained had the IIT been sponsored and conducted by us, then our ability to design and conduct any future clinical trials ourselves may be adversely affected. Negative results in IITs could have a material adverse effect on our efforts to obtain regulatory approval for such product candidates and the public perception of such product candidates. In addition, third parties that are investigating product candidates which have not been provided by us may seek and obtain regulatory approval of product candidates before we do, which may adversely affect our development strategy and eligibility for certain exclusivities for which we may otherwise be eligible.

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. Refer to "*Item 1. Business - Patents, Proprietary Technology, Trade Secrets* for further details.

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 healthcare 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 intends to continue 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 are granted, there is no certainty 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 2024, we reiterated our belief that current cash and investments and other assets are adequate to support continued operations, including the share repurchase program. This and similar statements are based on estimates, assumptions and the judgment of management at such time. 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 senior management team during 2023, 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 globally 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 pursue 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, where we have recently eliminated all sales force positions, employees are increasingly being recruited by other companies. The current and potential threat of generic competition and our recent reductions in force, including as part of our Organizational Restructuring Program announced in July 2023, 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. For example, in June 2019, a report published by security researchers claimed that a database belonging to one of our vendors containing information about individuals who use or have expressed interest in VASCEPA was accessible to unauthorized users. Although we were informed that such breach did not include social security numbers or credit card information, 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 have 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 36%, 28%, and 29%, respectively, of gross product sales for the year ended December 31, 2023 and represented 36%, 18%, and 38%, respectively, of the gross accounts receivable balance as of December 31, 2023. Customers A, B, and C accounted for 35%, 31%, and 27%, respectively, of gross product sales for the year ended December 31, 2022 and represented 35%, 21%, and 39%, respectively, of the gross accounts receivable balance as of December 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, 2023 and 2022, we reported net losses of approximately $59.1 million and $105.8 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, 2023 of $1.6 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 commercialization efforts in the United States and 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. 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, 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 ORP announced in July 2023, 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; 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 $199.3 million and short-term investment balance of $121.4 million as of December 31, 2023, will be sufficient to fund our projected operations, including the share repurchase program, for at least 12 months from the issuance date of consolidated financial statements included elsewhere in this Annual Report on Form 10-K. 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 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 do not expect the provisions of the IRA to have a material impact.

Risks Related to Ownership of our ADSs and Common Shares

Our efforts to return capital to our shareholders and increase shareholder value, including our share repurchase program (which is subject to shareholder and UK court approval), may not be implemented in a timely manner or at all, or may not have the expected results.

The implementation of our announced share repurchase agreement is conditional upon shareholder and UK court approval, as required under UK company law. Although we intend to accelerate our annual general meeting of shareholders to April 2024 to seek such shareholder approval, we will thereafter need to proceed with the requisite court process to undertake a reduction of capital in order to create the necessary distributable profits for the funding of the repurchases, which process could be completed by the end of the second quarter of 2024, with share repurchases commencing shortly thereafter; however, we cannot guarantee that the share repurchase program will receive shareholder or court approval in a timely manner or at all. Further, the share repurchase program and other efforts to return capital to shareholders may not have the anticipated effect or increase shareholder value in the long term.

If we are no longer able to meet the listing requirements of the NASDAQ Stock Market, our stock may be delisted.

The NASDAQ Stock Market, or NASDAQ, on which our ADSs are listed and traded, has listing requirements that include a $1.00 minimum closing bid price requirement. NASDAQ will issue a deficiency notice if an issuer is in violation of a listing standard for a period of 30 business consecutive days. Such deficiency letter does not result in the immediate delisting of an issuer as there is a period of 180 calendar days from the deficiency notice to regain compliance with NASDAQ's minimum bid price requirement. If an issuer is unable to comply with NASDAQ's minimum bid price requirement after this 180 day calendar period, NASDAQ may elect, subject to any potential additional cure periods, to initiate a process that could delist the issuer from trading on the NASDAQ. We received a deficiency letter from NASDAQ in October 2023, as our ADSs had traded below $1.00 for 30 consecutive business days. In January 2024 we regained compliance with the NASDAQ listing requirements as our ADSs had traded above $1.00 for 10 consecutive business days.

Should such a delisting occur, it would adversely impact the liquidity and price of our ADSs and would impede our ability to raise capital.

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 February 23, 2024, we had 410,671,800 common shares outstanding including 401,870,067 shares held as ADSs and 8,801,733 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. Our planned share repurchase program, which is subject to requisite shareholder and UK High Court approval under UK law, would, if implemented, reduce the number of shares outstanding and could result in reduced trading volumes. 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.

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 ordinary shares, we believe that we will not be classified as a PFIC for the taxable year ended December 31, 2023, 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 UK, 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.

We believe that our place of central management and control is not currently in the UK (or the Channel Islands or the Isle of Man) for the purposes of the jurisdictional criteria of the Takeover Code. Accordingly, we believe that we are not currently subject to the Takeover Code and, as a result, our shareholders are not currently entitled to the benefit of certain takeover offer protections provided under the Takeover Code, including the rules regarding mandatory takeover bids.

In the event that this changes, or if the interpretation and application of the Takeover Code by the Panel on Takeovers and Mergers, or Takeover Panel, changes (including changes to the way in which the Takeover Panel assesses the application of the Takeover Code to English companies whose shares are listed outside of the UK), the Takeover Code may apply to us in the future.

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 any person acquires, whether by a series of transactions over a period of time or not, an interest in shares which (taken together with shares already held by that person and an interest in shares held or acquired by persons acting in concert with him or her) carry 30% or more of the voting rights of a company that is subject to the Takeover Code, that person is generally required to make a mandatory offer to all the holders of any class of equity share capital or other class of transferable securities carrying voting rights in that company to acquire the balance of their interests in the company.

- When any person who, together with persons acting in concert with him or her, is interested in shares representing not less than 30% but does not hold more than 50% of the voting rights of a company that is subject to the Takeover Code, and such person, or any person acting in concert with him or her, acquires an additional interest in shares which increases the percentage of shares carrying voting rights in which he or she is interested, then such person is generally required to make a mandatory offer to all the holders of any class of equity share capital or other class of transferable securities carrying voting rights of that company to acquire the balance of their interests in the company.
- A mandatory offer triggered in the circumstances described in the two paragraphs above must be in cash (or be accompanied by a cash alternative) and at not less than the highest price paid within the preceding 12 months to acquire any interest in shares in the company by the person required to make the offer or any person acting in concert with him or her.
- In relation to a voluntary offer (i.e., any offer which is not a mandatory offer), 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) and any person acting in concert with it 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 not less than the highest price paid for any interest in shares of that class 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 not less than the highest price paid for such shares during the offer period.
- If after an announcement is made, the offeror or any person acting in concert with them 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 to not less than the highest price paid for the interest in shares so acquired.
- 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.
- Special or 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.
- Each document published in connection with an offer by or on behalf of the offeror or offeree must state that the directors of the offeror or the offeree, as the case may be, accept responsibility for the information contained therein.
- 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.

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. 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 re-evaluate 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., Europe and the Middle East, caused by political instability and conflict, such as Russia's invasion of Ukraine and current armed conflict in Israel and the Gaza Strip, and economic challenges caused by pandemics or other health crises, such as the recent 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, the current armed conflict in Israel and the Gaza Strip, 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 1B. ***Unresolved Staff Comments***

None.

Item 1C. ***Cybersecurity***

We recognize the importance of safeguarding the security of our computer systems, software, networks, and other technology assets. Our security efforts are aimed at preserving the confidentiality, integrity, and continued availability of information under our ownership or care with the aim to continually improve security features in order to keep pace with the evolving cyber threat landscape.

Overview of Cybersecurity Risk Management and Strategy

Based on our business model, we rely on the outsourcing of certain key business functions, including laboratory work, clinical research, and the manufacturing and distribution of our product. We utilize the vetted processes and procedures of these partners and ensure proper cybersecurity and risk mitigation strategies are in place and functioning, which is accessed through our Vendor Risk Assessment process prior to engaging with our partners. Our cybersecurity risk identification, assessment and management response process is a critical part of our overall enterprise risk management, or ERM, program. Within our ERM framework, we adhere to our Global Information Technology Policy, or IT Policy, among a host of other policies and procedures aimed at providing guidelines and standards to ensure the security, integrity, reliability and recoverability of our systems and infrastructure.

We employ and manage various third party partnerships to help protect us from cybersecurity threats. These organizations provide services such as penetration testing, security assessments, as well as twenty-four hours per day monitoring, alerting and response, including incident responses, all of which adhere to our overall ERM framework. Our partners evaluate and rank our cybersecurity maturity and coverage as part of their services and keep us informed of emerging global threats. Our digital infrastructure undergoes both internal and external audits as part of our Sarbanes-Oxley audit process and is designed to address the requirements of applicable information security standards and an evolving cyber landscape.

Board Oversight of Risks from Cybersecurity Threats

Our Board of Directors has delegated to the Audit Committee oversight of risks from cybersecurity threats. The management team provides quarterly reports to the Audit Committee which cover cybersecurity and other information technology-related risks, based on our ERM framework. These quarterly updates keep the Audit Committee apprised of our ongoing cybersecurity enhancements and any emerging global threats. The Audit Committee keeps the remaining Board of Directors apprised of material risks from cybersecurity threats.

Management's Role in Assessing and Managing Material Risks from Cybersecurity Threats

Our Information Technology and Security team is responsible for the management, maintenance, monitoring and response of our critical internal digital assets. This team is led by our Senior Director of Global Information Technology and Security, who has 25

years of cyber and Enterprise IT management experience. This position monitors current cyber risk trends, engages with 3rd party cyber security experts, and meets with the Infrastructure and Security team regularly to stay apprised of internal cyber risks.

Our internal cybersecurity testing and reporting processes allow us to rank our overall risk on a periodic basis to ensure we identify and respond to internal risk trends. We follow escalation procedures to ensure communication of cyber-related events. The Board and management have made cybersecurity education and training a part of our overall corporate objectives, setting the tone for the organization about the importance of cybersecurity.

As of the date of this report, cybersecurity threats, including as a result of any previous cybersecurity incidents, have not materially affected or are not reasonably likely to affect the Company, including our business strategy, results of operations or financial condition. For information regarding cybersecurity risks, see our discussion above in *Item 1A. Risk Factors - Risks Related to Our Business - 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*.

Item 2. ***Properties***

The following table lists the location, use and ownership interest of our principal properties as of February 29, 2024:

Location	Use	Ownership	Size (sq. ft.)
Dublin, Ireland	Offices	Leased	2,674
Bridgewater, New Jersey, USA	Offices	Leased	67,747
Zug, Switzerland	Offices	Leased	4,511

On September 13, 2022, we entered into a license agreement for office space in Dublin, Ireland, effective October 1, 2022 which terminates on September 30, 2024, and can be extended automatically for successive two-year periods. On May 2, 2023, we entered into an agreement to lease additional office space at our Dublin office, effective June 1, 2023 which terminates on September 30, 2024, and can be extended automatically for successive two year periods.

Effective February 5, 2019, we entered into a lease agreement for approximately 67,747 square feet of office space in Bridgewater, New Jersey. The lease commenced on August 15, 2019, for an 11-year period, with two five-year renewal options. On January 20, 2023, we entered into a sublease agreement to sublease 50,000 square feet of the leased 67,747 square feet of office space in Bridgewater, New Jersey. The sublease commenced on February 1, 2023 and terminates as of the date of the head lease.

On October 10, 2021, we entered into a lease agreement for approximately 4,511 square feet of office space in Zug, Switzerland. The lease commenced on February 1, 2022 for a five-year period, with one five-year renewal option.

We believe that our facilities are adequate for our current and anticipated near-term needs and that suitable additional or substitute space would be available if needed.

Item 3. ***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. Refer to *Note—7 Commitments and Contingencies* to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for further details on our legal proceedings.

Item 4. ***Mine Safety Disclosures***

Not applicable.

PART II

Item 5. ***Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities***

Market Information

Our ADSs are listed on The NASDAQ Global Market under the symbol "AMRN". Each ADS represents one ordinary share.

The following table sets forth the high and low prices for our ADSs in each of the quarters over the past two fiscal years, as quoted on The NASDAQ Global Market under the symbol "AMRN."

	Common Stock Price			
	Fiscal 2023		Fiscal 2022	
	High	Low	High	Low
First Quarter	$ 2.23	$ 1.15	$ 3.82	$ 2.76
Second Quarter	$ 1.50	$ 1.10	$ 3.74	$ 1.11
Third Quarter	$ 1.49	$ 0.84	$ 1.71	$ 1.04
Fourth Quarter	$ 0.93	$ 0.65	$ 1.38	$ 1.06

Shareholders

As of January 31, 2024, there were approximately 350 holders of record of our ordinary shares. Because many ordinary shares are held by broker nominees, we are unable to estimate the total number of shareholders represented by these record holders. Our depositary, Citibank, N.A., constitutes a single record holder of our ordinary shares.

Dividends

We have never paid dividends on our ordinary shares and do not anticipate paying any cash dividends on our 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.

Share Repurchase Program

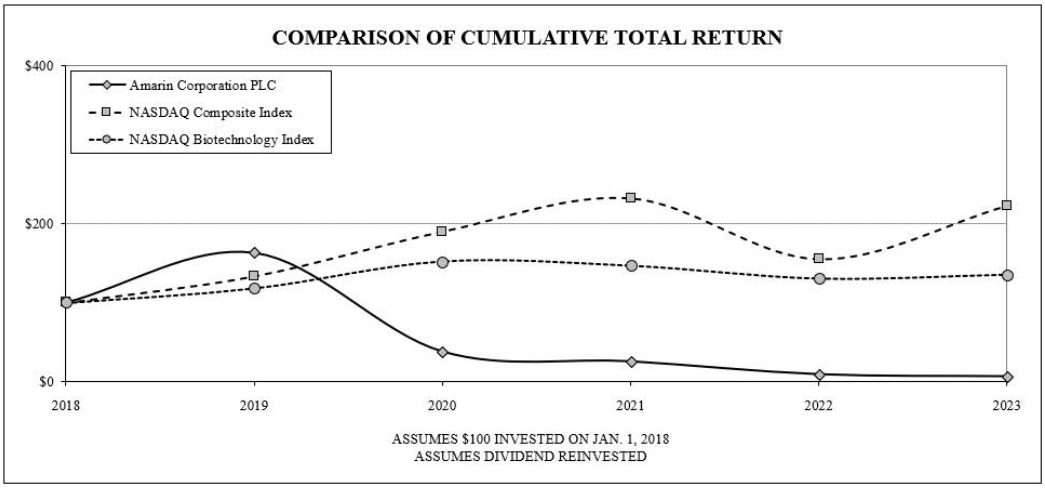
On January 10, 2024, we announced plans to initiate a share repurchase program to purchase up to $50.0 million of our ordinary shares held in the form of ADSs. The implementation of the share repurchase program will require shareholder approval as well as UK High Court approval, as required under UK company law.

Performance Graph—5 Year

The following performance graph and related information shall not be deemed "soliciting material" or to be "filed" with the SEC, nor shall such information be incorporated by reference into any future filing under the Securities Act of 1933 or Securities Exchange Act of 1934, each as amended, except to the extent that we specifically incorporate it by reference into such filing.

The following graph compares the cumulative five-year return provided to shareholders of our ADSs relative to the cumulative total returns of the NASDAQ Composite Index and the NASDAQ Biotechnology Index. We believe these indices are the most appropriate indices against which the total shareholder return of Amarin should be measured. The NASDAQ Biotechnology Index has been selected because it is an index of U.S. quoted biotechnology and pharmaceutical companies. An investment of $100 (with reinvestment of all dividends) is assumed to have been made in our ADSs and in each of the indices on December 31, 2018, and its relative performance is tracked through December 31, 2023.

Included in this five-year time period is the substantial positive impact on the price of Amarin's ADSs in 2018 following presentation and publication of positive REDUCE-IT results and, in late 2019, following approval by the FDA of a new indication and label expansion for VASCEPA to reduce cardiovascular risk. Also included during this five-year period is the substantial negative impact on the price of Amarin's ADSs in 2020 following the loss of the Company's patent litigation and subsequent appeal.



Company/Market/Peer Company	12/31/2019	12/31/2020	12/31/2021	12/31/2022	12/31/2023
Amarin Corporation PLC	$ 163.26	$ 37.95	$ 25.53	$ 9.17	$ 6.59
NASDAQ Composite Index	$ 133.65	$ 190.01	$ 232.16	$ 155.32	$ 222.76
NASDAQ Biotechnology Index	$ 118.20	$ 151.85	$ 146.49	$ 130.51	$ 135.39

Information about Our Equity Compensation Plans

Information regarding our equity compensation plans is incorporated by reference in Item 12 of Part III of this Annual Report on Form 10-K.

Recent Sales of Unregistered Securities

None

Issuer Purchases of Equity Securities

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

Period	Total Number of Shares Purchased [1]	Average Price Paid per Share
October 1 – 31, 2023	20,290	$ 0.87
November 1 – 30, 2023	35,343	0.74
December 1 – 31, 2023	161,456	0.86
Total	217,089	$ 0.84

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

Taxation

The following summary contains a description of material U.S., UK and Irish federal income tax consequences of the ownership and disposition of our ordinary shares or ADSs. This summary should not be considered a comprehensive description of all the tax considerations that may be relevant to beneficial owners of ordinary shares or ADSs.

Certain Material U.S. Tax Considerations

The following is a summary of certain U.S. federal income tax considerations with respect to the ownership and disposition of ordinary shares or ADSs by a U.S. Holder (as defined below). This summary applies to you only if you hold ordinary shares or ADSs as a capital asset. This summary is based upon the U.S. Internal Revenue Code of 1986, as amended, which is referred to herein as the Code, regulations promulgated under the Code and administrative rulings and judicial decisions as in effect on the date of this Annual Report on Form 10-K, all of which are subject to change and to differing interpretations, possibly with retroactive effect, which could result in U.S. federal income tax considerations different from those summarized below.

This summary is general in nature and does not address the effects of any state or local taxes, the tax consequences in jurisdictions other than the United States or any U.S. federal taxes other than income tax (such as estate or gift tax). In addition, it does not address U.S. federal income tax consequences that may be relevant to you in your particular circumstances, including alternative minimum tax consequences, nor does it apply to you if you are a holder with a special status, such as:

- a person that owns, or is treated as owning under certain ownership attribution rules, 10% or more of the voting power or value of the stock of Amarin;
- a broker, dealer or trader in securities or currencies;
- a bank, mutual fund, life insurance company or other financial institution;
- a tax-exempt entity;
- a qualified retirement plan or individual retirement account;
- a person that holds ordinary shares or ADSs as part of a straddle, hedge, constructive sale or other integrated transaction for tax purposes;
- a partnership, S corporation or other pass-through entity;
- an investor in a partnership, S corporation or other pass-through entity;
- a person that is required to report income with respect to ordinary shares or ADSs no later than such income is reported on an "applicable financial statement;"
- a person who received ordinary shares or ADSs in connection with the performance of services; and
- a person whose functional currency for U.S. federal income tax purposes is not the U.S. dollar.

If an entity treated as a partnership for U.S. federal income tax purposes holds ordinary shares or ADSs, the tax treatment of a partner will generally depend upon the status of the partner and upon the activities of the partnership. A partner of a partnership that owns or disposes of ADSs should consult the partner's tax advisor regarding the specific tax consequences of the ownership and disposition of ordinary shares or ADSs.

YOU SHOULD CONSULT YOUR OWN ADVISOR REGARDING THE TAX CONSEQUENCES OF THE OWNERSHIP AND DISPOSITION OF ORDINARY SHARES AND ADSS IN LIGHT OF YOUR PARTICULAR CIRCUMSTANCES.

U.S. holders

For purposes of this discussion, a U.S. Holder is any beneficial owner of an ordinary share or ADS that is, for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States, any state thereof or the District of Columbia;
- a corporation created or organized under the laws of the United States, any state thereof or the District of Columbia;
- an estate the income of which is subject to U.S. federal income taxation regardless of its source; or,
- a trust (i) that validly elects to be treated as a U.S. person for U.S. federal income tax purposes, or (ii) the administration over which a U.S. court can exercise primary supervision and all of the substantial decisions of which one or more U.S. persons have the authority to control.

Distributions

Subject to the discussion under "—Passive Foreign Investment Company," below, the gross amount of distributions, if any, payable on ordinary shares and ADSs generally would be treated as dividend income to the extent paid out of current or accumulated earnings and profits (as determined for U.S. federal income tax purposes). A U.S. Holder would be required to include the amount of such distribution in gross income as a dividend (without reduction for any income tax withheld from such distribution). Because we do not maintain calculations of our earnings and profits in accordance with U.S. federal income tax principles, U.S. Holders should assume that any distribution by us with respect to the ordinary shares and ADSs will constitute ordinary dividend income.

Subject to the discussion under "—Passive Foreign Investment Company," below, as long as our ordinary shares or ADSs (as applicable) are treated as publicly traded on an established securities market, or we are eligible for the benefits of the U.S.-Irish Tax Treaty, any distributions treated as dividends will generally be qualified dividend income in the hands of non-corporate U.S. Holders, provided that certain significant holding period and other requirements are met. Any dividends that are qualified dividend income will

generally be taxed at preferential rates to a non-corporate U.S. Holder. Any dividends paid to a corporate holder will not be eligible for the dividends received deduction.

U.S. Holders generally may claim the amount of Irish withholding tax withheld either as a deduction from gross income or as a credit against U.S. federal income tax liability. However, the foreign tax credit is subject to numerous complex limitations that must be determined and applied on an individual basis. Generally, the credit cannot exceed the proportionate share of a U.S. Holder's U.S. federal income tax liability that such U.S. Holder's foreign source taxable income bears to such U.S. Holder's worldwide taxable income. In applying this limitation, a U.S. Holder's various items of income and deduction must be classified, under complex rules, as either foreign source or U.S. source. In addition, this limitation is calculated separately with respect to specific categories of income. The amount of a distribution with respect to the ordinary shares or ADSs that is treated as a dividend may be lower for U.S. federal income tax purposes than it is for Irish income tax purposes, potentially resulting in a reduced foreign tax credit for the U.S. Holder. Each U.S. Holder should consult its own tax advisors regarding the foreign tax credit rules.

The amount of a distribution paid to a U.S. Holder of ordinary shares or ADSs in foreign currency generally will be equal to the U.S. dollar value of such distribution based on the exchange rate applicable on the date of receipt. A U.S. Holder that does not convert foreign currency received as a distribution into U.S. dollars on the date of receipt generally will have a tax basis in such foreign currency equal to the U.S. dollar value of such foreign currency on the date of receipt. Such a U.S. Holder generally will recognize ordinary income or loss on the subsequent sale or other taxable disposition of such foreign currency (including an exchange for U.S. dollars).

Sale or other disposition of ordinary shares or ADSs

Subject to the discussion under "—Passive Foreign Investment Company," below, in general, if you sell or otherwise dispose of ordinary shares or ADSs in a taxable disposition:

- you will recognize gain or loss equal to the difference (if any) between the U.S. dollar value of the amount realized on such sale or other taxable disposition and your adjusted tax basis in such ordinary shares or ADSs;
- any gain or loss will be capital gain or loss and will be long-term capital gain or loss if your holding period for the ordinary shares or ADSs sold or otherwise disposed of is more than one year at the time of such sale or other taxable disposition; and,
- any gain or loss will generally be treated as U.S.-source income for U.S. foreign tax credit purposes, although special rules apply to U.S. Holders who have a fixed place of business outside the United States to which this gain is attributable.

Under current law, long-term capital gains of non-corporate U.S. Holders are taxed at reduced rates. The deductibility of capital losses is subject to limitations.

In certain circumstances, amounts received by a U.S. Holder upon the redemption of ordinary shares or ADSs may be treated as a dividend with respect to such ordinary shares or ADSs, rather than as a payment in exchange for such ordinary shares or ADSs that results in the recognition of capital gain or loss. In these circumstances, the redemption payment would be included in a U.S. Holder's gross income as a dividend to the extent such payment is made out of our earnings and profits (as described above). The determination of whether redemption of ordinary shares or ADSs will be treated as a dividend, rather than as a payment in exchange for such ordinary shares or ADSs, will depend, in part, on whether and to what extent the redemption reduces the U.S. Holder's ownership in us (including as a result of certain constructive ownership attribution rules). The rules applicable to redemptions are complex, and each U.S. Holder should consult its own tax adviser to determine the consequences of any redemption.

Passive foreign investment company

PFIC Rules Generally. U.S. Holders of ordinary shares and ADSs should be aware that each of Amarin and certain of its subsidiaries could constitute a PFIC for U.S. federal income tax purposes. The tests for determining PFIC status for a taxable year depend upon the relative values of certain categories of assets and the relative amounts of certain kinds of income. The application of these factors depends upon our financial results for the year, which are beyond our ability to predict or control, and the application of the relevant rules is subject to legal and factual uncertainties. Based on certain estimates of our gross income and gross assets, the latter determined by reference to the expected value of our ADSs and ordinary shares, we believe that we will not be classified as a PFIC for the taxable year ended December 31, 2023, and we do not expect to be treated as a PFIC in any future taxable year for the foreseeable future. However, there can be no assurance that we will not be classified as a PFIC for any taxable year.

In general terms, we will be a PFIC for any taxable year in which either (i) 75% or more of its our gross income is passive income, or the income test, or (ii) the average percentage, by fair market value, of our assets that produce or are held for the production of passive income is 50% or more, or the asset test. "Passive income" includes, for example, dividends, interest, certain rents and royalties, certain gains from the sale of stock and securities, and certain gains from commodities transactions.

If we are a PFIC for any year, subject to the discussion of QEF (as defined herein) and mark-to-market elections below, a U.S. taxpayer who disposes or is deemed to dispose of an ordinary share or ADS at a gain or who receives a distribution treated as an "excess distribution" on an ordinary share or ADS generally would be required to allocate such gain and distribution ratably to each day in the U.S. taxpayer's holding period for the ordinary share or ADS in question.

The portion of any excess distributions including gains, which are treated for all purposes as excess distributions, allocated to the current taxable year or to a year prior to the first year in which we were a PFIC would be includible as ordinary income in the current taxable year. In contrast, the portion of any excess distributions allocated to the first year in the U.S. Holder's holding period in which we were a PFIC and any subsequent year or years (excluding the current year) would be taxed at the highest marginal rate applicable to ordinary income for each year (regardless of the U.S. Holder's actual marginal rate for that year and without reduction by any losses or loss carryforwards) and would be subject to interest charges to reflect the value of the U.S. federal income tax deferral.

In accordance with the rules above, if we are or were a PFIC at any time during the U.S. Holder's holding period, none of the gain recognized on the sale or other disposition of an ordinary share or ADS would be eligible for the preferential long-term capital gains rate. In addition, dividends generally will not be qualified dividend income if in the year of payment or the preceding year we are a PFIC.

Certain elections may sometimes be used to reduce the adverse impact of the PFIC rules on U.S. Holders qualifying electing fund, or QEF, and mark-to-market elections, but these elections may accelerate the recognition of taxable income and may result in the recognition of ordinary income.

QEF Election. The rules described above for excess distributions would not apply to a U.S. Holder if the U.S. Holder makes a timely QEF election for the first taxable year of the U.S. Holder's holding period for ordinary shares or ADSs during which we are a PFIC and we comply with specified reporting requirements. A timely QEF election for a taxable year generally must be made on or before the due date (as may be extended) for filing the taxpayer's U.S. federal income tax return for the year. A U.S. Holder who makes a QEF election generally must report and include in income on a current basis a pro rata share of our ordinary earnings and net capital gain for any taxable year in which we are a PFIC, whether or not those earnings or gains are distributed. A U.S. Holder who makes a QEF election must file a Form 8621 with its annual income tax return. For U.S. Holders who seek to make a QEF election, with respect to our ordinary shares or ADSs, we will make available an information statement that will contain the necessary information required for making a QEF election and permit such U.S. Holders access to certain information in the event of an audit by the U.S. tax authorities.

If a U.S. Holder does not make a QEF election for the first taxable year of the U.S. Holder's holding period for ordinary shares or ADSs during which we are a PFIC, the QEF election will not be treated as timely and the adverse tax regime described above would apply to dispositions of or excess distributions on the ordinary shares or ADSs. In such case, a U.S. Holder may make a deemed sale election whereby the U.S. Holder would be treated as if the U.S. Holder had sold the ordinary shares or ADSs in a fully taxable sale at fair market value on the first day of such taxable year in which the QEF election takes effect. Such U.S. Holder would be required to recognize any gain on the deemed sale as an excess distribution and pay any tax and interest due on the excess distribution when making the deemed sale election. The effect of such further election would be to restart the U.S. Holder's holding period in the ordinary shares or ADSs, subject to the QEF regime, and to purge the PFIC status of such ordinary shares or ADSs going forward.

Mark-to-Market Election. If we are or become a PFIC, a U.S. Holder of ordinary shares or ADSs may elect to recognize any gain or loss on ordinary shares or ADSs on a mark-to-market basis at the end of each taxable year, so long as the ordinary shares and ADSs, respectively, are regularly traded on a qualifying exchange. The mark-to-market election under the PFIC rules is an alternative to the QEF election. A U.S. Holder who makes a mark-to-market election generally must recognize as ordinary income all appreciation inherent in the U.S. Holder's investment in ordinary shares or ADSs on a mark-to-market basis and may recognize losses inherent in such ordinary shares or ADSs only to the extent of prior mark-to-market gain recognition. The income and deductions entailed by the mark-to-market regime will increase and decrease the U.S. Holder's adjusted basis in its ordinary shares or ADSs. Upon a sale or other disposition of ordinary shares or ADSs that have been marked-to-market, any gain recognized will be treated as ordinary income. The mark-to-market election must be made by the due date (as may be extended) for filing the U.S. Holder's federal income tax return for the first year in which the election is to take effect. If a mark-to-market election is made after the first taxable year of a U.S. Holder's holding period, any gain recognized in the year of the election will be treated like an excess distribution (as described above). Whether or not the mark-to-market election is available will depend on whether the ordinary shares or ADSs are regularly traded on a qualifying exchange and we cannot provide assurance that the ordinary shares or ADSs will be considered regularly traded (which determination is based on the volume of trading of the ordinary shares or ADSs) for all years in which we may be a PFIC.

Rules for Lower-Tier PFIC Subsidiaries. Special adverse rules apply to U.S. Holders of ordinary shares or ADSs for any year in which we are a PFIC and have a non-U.S. subsidiary that is also a PFIC, or a lower-tier PFIC. If we are or become a PFIC and a

U.S. Holder does not make a QEF election (as described above) in respect of any lower-tier PFIC, the U.S. Holder could incur liability for the deferred tax and interest charge described above if (i) we receive a distribution from, or disposes of all or part of our interest in, the lower-tier PFIC or (ii) the U.S. Holder disposes of all or part of its ordinary shares or ADSs. A QEF election that is made for ordinary shares or ADSs will not apply to a lower tier PFIC, although a separate QEF election may be made with respect to a lower-tier PFIC. For U.S. Holders who seek to make a QEF election, with respect to our ordinary shares or ADSs, we will make available an information statement that will contain the necessary information required for making a QEF election with respect to any lower-tier PFIC and permit such U.S. Holders access to certain information in the event of an audit by the U.S. tax authorities. For U.S. Holders that make a mark-to-market election for Amarin, if available, no such election may be made with respect to the stock of a lower-tier PFIC that a U.S. Holder is treated as owning if such stock is not marketable. Hence, the mark-to-market election will not be effective to eliminate a U.S. Holder's liability for the deferred tax and interest charge described above with respect to deemed dispositions of lower-tier PFIC stock or distributions from a lower-tier PFIC.

Taxpayer Reporting Obligations. A U.S. Holder's ownership of ordinary shares or ADSs in a PFIC generally must be reported by filing Form 8621 with the U.S. Holder's annual U.S. federal income tax return. Every U.S. Holder who is a shareholder in a PFIC must file an annual report containing the information required by the IRS.

The PFIC rules are extremely complex, and U.S. Holders are urged to consult their own tax advisers regarding the potential tax consequences of Amarin being classified as a PFIC.

Medicare tax

Certain U.S. Holders that are individuals, estates or trusts are required to pay up to an additional 3.8% tax on the lesser of (i) the U.S. person's net investment income (or undistributed net investment income in the case of an estate or trust) for the relevant taxable year and (ii) the excess of the U.S. person's modified adjusted gross income (or adjusted gross income, in the case of an estate or trust) for the taxable year over a certain threshold (which in the case of individuals will be between $125,000 and $250,000, depending on the individual's circumstances). A U.S. Holder's net investment income will include dividends and capital gains on the U.S. Holder's ordinary shares and ADSs. U.S. Holders should consult their own tax advisors regarding the effect, if any, of the Medicare tax on the ownership and disposition of ordinary shares or ADSs.

Taxpayer reporting obligations

Certain U.S. Holders that hold certain foreign financial assets are required to report information relating to such assets to the IRS, subject to certain exceptions. U.S. Holders may also be required to make other tax filings with respect to their investments in our ordinary shares and ADSs, including IRS Form 926 (Return by a U.S. Transferor of Property to a Foreign Corporation). Failure to provide such information could result in significant additional taxes and penalties. U.S. Holders should consult their own tax advisors regarding potential reporting obligations.

U.S. Information reporting and backup withholding

U.S. Holders of ordinary shares and ADSs may be subject to information reporting and may be subject to backup withholding on distributions on ordinary shares and ADSs or on the proceeds from a sale or other disposition of ordinary shares and ADSs paid within the United States. Payments of distributions on, or the proceeds from the sale or other disposition of ordinary shares and ADSs to or through a foreign office of a broker generally will not be subject to backup withholding, although information reporting may apply to those payments in certain circumstances. Backup withholding will generally not apply, however, to a U.S. Holder who:

- furnishes a correct taxpayer identification number and certifies that the U.S. Holder is not subject to backup withholding on IRS Form W-9, Request for Taxpayer Identification Number and Certification (or substitute form); or
- is otherwise exempt from backup withholding.

Backup withholding is not an additional tax. Any amounts withheld from a payment to a holder under the backup withholding rules may be credited against the holder's U.S. federal income tax liability, and a holder may obtain a refund of any excess amounts withheld by filing the appropriate claim for refund with the IRS in a timely manner. U.S. Holders should consult their own tax advisors regarding information reporting and potential back up withholdings.

Certain Material UK Tax Considerations

The following discussion is limited to an overview of the tax consequences of ownership and disposition of ordinary shares, or such shares represented by ADSs (those ordinary shares or ADSs deriving over 75% of their value otherwise than from United Kingdom land). Each shareholder should however seek individual tax advice as specific rules may apply in certain circumstances.

Capital gains

If you are not resident in the United Kingdom, or UK, for UK tax purposes, you will not be liable for UK tax on capital gains realized or accrued on the sale or other disposition of ordinary shares or ADSs unless the ordinary shares or ADSs are held in connection with your trade carried on in the UK through a branch or agency and the ordinary shares or ADSs are or have been used, held or acquired for the purposes of such trade or such branch or agency.

An individual holder of ordinary shares or ADSs who ceases to be resident in the UK for UK tax purposes for a period of less than five years and who disposes of ordinary shares or ADSs during that period may also be liable on returning to the UK for UK capital gains tax despite the fact that the individual may not be resident in the UK at the time of the disposal.

Inheritance tax

If you are an individual domiciled in the United States and are not a national of the UK for the purposes of the Inheritance and Gift Tax Treaty 1978 between the United States and the UK, any ordinary shares or ADS beneficially owned by you will not generally be subject to UK inheritance tax on your death or on a gift made by you during your lifetime, provided that any applicable United States federal gift or estate tax liability is paid, except where the ordinary share or ADS is part of the business property of your UK permanent establishment. Where the ordinary shares or ADSs have been placed in trust by a settlor who, at the time of the settlement, was domiciled in the United States and not a national of the UK, the ordinary shares or ADSs will not generally be subject to UK inheritance tax.

Stamp duty and stamp duty reserve tax

Transfer of ADSs and ADRs representing ADSs

No UK stamp duty or stamp duty reserve tax will be payable on an instrument transferring an ADS or an American Depositary Receipt, or ADR, representing an ADS or on a written agreement to transfer an ADS or an ADR representing an ADS whether made in or outside the UK.

Issue and transfer of ordinary shares

The issue of ordinary shares by Amarin will not give rise to a charge to UK stamp duty or stamp duty reserve tax. Transfers of ordinary shares, as opposed to ADSs or ADRs representing ADSs, will generally attract ad valorem stamp duty at the rate of 0.5% of the amount or value of the consideration (or in some circumstances, the open market value of those ordinary shares, if higher). A charge to stamp duty reserve tax, at the rate of 0.5% of the amount or value of the consideration (or in some circumstances, the open market value of the ordinary shares, if higher), will generally arise on an agreement to transfer ordinary shares. The stamp duty reserve tax is payable on the seventh day of the month following the month in which the charge arises. Where an instrument of transfer is executed and duly stamped before the expiry of a period of six years beginning with the date of that agreement, any stamp duty reserve tax that has not been paid ceases to be payable.

Taxation of dividends

Under UK law, there is no withholding tax on dividends paid on the ordinary shares or ADSs.

Certain Material Irish Tax Considerations

The summary only applies to U.S. Holders that legally and beneficially hold their ordinary shares, or such shares represented by ADSs evidenced by ADRs as capital assets (i.e., investments) and does not address special classes of holders including, but not limited to, dealers in securities, insurance companies, pension schemes, employee share ownership trusts, collective investment undertakings, charities, tax-exempt organizations, financial institutions and close companies, each of which may be subject to special rules not discussed below.

Solely for the purposes of this summary of Irish Tax Considerations, a U.S. Holder means a holder of shares or ADSs evidenced by ADRs that (i) beneficially owns the shares or ADSs registered in their name, (ii) is resident in the United States for the purposes of the Ireland-United States Double Taxation Convention, or the Treaty, (iii) in the case of an individual holder, is not also resident or ordinarily resident in Ireland for Irish tax purposes, (iv) in the case of a corporate holder, is not a resident in Ireland for Irish tax purposes and is not ultimately controlled by persons resident in Ireland, and (v) is not engaged in any trade or business and does not perform independent personal services through a permanent establishment or fixed base in Ireland, and (vi) is a qualified person as defined in Article 23 of the Treaty.

For Irish taxation purposes, and for the purposes of the Treaty, U.S. Holders of ADSs will be treated as the owners of the shares represented by such ADSs.

The following discussion is limited to the tax consequences of ownership and disposition of shares or ADSs. Tax considerations applicable to other types of securities will be described in the related prospectus supplement.

Taxation of dividends

We do not expect to pay dividends in the foreseeable future. Should we begin paying dividends, such dividends will generally be subject to dividend withholding tax, or DWT, in Ireland at a rate of 25%. Where DWT applies, we will be responsible for withholding such tax at source.

Dividends paid by us to U.S. Holders of shares or ADSs evidenced by ADRs will be exempt from DWT if, prior to the payment of such dividends, the recipient U.S. Holder delivers to us a declaration in the form prescribed by the Irish Revenue Commissioners. In addition, a certificate of residency in the form prescribed by the Irish Revenue Commissioners, will also be required if the U.S. holder is an individual.

Where DWT is withheld from dividend payments to U.S. Holders of shares or ADSs evidenced by ADRs, such U.S. Holders can apply to the Irish Revenue Commissioners claiming a full refund of DWT paid by filing a declaration in the form prescribed by the Irish Revenue Commissioners. As above, a certificate of residency in the form prescribed by the Irish Revenue Commissioners, will also be required if the U.S. holder is an individual.

The DWT rate applicable to U.S. Holders may be reduced under the terms of the Treaty, however, in the first instance, an exemption should be in place under Irish domestic legislation.

Irish source income

U.S. Holders will not be liable to Irish income tax on dividends paid by us.

Capital gains on disposals of shares or ADSs

U.S. Holders will not be subject to Irish capital gains tax, or CGT, on the disposal of shares or ADSs provided that such shares or ADSs are quoted on a stock exchange at the time of disposition such as Nasdaq. While it is our intention to continue the listing of ADSs on Nasdaq, no assurances can be given in this regard.

If, for any reason, our ADSs cease to be listed on Nasdaq, U.S. Holders will not be subject to CGT on the disposal of their shares or ADSs provided that the shares or ADSs do not, at the time of the disposal, derive the greater part of their value from land, buildings, minerals, or mineral rights or exploration rights in Ireland.

Irish Capital Acquisitions Tax (CAT)

CAT comprises principally gift and inheritance tax. A gift or inheritance of shares or ADSs will come within the charge to CAT if either:

(i) the disponer or the donee/successor in relation to the gift or inheritance is resident or ordinarily resident in Ireland (please note that special rules with regard to residence apply where an individual is not domiciled in Ireland); or

(ii) the ordinary shares or ADSs are regarded as property situated in Ireland (e.g. shares would be regarded as Irish property if the share register is maintained in Ireland. ADSs, if registered, will be regarded as Irish property if the register is maintained in Ireland, or, if in bearer form, if the instrument of ownership is located in Ireland).

On the basis that the shares or ADSs (assuming they are registered) should not be regarded as property situated in Ireland (given that the registers are not maintained in Ireland), a gift or inheritance of the shares or ADSs should only come within the charge to Irish CAT if either the disponer or donee/successor is resident or ordinarily resident in Ireland at the date of the gift or inheritance.

The rate of CAT is currently 33% and is payable if the taxable value of the gift or inheritance exceeds certain tax-free thresholds. The appropriate tax-free threshold depends on the relationship between the disponer and the donee/successor. A gift or inheritance received from a spouse is exempt from CAT.

The person who receives the gift or inheritance is generally accountable for any CAT due.

Irish stamp duty

No Irish stamp duty should arise on the issue or transfer for cash of shares or ADSs on the basis that such a transfer does not relate to stocks or marketable securities of an Irish registered company.

Item 6. ***[Reserved]***

Item 7. ***Management's Discussion and Analysis of Financial Condition and Results of Operations***

This Annual Report on Form 10-K contains forward-looking statements concerning future events and our performance. When used in this Annual Report on Form 10-K, the words "may," "would," "should," "could," "expects," "aims," "plans," "anticipates," "believes," "estimates," "predicts," "projects," "potential," or "continue" or the negative of these terms or other comparable terminology are included to identify forward-looking statements. These statements include but are not limited to statements regarding the commercial success of VASCEPA and factors that can affect such success; interpretation of court decisions; plans with respect to litigation; expectation on determinations and policy positions of the United States Food and Drug Administration, or U.S. FDA; the safety and efficacy of our product and product candidates; expectation regarding the potential for VASCEPA to be partnered, developed and commercialized outside of the United States; expectation on the scope and strength of our intellectual property protection and the likelihood of securing additional patent protection; estimates of the potential markets for our product candidates; estimates of the capacity of manufacturing and other facilities to support our products; our operating and growth strategies; our industry; our projected cash needs, liquidity and capital resources; and our expected future revenues, operations and expenditures. These forward-looking statements are based on our current expectations and assumptions and many factors could cause our actual results to differ materially from those indicated in these forward-looking statements. You should review carefully the factors identified in this Annual Report on Form 10-K in Item 1A, "Risk Factors". We disclaim any intent to update or announce revisions to any forward-looking statements to reflect actual events or developments, except as required by law. Except as otherwise indicated herein, all dates referred to in this Annual Report on Form 10-K represent periods or dates fixed with reference to our fiscal year ended December 31, 2023.

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. On June 1, 2023, we announced that regulatory approval from the National Medical Products Administration, or NMPA, for VASCEPA in Mainland China was received by our partner for the MARINE indication.

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.

Organizational Restructuring Program

On July 18, 2023, we announced that we were implementing a new Organizational Restructuring Program, or the ORP, resulting in the elimination and consolidation of certain roles across our organization, both in the U.S. and abroad, representing a reduction of our total employee base by approximately 30%. The ORP was implemented following a review of our business and to better position the organization for a new strategic focus. We expect the ORP will reduce operating costs by approximately $40.0 million annually. Our refocused strategic priorities and restructuring plan focuses on three core areas:

- *Maximizing U.S. Cash Flow Through Streamlined Model:* We have maintained VASCEPA as a cost-competitive option to generics despite the elimination of all U.S. sales force positions and approximately 30% of non-sales positions. We maintained our managed care and trade organization to support these efforts. We continue to explore innovative approaches to driving revenue to maintain our leadership position in the icosapent ethyl, or IPE, market.
- *European Redesign:* We redesigned our commercial infrastructure in Europe to better align with pricing and reimbursement status, commercial progress to date, as well as streamline certain cross-geographic functions and better leverage learnings across countries. In addition, we will continue to advance our pricing and reimbursement activities to drive access in remaining geographies, including those where progress has been delayed.

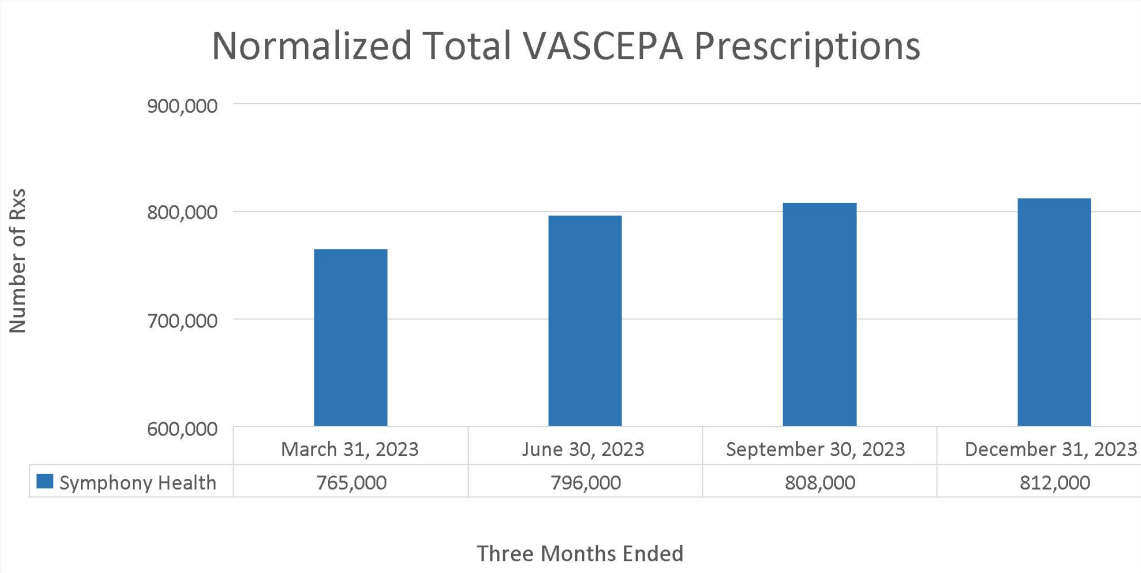
- *Expanding Upon International Partnerships:* We continue to work on generating revenue from our partnerships in key international markets, including Canada, MENA, China, South Korea, Australia and New Zealand and will continue to explore additional partnerships.

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, approximately 25 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:

Company	FDA MARINE Indication Approval	1-gram Launch Date	0.5-gram Launch Date
Hikma Pharmaceuticals USA Inc.	May 2020	November 2020	March 2023
Dr. Reddy's Laboratories, Inc.	August 2020	June 2021	June 2023
Teva Pharmaceuticals USA, Inc.	September 2020	January 2023	September 2022
Apotex, Inc.	June 2021	January 2022	N/A
Zydus Lifesciences	April 2023	N/A	N/A
Strides Pharma	September 2023	N/A	N/A
Epic Pharma	December 2023	N/A	N/A

We obtain data from a third party, Symphony Health, which 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 is 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 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 Annual 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	N/A	March 2022	March 2022	March 2022
Finland	N/A	October 2022	December 2022	December 2022
England/Wales	N/A	July 2022	October 2022	October 2022
Spain	N/A	July 2023	September 2023	September 2023
Netherlands	N/A	August 2023	September 2023	September 2023
Scotland	N/A	August 2023	August 2023	September 2023
Austria	September 2022	N/A	September 2022	N/A
Denmark	June 2022	N/A	June 2022	N/A

We continue to advance our pricing and reimbursement activities to drive access in remaining geographies, including those where progress has been delayed. We are leveraging third-party relationships for various support activities and 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

As discussed above, one of the core areas of focus from our ORP is continuing to work on generating revenue from our partnerships in key international markets, including Canada, MENA, China, Australia and New Zealand and we will continue to explore additional partnerships.

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. 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 Mainland China, the 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. 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. The Company announced on June 1, 2023 that Edding received approval from NMPA for VASCEPA in Mainland China under the MARINE indication and launched commercially in October 2023. In October 2023, Edding's submission of a regulatory filing to the NMPA for VASCEPA under the REDUCE-IT indication was accepted.

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	N/A
Bahrain	April 2021	April 2022	N/A
Kuwait	December 2021	March 2023	September 2023
Saudi Arabia	March 2022	June 2023	September 2023

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 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 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. 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 completed the second year of a three-year plan to submit and obtain regulatory approval in 20 or more additional countries and regions in order to ensure that patients in the top 50 cardiometabolic markets worldwide can benefit from VASCEPA. Through the date of this Annual Report, we have filed for regulatory review in 20 countries and regions and have received approval in 13 countries and regions 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. In July 2023, the Company entered into an agreement with Lotus Pharmaceuticals to commercialize and distribute VAZKEPA in South Korea and nine countries in Southeast Asia. In August 2023, the Company entered into an agreement with Neopharm (Israel) 1996 Ltd., or Neopharm, to distribute VAZKEPA in Israel, Gaza, West Bank, and the territories of the Palestinian Authority. The Company will be responsible for supplying finished product to these partners. 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

Since its inception in 2011, conduct of the REDUCE-IT cardiovascular outcomes study of VASCEPA has been the centerpiece of our research and development. Most of our other research and development during this period also pertained to VASCEPA, including study of the mechanism of action of the single active ingredient in VASCEPA, icosapent ethyl. Based on the final positive results of REDUCE-IT, we sought additional indicated uses for VASCEPA in the United States and continue to pursue approval for VASCEPA around the world. We also anticipate continuing to publish additional details of the REDUCE-IT study to address scientific interest beyond the primary results of this study derived from the over 35,000 patient years of study experience which were accumulated in the REDUCE-IT study.

Based on REDUCE-IT results, as of the date of the filing of this Annual Report on Form 10-K, more than 40 clinical treatment guidelines, consensus statements or scientific statements from medical societies or journals have been updated recommending the use of icosapent ethyl in appropriate at-risk patients, including those statements which we were informed of by our global partners in Canada, China and the Middle East as well as guidelines which were newly received during the fourth quarter of 2023 as listed below:

- In December 2023, the Hellenic Atherosclerosis Society published guidelines for the diagnosis and treatment of dyslipidemia. The publication stated that clinical trials and meta-analyses have not shown that increasing consumption of omega-3 PUFA decreases the risk of atherosclerotic cardiovascular disease, or ASCVD, except for IPE. Based on the findings of REDUCE-IT, IPE (at a dose of 2 g twice daily) should be added in combination with a statin (and fenofibrate if needed) for patients with type 2 diabetes and established ASCVD or with ≥1 major risk factor and TG >150 mg/dL.
- The Cardiological Society of India released clinical practice guidelines for dyslipidemia management in December 2023. The guidelines state that in patients with mild to moderate hypertriglyceridemia (TG 150–499 mg/dL), there is no role for fibric acid derivatives. In those with diabetes (≥40 years of age) or ASCVD, IPE may be considered if TG remains high after lifestyle changes and diabetes control have been achieved. In addition, the guidelines not that the REDUCE-IT randomized controlled trial of highly purified IPE showed significant reduction of MACE.

During 2023, we announced the following data which added to our growing body of knowledge on VASCEPA as a result of our continued analysis of the REDUCE-IT trial results:

- In March 2023, a new prespecified and post hoc exploratory analysis of REDUCE-IT, presented at the American College of Cardiology scientific session, 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).
- In April 2023, the EVAPORATE- FFRCT study was published online in the European Heart Journal - Cardiovascular Imaging. This subgroup analysis assessed the impact of VASCEPA on coronary physiology assessed by fractional flow reserve derived from coronary CTA data sets, or FFRCT, using imaging data from EVAPORATE. FFRCT has been associated with various clinical outcomes, such as the safe deferral of invasive coronary angiography, cardiovascular death or myocardial infarction, and revascularization. This study is the first assessment of FFRCT to determine drug effect, and there was significant improvement in the pre-specified primary endpoint of FFRCT value in the distal coronary segment from baseline to follow-up in the most diseased vessel per patient using VASCEPA compared with placebo. VASCEPA improved mean distal segment FFRCT at 9- and 18-months follow-up compared with placebo (P = 0.02, P = 0.03 respectively). The secondary endpoint, change in translesional FFRCT (change in FFRCT across the most severe (minimum 30%) diameter stenosis) coronary lesion per vessel was improved with VASCEPA treatment compared with placebo, although it was not statistically significant (P = 0.054).
- In August 2023, we supported research that was presented at the ESC Congress, both onsite and online in Amsterdam. This new research included, along with other topics, the REDUCE-IT mediation analysis report of the contribution of IPE and other biomarkers to MACE reduction.

In total, Amarin and global medical and scientific collaborators supported close to 50 publications inclusive of accepted abstracts, posters, and manuscripts.

Commercial and Clinical Supply

We manage the manufacturing and supply of VASCEPA and 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. Beginning 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 December 31, 2023, we had inventory of $336.2 million, of which 80% 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 years ended December 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. 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 years ended December 31, 2023 and 2022, we incurred costs within 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.

Restructuring expense. Restructuring expense consists of restructuring costs incurred under our July 2023 ORP, June 2022 Cost Reduction Plan, or CRP, and August 2022 discontinuation of German operations, which consists of severance pay, incentive compensation, insurance benefits, stock-based compensation expense and other contract related costs.

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 of the Employee Retention Credit, or ERC, awarded as part of the Coronavirus Aid, Relief and Economic Stabilization Act, or CARES Act, and 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 the year-ended December 31, 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 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 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 current market-specific indicators, environment 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 Note 2—Significant Accounting Policies to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K. We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our consolidated financial statements.

Revenue Recognition—In accordance with GAAP, under Accounting Standards Codification, or ASC, Topic 606, *Revenue from Contracts with Customers*, which we adopted on a modified retrospective basis effective January 1, 2018, revenue is recognized when product has been delivered to the wholesaler, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. To determine revenue recognition for arrangements that we determine are within the scope of Topic 606, we perform the following five steps: (i) identify the contract(s) with a Distributor; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy a performance obligation. We apply the five-step model to contracts only when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the Distributor. At contract inception, once the contract is determined to be within the scope of Topic 606, we assess the goods or services promised within each contract, determine those that are performance obligations and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. We recognized total revenue, net of $306.9 million and $369.2 million during the years ended December 31, 2023 and 2022, respectively, of which $285.3 million and $366.5 million, respectively, was based on product revenue sales. For a complete discussion of our accounting for net product revenue, licensing and royalty revenues, which make up Total revenue, net, see Note 2—Significant Accounting Policies.

We have written contracts with our distributors, and transfer of control typically occurs upon delivery of our product to the Distributor. We evaluate the creditworthiness of each of our distributors to determine whether revenues can be recognized upon delivery, subject to satisfaction of the other requirements, or whether recognition is required to be delayed until receipt of payment. We calculate gross product revenues based on the wholesale acquisition cost charged to our distributors for VASCEPA. We estimate our Product revenue, net by deducting from our gross product revenues (a) trade allowances, such as invoice discounts for prompt payment and distributor fees, (b) estimated government and private payor rebates, chargebacks and healthcare discounts, such as Medicaid reimbursements, (c) expected product returns and (d) estimated costs of incentives offered to certain indirect customers, including patients. The gross to net deductions are estimated based on available actual prescription data, historical industry trends, and levels of inventory in the distribution channel. We rely on resale data provided by our distributors as well as prescription data provided by Symphony Health and IQVIA in estimating the level of inventory held in the distribution channel. A hypothetical 5% change in estimated aggregate bottles of channel inventory would result in a change of less than 1% in net product revenues reported during the years ended December 31, 2023 and 2022.

When evaluating licensing arrangements, we perform the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) we satisfy each

performance obligation. In determining performance obligations, we evaluate whether the license is distinct from the other performance obligations with the collaborative partner based on the consideration of the relevant facts and circumstances for each arrangement. Factors considered include the stage of development of the license delivered, research and development capabilities of the partner and the ability of partners to develop and commercialize VASCEPA independent of us.

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

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

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

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

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

We assess our ability to realize deferred tax assets at each reporting period. The realization of deferred tax assets depends on generating future taxable income during the periods in which the tax benefits are deductible or creditable. When making our assessment about the realization of our deferred tax assets as of December 31, 2023, we considered all available evidence, placing particular weight on evidence that could be objectively verified. The evidence considered included the (i) historical taxable profitability of our U.S. operations, (ii) historical pre-tax book loss position, (iii) sources of future taxable income, giving weight to sources according to the extent to which they can be objectively verified, (iv) the provisions of the Tax Cuts and Jobs Act enacted in 2017 and their impact on our future taxable income, and (v) the risks to our business related to the commercialization and development of VASCEPA. Based on our assessment, we concluded that all of our net deferred tax assets are not more likely than not to be realizable as of both December 31, 2023 and 2022. Changes in historical earnings performance, future earnings projections, and changes in tax laws and tax rates, among other factors, may cause us to adjust our valuation allowance on deferred tax assets in the future, which would impact our income tax expense in the period in which we determine that these factors have changed. We intend to maintain the valuation allowance until sufficient positive evidence exists to conclude that it is more likely than not that our deferred tax benefits will be realized. We will continue to monitor the need for valuation allowances in each jurisdiction and may adjust our positions in the future.

Excess tax benefits and deficiencies that arise upon vesting or exercise of share-based payments are recognized as an income tax benefit and expense, respectively, in the consolidated statement of operations.

Recent Accounting Pronouncements

For a discussion of recent accounting pronouncements, see Note 2—Significant Accounting Policies in the accompanying Notes to Consolidated Financial Statements in this Annual Report on Form 10-K.

Effects of Inflation

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

Results of Operations

The discussion that follows includes a comparison of our results of operations and liquidity and capital resources for fiscal years 2023 and 2022. For a comparison of our results of operations and financial condition for fiscal years 2022 and 2021, see "Item 7—Management's Discussion and Analysis of Financial Condition and Results of Operations" of our 2022 Annual Report on Form 10-K, filed with the SEC on March 1, 2023.

Comparison of Fiscal Years Ended December 31, 2023 and December 31, 2022

Total revenue, net. We recorded total revenue, net, of $306.9 million and $369.2 million during the years ended December 31, 2023 and 2022, respectively, a decrease of $62.3 million, or 17%. Total revenue, net consists primarily of revenue from the sale of VASCEPA in the United States. In addition to the United States, we also sell VASCEPA by prescription in certain countries in Europe as well as certain countries outside of the United States and Europe, such as China and Canada, through collaborations with third-party companies. As further discussed below, the aforementioned decrease consists of an $86.0 million decrease in U.S. net product revenue, offset by increases of $18.9 million in licensing and royalty revenue and $4.7 million in net product revenue from sales of VASCEPA outside of the United States.

Product revenue, net. We recorded product revenue, net, of $285.3 million and $366.5 million during the years ended December 31, 2023 and 2022, respectively, a decrease of $81.2 million, or 22%. This decrease was due primarily to a 24% decrease in VASCEPA sales in the United States.

We recorded U.S. product revenue, net, of $273.9 million and $359.9 million for the years ended December 31, 2023 and 2022, respectively. This decrease was primarily due to a decline in net selling price as a result of the impact from an increase in generic competition in the market, offset by an adjustment primarily related to Medicaid rebates of $15.1 million. During the year ended December 31, 2023 there were four generics in the market. During the majority of the year ended December 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 year ended December 31, 2023 by 4% as compared to the year ended December 31, 2022. Our share of the icosapent ethyl market has decreased to approximately 57% in the year ended December 31, 2023 from approximately 60% in the year ended December 31, 2022. Additionally, based on prescription levels reported by Symphony Health, VASCEPA branded prescriptions decreased by 8% in the year ended December 31, 2023 as compared to the year ended December 31, 2022.

In Europe, we recorded product revenue, net of $3.3 million and $2.6 million as of December 31, 2023 and 2022, respectively. Revenue in 2023 was primarily related to sales in the U.K. and Spain, whereas 2022 was primarily related to sales in Germany, from which we subsequently withdrew in the third quarter of 2022.

For the year ended December 31, 2023, we recorded $8.1 million of product revenue, net, to our collaboration partners compared to $4.1 million during the year ended December 31, 2022.

Despite the generic competition in the U.S., we remain confident that the global patient need for VASCEPA is high. In 2024, we will continue to focus on extending the lifecycle of VASCEPA in the U.S., obtaining pricing reimbursement and launching commercial operations in all remaining European markets as well as supporting our partners to advance access and growing commercial operations throughout the rest of the world.

Licensing and royalty revenue. Licensing and royalty revenue during the years ended December 31, 2023 and 2022 was $21.6 million and $2.7 million, respectively, an increase of $18.9 million, or 706%. The increase is primarily due to the recognition of previously deferred milestone and upfront payments relating to Edding and HLS due to a change in the estimates in which we previously recognized revenue as well as recognition of regulatory milestones achieved during the year. Licensing and royalty revenue relates to the recognition of amounts received in connection with the following VASCEPA licensing agreements:

- Edding – a $15.0 million upfront payment received in February 2015, a $1.0 million milestone payment achieved in March 2016 following submission of the clinical trial application to the Chinese regulatory authority, a $5.0 million milestone payment achieved in June 2023 following NMPA approval of VASCEPA under the MARINE indication,

and a $3.0 million milestone payment achieved in October 2023 following a regulatory submission to the NMPA for VASCEPA under the REDUCE-IT indication.

- HLS – a $5.0 million upfront 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 upfront payment which was received upon closing of the agreement in January 2023.
- Lotus – a $0.3 million upfront payment which was received upon closing of the agreement in August 2023.

The upfront and milestone payments from 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 upfront payment from CSL and Lotus are 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. During the second quarter of 2023, the performance period for Edding and HLS was reevaluated and adjusted, resulting in the Company recognizing an additional $5.0 million and $5.3 million, respectively, in license revenues related to this change in estimate for the year ended December 31, 2023. For additional information over the change in estimate refer to Note 13 - Development, Commercialization and Supply Agreements.

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 years ended December 31, 2023 and 2022 was $141.4 million and $126.7 million, respectively, an increase of $14.7 million, or 12%. 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 2023 and 2022, we have taken steps to amend supplier agreements to align supply arrangements with current and future demand resulting in charges of $39.2 million and $18.1 million, respectively, which were recorded as cost of goods sold - restructuring inventory. During 2023, approximately $5.1 million of inventory was expensed through cost of goods sold due to both product dating and non-product dating unsellable inventory. During 2022, approximately $9.6 million of inventory was expensed through cost of goods sold not due to product dating unsellable inventory.

The API included in the calculation of the average cost of goods sold during the years ended December 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 the years ended December 31, 2023 and 2022 was 50% and 65%, respectively. Excluding the restructuring inventory and inventory write-off charges, gross margin was 66% and 73% for the years ended December 31, 2023 and 2022, respectively. 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 years ended December 31, 2023 and 2022 was $199.9 million and $304.4 million, respectively, a decrease of $104.5 million, or 34%. Selling, general and administrative expenses for the years ended December 31, 2023 and 2022 are summarized in the table below:

	Year Ended December 31,	
In thousands	**2023**	**2022**
Selling expense (1)	$ 111,326	$ 185,614
General and administrative expenses (2)	76,119	96,462
Non-cash stock-based compensation expense (3)	12,493	22,340
Total selling, general and administrative expense	$ 199,938	$ 304,416

(1) Selling expense for the years ended December 31, 2023 and 2022 was $111.3 million and $185.6 million, respectively, a decrease of $74.3 million, or 40%. This decrease is primarily due to a reduction in costs from the elimination of our U.S. sales

force as part of our ORP and previous cost reduction plans which also led to a decrease in promotional initiatives and reduced travel.

(2) General and administrative expense for the years ended December 31, 2023 and 2022 was $76.1 million and $96.5 million, respectively, a decrease of $20.3 million, or 21%. This decrease is primarily due to a decrease in employee-related costs as a result of the reduction in force from the ORP and previous 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 2023 shareholder's special meeting.

(3) Non-cash stock-based compensation expense for the years ended December 31, 2023 and 2022 was $12.5 million and $22.3 million, respectively, a decrease of $9.8 million, or 44%. Non-cash stock-based compensation expense represents the estimated costs associated with equity awards issued to internal personnel supporting our selling, general and administrative functions. The decrease is due to the reversal of expense associated with the resignation of our former board members and our former CEO, the ORP announced in July 2023, as well as certain performance-based awards as it was no longer deemed probable that the performance criteria for vesting would be achieved within the required timeframe.

As part of our ORP announced in July 2023, we have redesigned our commercial infrastructure in Europe to better align with pricing and reimbursement status, commercial progress to date, as well as streamline certain cross-geographic functions. In addition, we are continuing to advance our pricing and reimbursement activities to drive access in remaining geographies, as well as advancing regulatory filings internationally and focusing on maximizing U.S. cash flow through a streamlined model. We will continue to evaluate all of our spending commitments and priorities based on our refocused strategic priorities and restructuring plan.

Research and development expense. Research and development expense for the years ended December 31, 2023 and 2022 was $22.2 million and $30.4 million, respectively, a decrease of $8.2 million, or 27%. Research and development expenses for the years ended December 31, 2023 and 2022 are summarized in the table below:

	Year Ended December 31,	
In thousands	**2023**	**2022**
REDUCE-IT study (1)	$ 1,020	$ 1,724
Fixed-dose combination (2)	1,395	5,777
Regulatory filing fees and expenses (3)	966	1,959
Internal staffing, overhead and other (4)	14,651	16,486
Research and development expense, excluding non-cash expense	18,032	25,946
Non-cash stock-based compensation expense (5)	4,187	4,465
Total research and development expense	$ 22,219	$ 30,411

(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) The decrease in fixed-dose combination expenses is primarily due to initial start-up and other costs beginning in 2022 associated with planning and development of the fixed-dose combination of VASCEPA and a statin. The development of the fixed-dose combination was deprioritized during 2023 after it became clear that it would not drive short-term value.

(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 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. The decrease is due to the reversal of expense associated with certain performance-based awards as it was no longer deemed probable that the performance criteria for vesting would be achieved within the required timeframe.

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.

Restructuring expense. Restructuring expense for the years ended December 31, 2023 and 2022 was $11.0 million and $13.5 million, respectively, a decrease of $2.6 million, or 19%. The charge in the current year is due to the implementation of the ORP which was approved in the second quarter 2023 and announced on July 18, 2023, which resulted in a reduction of our entire U.S. sales field force, with our managed care and trade organization continuing to support our U.S. commercial efforts, as well as a reduction of approximately 30% of non-sales positions. The prior year charge was the result of the implementation of the CRP announced on June 6, 2022, which primarily related to the reduction of our U.S. field force from approximately 300 sales representatives to approximately 75 sales representatives, as well as the discontinuation of the German operations announced on August 19, 2022. Refer to *Note 2 Significant Accounting Policies* for additional information.

Interest income, net. Interest income, net for the years ended December 31, 2023 and 2022 was $11.9 million and $2.8 million, respectively, an increase of $9.1 million, or 323%. Interest income, net, represents income earned on cash and investment balances. The increase is primarily due to higher interest rates in the current year period compared to the prior year period.

Other income (expense), net. Other income (expense), net, for the year ended December 31, 2023 and 2022 was income of $2.1 million and expense of $0.7 million, respectively, an increase of $2.8 million or 379%. Other income (expense), net, primarily consists of the ERC awarded as part of the CARES Act, gains and losses on foreign exchange transactions and sublease income related to our Bridgewater, NJ facility.

Provision for income taxes. Provision for income taxes for the year ended December 31, 2023 and 2022 was $5.4 million and $2.0 million, respectively. The increase in the provision for income taxes is due to a change in geographic mix of pre-tax income.

On August 16, 2022, the Inflation Reduction Act of 2022, or the Act, was signed into law by the Biden Administration, with tax provisions effective January 1, 2023 primarily focused on implementing a 15% minimum tax on global adjusted financial statement income (CAMT) and a 1% excise tax on share repurchases. We do not expect either of these provisions to have a material impact on our financial results, including the impact from our share repurchase program announced in January 2024.

Liquidity and Capital Resources

As of December 31, 2023, our aggregate sources of liquidity include cash and cash equivalents and restricted cash of $199.8 million and short-term investments of $121.4 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. 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 consolidated statements of cash flows, are summarized in the following table:

	Year Ended December 31,		
In millions	**2023**	**2022**	**2021**
Cash provided by (used in):			
Operating activities	$ 6.9	$ (180.1)	$ (66.5)
Investing activities	(25.5)	175.3	104.1
Financing activities	0.2	(0.4)	(5.1)
(Decrease) increase in cash and cash equivalents and restricted cash	$ (18.4)	$ (5.2)	$ 32.5

Net cash provided by operating activities increased during 2023 as compared to net cash used in operating activities during the same period in 2022. This is primarily as a result of higher costs in 2022 associated with commercial and pre-launch operations in Europe as well as higher inventory purchases in the first half of 2022, offset by a decrease in U.S. product revenue in 2023.

Net cash used in investing activities decreased during the year ended December 31, 2023 compared to net cash provided by investing activities during the same period in 2022. This is primarily due to the purchase of investment grade interest bearing instruments of $215.1 million partially offset by $190.1 million from proceeds from the maturity of 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 $257.5 million, partially offset by $81.6 million in purchases of investment grade interest bearing instruments.

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

As of December 31, 2023, we had net accounts receivable of $133.6 million, current inventory of $258.6 million and long-term inventory of $77.6 million. We have incurred annual operating losses since our inception and, as a result, we had an accumulated deficit of $1.6 billion as of December 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 July 2023, we announced that we were implementing an ORP resulting in the elimination and consolidation of certain roles across the organization, both in the United States and abroad, representing a reduction of our total employee base by approximately 30%. In the U.S., all sales force positions were eliminated, with the managed care and trade organization continuing to support U.S. commercial efforts, and 30% of non-sales positions were eliminated. In Europe, we have redesigned our commercial infrastructure to better align with pricing and reimbursement status, commercial progress to date, as well as streamlining certain cross-geographic functions and better leveraging learnings across countries. We expect these actions will reduce operating costs by approximately $40.0 million annually.

On January 10, 2024, we announced plans to initiate a share repurchase program to purchase up to $50.0 million of the Company's ordinary shares held in the form of American Depository Shares. The implementation of the share repurchase program will require shareholder approval as well as UK High Court approval, as required under UK company law.

As of December 31, 2023, we had cash and cash equivalents of $199.3 million and short-term investments of $121.4 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, including the share repurchase program, for at least one year from the issuance date of our audited consolidated financial statements included elsewhere in this Annual Report and is adequate to support continued operations based on our current plans. We have based this estimate on assumptions that may prove to be wrong, including as a result of the risks discussed under Part II, Item IA, “Risk Factors”, and we could use our capital resources sooner than we expect or fail to achieve positive cash flow.

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

Item 7A. ***Quantitative and Qualitative Disclosures about Market Risk***

We are exposed to market risks, which include changes in interest rates. We do not use derivative financial instruments in our investment portfolio, and we do not enter into foreign exchange contracts. Our investments meet high credit quality and diversification standards, as specified in our investment policy.

Foreign Currency Exchange Risk. Our results of operations and cash flows are subject to fluctuations due to changes in the Euro, Sterling, Swiss Franc and Yen. The majority of cash and cash equivalents, investments, and the majority of our vendor relationships are denominated in U.S. dollars. We therefore believe that the risk of a significant impact on our operating income from foreign currency fluctuations is not substantial. All of our investments are held in U.S. dollars. We maintain a small amount of our cash and cash equivalents in Euro and from time to time, maintain a small amount of our cash and cash equivalents in other currencies. We purchase a portion of our supply based on a U.S. dollar to Euro exchange rate and, as such, remain subject to currency fluctuation risk for such purchases. Based on the size of our international operations and the amount of our expenses denominated in foreign currencies, currency fluctuation would not have a material effect on our financial position or results of operations. We believe the impact of inflation on operations has been minimal during the past three years.

Interest Rate Risk. We believe that we are not exposed to significant interest rate risk through market value fluctuations of balance sheet items (i.e., price risk) or through changes in interest income or expenses (i.e., refinancing or reinvestment risk). Interest rate risk mainly arises through interest bearing liabilities and assets. Our portfolio of investments as of December 31, 2023 was composed primarily of U.S. Treasury securities and other government-related securities. At December 31, 2023 and 2022, we had short-term investments and long-term investments of $121.4 million and $93.0 million, respectively. We invest funds to have a continuous inflow of cash from diversified short-term and long-term investments, consisting primarily of investment grade securities. A hypothetical 10 percent change in interest rates would not result in a material decrease or increase in the fair value of our securities due to the balance and diversified investment portfolio.

Credit Risk. We monitor our investments with our investment managers with the objective of minimizing concentrations of credit risks. Our short-term investments consist of securities that mature in one year or less. Our long-term investments consist of securities that mature in more than one year. We invest cash in excess of our immediate requirements, in accordance with our investment policy, which limits the amounts we may invest in any one type of investment and requires all investments held by us to maintain minimum ratings from Nationally Recognized Statistical Rating Organizations so as to primarily achieve our goals of liquidity and capital preservation. Additionally, our investment policy is to invest only in institutions that meet high credit quality and diversification standards and established limits on the amount and time to maturity of investments.

Item 8. ***Financial Statements and Supplementary Data***

Our consolidated financial statements are annexed to this Annual Report on Form 10-K beginning on page F-1.

Item 9. ***Changes in and Disagreements with Accountants on Accounting and Financial Disclosure***

None.

Item 9A. ***Controls and Procedures***

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is (i) recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and (ii) accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure.

As of December 31, 2023, our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer have concluded based upon the evaluation described above that, as of December 31, 2023, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting for our company. Internal control over financial reporting is defined in Rules 13a-15(f) and 15(d)-15(f) under the Exchange Act as a process designed by, or under the supervision of, our principal executive officer and principal financial officer and effected by our board of directors, management, and other personnel 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 and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and disposition of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles;
- provide reasonable assurance that our receipts and expenditures are being made only in accordance with authorization of our management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the financial statements.

Because of inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate.

Our management, including our principal executive officer and principal financial officer, has conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2023. In conducting this evaluation, we used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, in *Internal Control-Integrated Framework (2013)*.

Based upon this evaluation and those criteria, management has concluded that, as of December 31, 2023, our internal control over financial reporting was effective.

Ernst & Young LLP (PCAOB ID 42), our independent registered public accounting firm, has audited our consolidated financial statements and the effectiveness of our internal control over financial reporting as of December 31, 2023. This report appears below.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the fourth quarter of 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of Amarin Corporation plc

Opinion on Internal Control over Financial Reporting

We have audited Amarin Corporation plc's internal control over financial reporting as of December 31, 2023, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Amarin Corporation plc (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2023, based on the COSO criteria**.**

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2023 and 2022, the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2023, and the related notes and our report dated February 29, 2024 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP
Iselin, New Jersey
February 29, 2024

Item 9B. ***Other Information***

Entry into Rule 10b5-1 Trading Plans

None.

Item 9C. ***Disclosure Regarding Foreign Jurisdictions that Prevent Inspections***

Not applicable.

PART III

Item 10. ***Directors, Executive Officers and Corporate Governance***

The information required by this item will be contained in our definitive proxy statement, which will be filed with the SEC in connection with our 2024 Annual General Meeting of Shareholders. Such information is incorporated herein by reference.

Code of Ethics

Our board of directors has adopted a code of business conduct and ethical responsibility that applies to our directors, officers and employees. There have been no material modifications to, or waivers from, the provisions of such code. This code is available on the corporate governance section of our website (which is a subsection of the investor relations section of our website) at the following address: www.amarincorp.com. You may also request a printed copy of the code, without charge, by writing to us at Amarin Pharma, Inc., 440 Route 22, Bridgewater, NJ 08807, Attention: Investor Relations. In addition, should any changes be made to our code of business conduct and ethical responsibility, we intend to disclose within four business days on our website (or in any other medium required by law or the NASDAQ): (a) the date and nature of any amendment to our code of business conduct and ethical responsibility that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions and (b) the nature of any waiver, including an implicit waiver, from a provision of our code of business conduct and ethical responsibility that is granted to one of these specified officers, the name of such person is granted the waiver, and the date of the waiver.

Item 11. ***Executive Compensation***

The information required by this item will be contained in our definitive proxy statement, which will be filed with the SEC in connection with our 2024 Annual General Meeting of Shareholders. Such information is incorporated herein by reference.

Item 12. ***Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters***

The information required by this item will be contained in our definitive proxy statement, which will be filed with the SEC in connection with our 2024 Annual General Meeting of Shareholders to be filed within 120 days after the fiscal year ended December 31, 2023 ("Definitive Proxy Statement"). Such information is incorporated herein by reference.

Item 13. ***Certain Relationships and Related Transactions, and Director Independence***

The information required by this item will be contained in our Definitive Proxy Statement, which will be filed with the SEC in connection with our 2024 Annual General Meeting of Shareholders. Such information is incorporated herein by reference.

Item 14. ***Principal Accountant Fees and Services***

The information required by this item will be contained in our Definitive Proxy Statement, which will be filed with the SEC in connection with our 2024 Annual General Meeting of Shareholders. Such information is incorporated herein by reference.

PART IV

Item 15. ***Exhibits and Financial Statement Schedules***

(a)(1) For a list of the financial statements included herein, see Index to Consolidated Financial Statements on page F-1 of this Annual Report on Form 10-K.

(2) Financial statement schedules have been omitted because they are either not required or not applicable or the information is included in the consolidated financial statements or the notes thereto.

(3) Exhibits

The exhibits required by Item 601 of Regulation S-K and Item 15(b) of this Annual Report on Form 10-K are listed in the Exhibit Index below. The exhibits listed in the Exhibit Index are incorporated by reference herein.

(b) Exhibit Index

Exhibit Number	Description	Incorporated by Reference Herein	
		Form	Date
3.1	Articles of Association of the Company	Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2013, as Exhibit 3.1	August 8, 2013
4.1	Form of Amended and Restated Deposit Agreement, dated as of November 4, 2011, among the Company, Citibank, N.A., as Depositary, and all holders from time to time of American Depositary Receipts issued thereunder	Annual Report on Form 10-K for the year ended December 31, 2011, as Exhibit 4.1	February 29, 2012
4.2	Form of Ordinary Share certificate	Annual Report on Form 20-F for the year ended December 31, 2002, as Exhibit 2.4	April 24, 2003
4.3	Form of American Depositary Receipt evidencing ADSs	Annual Report on Form 10-K for the year ended December 31, 2011, as Exhibit 4.4	February 29, 2012
4.4	Description of Registrant's Securities	Annual Report on Form 10-K for the year ended December 31, 2019, as Exhibit 4.7	February 25, 2020
10.1	The Company 2011 Stock Option Plan*	Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2011, as Exhibit 10.4	August 9, 2011
10.2	Amendment No. 1 to 2011 Stock Option Incentive Plan*	Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2012, as Exhibit 10.1	August 8, 2012
10.3	Amendment No. 2 to 2011 Stock Option Incentive Plan*	Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2012, as Exhibit 10.2	August 8, 2012
10.4	Amendment No. 3 to 2011 Stock Option and Incentive Plan*	Annual Report on Form 10-K for the year ended December 31, 2012, as Exhibit 10.5	February 28, 2013
10.5	Amendment No. 4 to 2011 Stock Option and Incentive Plan*	Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2015, as Exhibit 4.1	August 6, 2015
10.6	Amendment No. 5 to 2011 Stock Option and Incentive Plan*	Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2015, as Exhibit 4.2	August 6, 2015
10.7	Amendment No.6 to 2011 Stock Incentive Plan*	Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2017, as Exhibit 4.1	August 2, 2017
10.8	Form of Incentive Stock Option Award Agreement*	Annual Report on Form 10-K for the year ended December 31, 2011, as Exhibit 10.3	February 29, 2012
10.9	Form of Non-Qualified Stock Option Award Agreement*	Annual Report on Form 10-K for the year ended December 31, 2011, as Exhibit 10.4	February 29, 2012
10.10	Form of Restricted Stock Unit Award Agreement*	Annual Report on Form 10-K for the year ended December 31, 2011, as Exhibit 10.5	February 29, 2012
10.11	2017 Employee Stock Purchase Plan*	Annual Report on Form 10-K for the year ended December 31, 2017, as Exhibit 10.64	February 27, 2018
10.12	2020 Stock Incentive Plan*	Current Report on Form 8-K dated July 13, 2020, as Exhibit 10.1	July 14, 2020
10.13	Amendment No. 1 to 2020 Stock Incentive Plan*	Current Report on Form 8-K dated June 27, 2022, as Exhibit 10.2	June 30, 2022

10.14	Form of Incentive Stock Option Award Agreement*	Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2020, as Exhibit 10.2	November 5, 2020
10.15	Form of Non-Qualified Stock Option Award Agreements*	Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2020, as Exhibit 10.3	November 5, 2020
10.16	Form of Restricted Stock Unit Award Agreement*	Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2022, as Exhibit 10.3	August 3, 2022
10.17	Form of Non-Qualified Stock Option for Non-Employee Director Award Agreement*	Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2020, as Exhibit 10.5	November 5, 2020
10.18	Form of Deferred Restricted Stock Unit Award Agreement*	Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2022, as Exhibit 10.2	August 3, 2022
10.19	Amarin Corporation plc Executive Severance and Change of Control Plan*	Current Report on Form 8-K dated January 28, 2021, as Exhibit 10.1	January 29, 2021
10.20	Contract of Employment between Karim Mikhail and Amarin Switzerland GmbH, Grafenauweg 8, 6300 Zug, dated April 12, 2021*	Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2021, as Exhibit 10.4	April 29, 2021
10.21	Letter Agreement with Steve Ketchum, dated February 8, 2012*	Registration Statement on Form F-1, as Exhibit 10.1	February 28, 2012
10.22	Amendment, dated July 6, 2015, to Letter Agreement with Steven Ketchum, dated February 8, 2012*	Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2015, as Exhibit 10.2	August 6, 2015
10.23	2012 Long Term Incentive Award with Steven Ketchum dated March 1, 2012*	Registration Statement on Form S-8, as Exhibit 4.2	March 16, 2012
10.24	Employment Agreement, dated April 20, 2018, by and between Amarin Corporation plc and Aaron Berg*	Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2019, as Exhibit 10.1	May 1, 2019
10.25	Offer Letter with Thomas Reilly, dated May 26, 2022*	Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2022, as Exhibit 10.4	August 3, 2022
10.26	API Commercial Supply Agreement, dated May 25, 2011, between Amarin Pharmaceuticals Ireland Ltd. and Chemport Inc. **	Annual Report on Form 10-K for the year ended December 31, 2021, as Exhibit 10.35	March 1, 2022
10.27	Amendment to API Commercial Supply Agreement by and between Amarin Pharmaceuticals Ireland Ltd and Chemport Inc., dated April 4, 2012 **	Annual Report on Form 10-K for the year ended December 31, 2021, as Exhibit 10.36	March 1, 2022
10.28	Second Amendment to API Commercial Supply Agreement by and between Amarin Pharmaceuticals Ireland Ltd. and Chemport Inc., dated July 19, 2012 **	Annual Report on Form 10-K for the year ended December 31, 2021, as Exhibit 10.37	March 1, 2022
10.29	Development, Commercialization and Supply Agreement dated February 26, 2015, by and between Amarin Pharmaceuticals Ireland Limited, Amarin Pharma, Inc. and Eddingpharm (Asia) Macao Commercial Offshore Limited††	Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2015, as Exhibit 10.1	May 8, 2015

10.30	Distribution Agreement, dated March 8, 2016, by and among Biologix FZCo, Amarin Pharmaceuticals Ireland Limited and Amarin Pharma, Inc. ††	Annual Report on Form 10-K for the year ended December 31, 2017, as Exhibit 10.67	February 27, 2018
10.31	Development, Commercialization and Supply Agreement, dated September 25, 2017, by and among Amarin Pharmaceuticals Ireland Limited, Amarin Pharma, Inc. and HLS Therapeutics Inc. ††	Annual Report on Form 10-K for the year ended December 31, 2017, as Exhibit 10.68	February 27, 2018
10.32	Lease Agreement, dated February 5, 2019, by and between 440 Route 22 LLC and Amarin Pharma, Inc.	Annual Report on Form 10-K for the year ended December 31, 2018, as Exhibit 10.69	February 27, 2019
10.33	English Summary of German Language Commercial Lease Agreement dated October 10, 2021, by and between Amarin Switzerland GmbH and Zug Estates AG	Annual Report on Form 10-K for the year ended December 31, 2021, as Exhibit 10.54	March 1, 2022
10.34	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
10.35	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
10.36	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
10.37	License Agreement dated September 13, 2022, between Amarin Pharmaceuticals Ireland Ltd and Weston Office Solutions Ltd	Annual Report on Form 10-K for the year ended December 31, 2022, as Exhibit 10.47	March 1, 2023
10.38	Non-Employee Director Compensation Policy	Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2023, as Exhibit 10.1	August 2, 2023
10.39	Employment Agreement between Aaron D. Berg and Amarin Corporation, plc. dated April 13, 2023	Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2023, as Exhibit 10.2	August 2, 2023
10.40	CEO Employment Agreement between Patrick Holt and Amarin Corporation, plc. dated July 18, 2023	Current Report on Form 8-K filed with the Commission on July 20, 2023, as Exhibit 10.1	July 20, 2023
10.41	Option Award Agreement (attached to Exhibit 10.1)	Current Report on Form 8-K filed with the Commission on July 20, 2023, as Exhibit 10.2	July 20, 2023
10.42	Amendment No. 2 to the Amarin Corporation plc 2020 Stock Incentive Plan	Current Report on Form 8-K filed with the Commission on July 25, 2023, as Exhibit 10.2	July 25, 2023
10.43	Offer Letter with Jonathan Provoost, dated October 9, 2023*	Filed herewith	
21.1	List of Subsidiaries	Filed herewith	
23.1	Consent of Independent Registered Public Accounting Firm	Filed herewith	
24.1	Power of Attorney	Included on the signature page(s) hereto	

31.1	Certification of President and Chief Executive Officer (Principal Executive Officer) pursuant to Section 302 of Sarbanes-Oxley Act of 2002	Filed herewith
31.2	Certification of Executive Vice President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer) pursuant to Section 302 of Sarbanes-Oxley Act of 2002	Filed herewith
32.1	Certification of President and Chief Executive Officer (Principal Executive Officer) and Executive Vice President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer) pursuant to Section 906 of Sarbanes-Oxley Act of 2002	Furnished herewith
97.1	Compensation Recovery Plan	
101.INS	Inline XBRL Instance Document	Filed herewith
101.SCH	Inline XBRL Taxonomy Extension Schema with Embedded Linkbases Document	Filed herewith
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibit 101.)	Filed herewith

†† Confidential treatment has been granted with respect to portions of this exhibit pursuant to an application requesting confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934. A complete copy of this exhibit, including the redacted terms, has been separately filed with the Securities and Exchange Commission.
** Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit.
* Management contract or compensatory plan or arrangement.

Item 16. ***Form 10-K Summary***

Not applicable.

SIGNATURES

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/ Patrick Holt
Patrick Holt
President and *Chief Executive Officer*
(Principal Executive Officer)

Date: February 29, 2024

We, the undersigned officers and directors of the Registrant hereby severally constitute and appoint Patrick Holt and Tom Reilly, and each of them singly, our true and lawful attorneys, with full power to them and each of them singly, to sign for us in our names in the capacities indicated below, all amendments to this report, and generally to do all things in our names and on our behalf in such capacities to enable the Registrant to comply with the provisions of the Securities Exchange Act of 1934, as amended, and all requirements of the Securities and Exchange Commission.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the date indicated.

Signature	Title	Date
/s/ Patrick Holt Patrick Holt	Director, President and Chief Executive Officer (Principal Executive Officer)	February 29, 2024
/s/ Tom Reilly Tom Reilly	Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	February 29, 2024
/s/ Patrice Bonfiglio Patrice Bonfiglio	Director	February 29, 2024
/s/ Paul Cohen, M.D. Paul Cohen, M.D.	Director	February 29, 2024
/s/ Mark DiPaolo Mark DiPaolo	Director	February 29, 2024
/s/ Keith L. Horn Keith L. Horn	Director	February 29, 2024
/s/ Odysseas Kostas, M.D. Odysseas Kostas, M.D.	Director	February 29, 2024
/s/ Louis Sterling III. Louis Sterling III.	Director	February 29, 2024
/s/ Diane E. Sullivan Diane E. Sullivan	Director	February 29, 2024
/s/ Oliver O'Connor Oliver O'Connor	Director	February 29, 2024

AMARIN CORPORATION PLC

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Financial Statement Schedules:

Financial statement schedules have been omitted for the reason that the required information is presented in the consolidated financial statements or notes thereto, the amounts involved are not significant or the schedules are not applicable.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of Amarin Corporation plc

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Amarin Corporation plc (the Company) as of December 31, 2023 and 2022, the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2023, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2023, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 29, 2024 expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the account or disclosure to which it relates.

Product Return Reserve Estimate

Description of the Matter

At December 31, 2023, the Company recorded a liability for product returns totaling $7.7 million. As discussed in Note 12 of the financial statements, the Company sells its product to distributors that in turn resell the product to retail pharmacies for subsequent sale to patients and healthcare providers. The Company estimates variable consideration resulting from product returns based on quantitative and qualitative data from various internal and external sources.

Auditing management's estimate of product returns was complex and judgmental due to the significant estimation required to determine inventory in the distribution channel that will not ultimately be sold to patients and healthcare providers and will be returned. Sales into the distribution channel could exceed market demand.

How We Addressed the Matter in Our Audit	We obtained an understanding, evaluated the design and tested the operating effectiveness of the controls over the Company's estimation process for product returns including inventory in the distribution channel. These procedures included controls over management's review of the inputs used and assumptions applied in the returns reserve calculation and channel inventory analysis. To test the estimated product return reserve, we performed audit procedures that included, among others, testing management's historical return rate calculation and testing the completeness and accuracy of sales and returns data used in the calculation. We also compared product expiration dates in the calculation to the related quality control documentation. We assessed the historical accuracy of management's estimate and performed analytical procedures to assess the correlation of monthly sales to distributors and monthly patient prescriptions. In addition, we assessed the Company's quarterly analysis of inventory held at various stages in the distribution channel. We confirmed prescription data directly with a third party, confirmed contract terms directly with significant customers, and tested credit memos issued subsequent to year-end for recording in the proper period. We read significant customer contracts and performed direct inquiries with management including the sales, legal, and contracting departments to identify any terms or conditions not included in customer contracts that could impact the estimate of product returns.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2014.

Iselin, New Jersey

February 29, 2024

AMARIN CORPORATION PLC

CONSOLIDATED BALANCE SHEETS
(in thousands, except share amounts)

	December 31, 2023	December 31, 2022
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 199,252	$ 217,666
Restricted cash	525	523
Short-term investments	121,407	91,695
Accounts receivable, net	133,563	130,990
Inventory	258,616	228,732
Prepaid and other current assets	11,618	19,492
Total current assets	724,981	689,098
Property, plant and equipment, net	114	874
Long-term investments	—	1,275
Long-term inventory	77,615	163,620
Operating lease right-of-use asset	8,310	9,074
Other long-term assets	1,360	458
Intangible asset, net	19,304	21,780
TOTAL ASSETS	$ 831,684	$ 886,179
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 52,762	$ 64,602
Accrued expenses and other current liabilities	204,174	192,678
Current deferred revenue	2,341	2,199
Total current liabilities	259,277	259,479
Long-Term Liabilities:		
Long-term deferred revenue	2,509	13,147
Long-term operating lease liability	8,737	10,015
Other long-term liabilities	9,064	8,205
Total liabilities	279,587	290,846
Commitments and contingencies (Note 7)		
Stockholders' Equity:		
Common stock, £0.50 par, unlimited authorized; 418,141,295 shares issued, 408,824,093 shares outstanding at December 31, 2023; 412,333,087 shares issued, 404,346,256 shares outstanding at December 31, 2022	302,756	299,002
Additional paid-in capital	1,899,456	1,885,352
Treasury stock; 9,317,202 shares at December 31, 2023; 7,986,831 shares at December 31, 2022	(63,752)	(61,770)
Accumulated deficit	(1,586,363)	(1,527,251)
Total stockholders' equity	552,097	595,333
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 831,684	$ 886,179

See the notes to the consolidated financial statements.

AMARIN CORPORATION PLC

CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share amounts)

	Year Ended December 31,		
	2023	2022	2021
Product revenue, net	$ 285,299	$ 366,511	$ 580,320
Licensing and royalty revenue	21,612	2,682	2,867
Total revenue, net	306,911	369,193	583,187
Less: Cost of goods sold	102,142	108,631	121,327
Less: Cost of goods sold - restructuring inventory	39,228	18,078	—
Gross margin	165,541	242,484	461,860
Operating expenses:			
Selling, general and administrative	199,938	304,416	408,334
Research and development	22,219	30,411	29,307
Restructuring	10,972	13,526	13,717
Total operating expenses	233,129	348,353	451,358
Operating (loss) income	(67,588)	(105,869)	10,502
Interest income	11,863	2,819	1,220
Interest expense	(8)	(15)	(129)
Other income (expense), net	2,063	(740)	(302)
(Loss) income from operations before taxes	(53,670)	(103,805)	11,291
Provision for income taxes	(5,442)	(1,998)	(3,562)
Net (loss) income	$ (59,112)	$ (105,803)	$ 7,729
(Loss) earnings per share:			
Basic	$ (0.15)	$ (0.26)	$ 0.02
Diluted	$ (0.15)	$ (0.26)	$ 0.02
Weighted average shares outstanding:			
Basic	407,655	401,155	395,992
Diluted	407,655	401,155	402,480

See the notes to the consolidated financial statements.

AMARIN CORPORATION PLC

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands, except share amounts)

	Common Shares	Treasury Shares	Common Stock	Additional Paid-in Capital	Treasury Stock	Accumulated Deficit	Total
December 31, 2021	**404,084,775**	**(7,486,767)**	**$ 294,027**	**$ 1,855,246**	**$ (60,726)**	**$ (1,421,448)**	**$ 667,099**
Issuance of common stock under employee stock purchase plan	456,696	—	283	322	—	—	605
Issuance of common stock for milestone payment	5,817,942	—	3,461	4,742	—	—	8,203
Exercise of stock options	33,303	—	21	39	—	—	60
Vesting of restricted stock units	1,940,371	(500,064)	1,210	(1,210)	(1,044)	—	(1,044)
Stock-based compensation	—	—	—	26,213	—	—	26,213
Loss for the period	—	—	—	—	—	(105,803)	(105,803)
December 31, 2022	**412,333,087**	**(7,986,831)**	**$ 299,002**	**$ 1,885,352**	**$ (61,770)**	**$ (1,527,251)**	**$ 595,333**
Issuance of common stock under employee stock purchase plan	319,610	—	200	130	—	—	330
Exercise of stock options	1,239,763	—	750	1,132	—	—	1,882
Vesting of restricted stock units	4,248,835	(1,330,371)	2,804	(2,804)	(1,982)	—	(1,982)
Stock-based compensation	—	—	—	15,646	—	—	15,646
Loss for the period	—	—	—	—	—	(59,112)	(59,112)
December 31, 2023	**418,141,295**	**(9,317,202)**	**$ 302,756**	**$ 1,899,456**	**$ (63,752)**	**$ (1,586,363)**	**$ 552,097**

See the notes to the consolidated financial statements.

AMARIN CORPORATION PLC

CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,		
	2023	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net (loss) income	$ (59,112)	$ (105,803)	$ 7,729
Adjustments to reconcile net (loss) income to net cash used in operating activities:			
Depreciation and amortization	160	551	587
(Accretion) amortization of investments	(3,696)	473	1,929
Stock-based compensation	15,646	26,213	36,938
Amortization of intangible asset	2,805	2,545	2,270
Changes in assets and liabilities:			
Accounts receivable, net	(2,573)	32,663	(9,079)
Inventory	56,121	(36,422)	(167,066)
Prepaid and other current assets	7,874	2,860	8,595
Other long-term assets	(278)	(2)	(24)
Interest receivable	248	341	738
Deferred revenue	(10,496)	(1,363)	(1,923)
Accounts payable, accrued expenses and other current liabilities	(164)	(102,729)	51,516
Other long-term liabilities	345	581	1,253
Net cash provided by (used in) operating activities	6,880	(180,092)	(66,537)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Maturities of securities	190,108	257,520	394,294
Purchases of securities	(215,097)	(81,633)	(290,195)
Investment in software and website development costs	(509)	(599)	—
(Purchases) disposal of furniture, fixtures and equipment	(24)	—	4
Net cash (used in) provided by investing activities	(25,522)	175,288	104,103
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of common stock under employee stock purchase plan	330	605	1,650
Proceeds from exercise of stock options	1,882	60	2,921
Taxes related to stock-based awards	(1,982)	(1,044)	(9,644)
Net cash provided by (used in) financing activities	230	(379)	(5,073)
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS AND RESTRICTED CASH	(18,412)	(5,183)	32,493
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH, BEGINNING OF PERIOD	218,189	223,372	190,879
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH, END OF PERIOD	$ 199,777	$ 218,189	$ 223,372
Supplemental disclosure of cash flow information:			
Cash (paid) received during the year for:			
Income taxes	$ (2,367)	$ (1,782)	$ 3,656
Supplemental disclosure of non-cash transactions:			
Laxdale milestone	$ —	$ —	$ 12,000
Shares issued in settlement of Laxdale milestone payment	$ —	$ 8,203	$ —
Initial recognition of operating lease right-of-use asset	$ 607	$ 2,041	$ —
Initial recognition of furniture, fixtures and equipment lease	$ 624	$ —	$ —

See the notes to the consolidated financial statements.

(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. The Company is commercialized in the United States, or the U.S, under the brand name VASCEPA® (icosapent ethyl). The Company has launched commercial operations in certain European countries, such as the United Kingdom, or the UK, and Spain and continues pre-launch commercial activities throughout the rest of Europe. The Company's operations outside of the U.S. and Europe are in varying stages of development and commercialization with reliance on third-party commercial partners in select geographies, including China and Canada.

The Company's lead product, VASCEPA, 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, or the MARINE indication. 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, or the REDUCE-IT indication.

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 MARINE indication. The Company sought appeals of the Nevada Court judgment up to the United States Supreme Court, but the Company was unsuccessful. 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	1-gram Launch Date	0.5-gram Launch Date
Hikma Pharmaceuticals USA Inc.	May 2020	November 2020	March 2023
Dr. Reddy's Laboratories, Inc.	August 2020	June 2021	June 2023
Teva Pharmaceuticals USA, Inc.	September 2020	January 2023	September 2022
Apotex, Inc.	June 2021	January 2022	N/A
Zydus Lifesciences	April 2023	N/A	N/A
Strides Pharma	September 2023	N/A	N/A
Epic Pharma	December 2023	N/A	N/A

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 June 1, 2023, the Company announced the National Medical Products Administration, or NMPA, granted approval for VASCEPA under the MARINE indication and launched commercially in October 2023. 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 and Europe. 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 countries 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 consolidated financial statements included herein have been prepared by the Company in accordance with accounting principles generally accepted in the United States and pursuant to the rules and regulations of the Securities and Exchange Commission, or the SEC.

The 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 consolidated financial statements in conformity with U.S. Generally Accepted Accounting Principles, or 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 years ended December 31, 2023, 2022 and 2021 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 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 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 December 31, 2023, the Company had total assets of $831.7 million, of which $320.7 million consisted of cash and liquid short-term investments. More specifically, the Company had current assets of $725.0 million, including cash and cash equivalents of $199.3 million, short-term investments of $121.4 million, accounts receivable, net, of $133.6 million and current inventory of $258.6 million. In addition, at December 31, 2023, the Company had long-term inventory of $77.6 million. At December 31, 2023, the Company had no debt outstanding.

(2) Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates

Accounting estimates are based on historical experience and other factors that are considered reasonable under the circumstances. Estimates and assumptions relied upon in preparing these consolidated financial statements relate to, but are not limited to, such items as provisions for sales returns, rebates and incentives, chargebacks, and other sales allowances; depreciable/amortizable lives; asset impairments; valuation allowance on deferred taxes; probabilities of achievement of performance conditions for certain equity awards; amounts recorded for licensing revenue; contingencies and accruals. Because of the uncertainties inherent in such estimates, actual results may differ from these estimates. Management periodically evaluates estimates used in the preparation of the consolidated financial statements for continued reasonableness.

Use of Forecasted Financial Information in Accounting Estimates

The use of forecasted financial information is inherent in many of the Company's accounting estimates including, but not limited to, determining the estimated fair values of intangible assets, evaluating the need for valuation allowances for deferred tax assets, and assessing the Company's ability to continue as a going concern. Such forecasted financial information is comprised of numerous assumptions regarding the Company's future revenues, cash flows, and operational results. Management believes that its financial forecasts are reasonable and appropriate based upon current facts and circumstances. Because of the inherent nature of forecasts, however, actual results may differ from these forecasts. Management regularly reviews the information related to these forecasts and adjusts the carrying amounts of the applicable assets prospectively, if and when actual results differ from previous estimates.

Revenue Recognition

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 12—Revenue Recognition.

Distribution Costs

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

Cash and Cash Equivalents and Restricted Cash

Cash and cash equivalents consist of cash, deposits with banks and short-term highly liquid money market instruments with 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 at December 31, 2023 and 2022:

In thousands	December 31, 2023	December 31, 2022
Gross trade accounts receivable	$ 160,686	$ 187,418
Trade allowances	(18,834)	(44,626)
Chargebacks	(8,289)	(11,802)
Accounts receivable, net	$ 133,563	$ 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 next 12 months. The Company classifies finished goods expected to be sold within the next 12 months 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.

Long-Lived Asset Impairment

The Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Recoverability of these assets is determined by comparing the forecasted undiscounted net cash flows of the operation to which the assets relate to their carrying amount. If impairment is indicated, the assets are written down to fair value. Fair value is determined based on discounted forecasted cash flows or appraised values, depending on the nature of the assets.

Intangible Asset, net

Intangible asset, net consists of website development costs and milestone payments to the former shareholders of Laxdale Limited, or 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 authorization in Europe in 2021. These assets are

amortized over its estimated useful life on a straight-line basis. See Note 7—Commitments and Contingencies for further information regarding other obligations related to the acquisition of Laxdale.

Costs for Patent Litigation and Legal Proceedings

Costs for patent litigation or other legal proceedings are expensed as incurred and included in Selling, general and administrative expense.

Research and Development Costs

The Company charges research and development costs to operations as incurred. Research and development expenses are comprised of costs incurred by the Company in performing research and development activities, including: salary and benefits; stock-based compensation expense; laboratory supplies and other direct expenses; contractual services, including clinical trial and pharmaceutical development costs; commercial supply investment in its drug candidates; and infrastructure costs, including facilities costs and depreciation expense. In addition, research and development costs include the costs of product supply received from suppliers when such receipt by the Company is prior to regulatory approval of the supplier, as well as license fees related to the Company's strategic collaboration with Mochida Pharmaceutical Co., Ltd., or Mochida.

Selling, General and Administrative Costs

The Company charges selling, general and administrative costs to operations as incurred. Selling, general and administrative costs include salaries and benefits, stock-based compensation expense, and infrastructure necessary for the general conduct of the Company's business, including those incurred as a result of the commercialization of VASCEPA in the United States and Europe.

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 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 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 state tax authorities. The Company is currently under audit by the IRS for its 2018 and 2019 U.S. income tax returns. An 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 consolidated financial position or results of operations.

(Loss) Earnings per Share

Basic net (loss) earnings per share is determined by dividing net (loss) income by the weighted average shares of common stock outstanding during the period. Diluted net (loss) earnings per share is determined by dividing net (loss) income 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) income and the number of shares used to compute basic and diluted net (loss) earnings per share for the years ended December 31, 2023, 2022, and 2021 are as follows:

In thousands	2023	2022	2021
Net (loss) income —basic and diluted	$ (59,112)	$ (105,803)	$ 7,729
Weighted average shares outstanding—basic	407,655	401,155	395,992
Effect of dilutive securities:			
Stock options	—	—	4,420
Restricted stock and restricted stock units	—	—	2,068
Weighted average shares outstanding—diluted	407,655	401,155	402,480
Net (loss) earnings per share—basic [1]	$ (0.15)	$ (0.26)	$ 0.02
Net (loss) earnings per share—diluted [1]	$ (0.15)	$ (0.26)	$ 0.02

(1) Excluding the licensing revenue change in estimate and Medicaid change in estimate, both discussed in Note 12 – Revenue Recognition, net loss per share basic and diluted for the year ended December 31, 2023 would have been $(0.21).

For the years ended December 31, 2023, 2022 and 2021, the following potentially dilutive securities were not included in the computation of net (loss) earnings per share because the effect would be anti-dilutive or because performance criteria were not yet met for awards contingent upon such measures:

In thousands	2023	2022	2021
Stock options	27,956	19,182	9,926
Restricted stock and restricted stock units	11,983	14,461	3,764
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.

Stock-Based Compensation

The Company accounts for stock-based compensation in accordance with the guidance of FASB ASC Topic 718, *Compensation-Stock Compensation*, or ASC 718, and requires the fair value of all stock-based payments to employees and non-employees to be recognized in the consolidated statement of operations over the requisite service period.

The fair value of the Company's restricted stock units is determined to be the market price on the date of the grant. The Company estimates the fair value of stock option awards on the date of the grant using the Black-Scholes Model, which requires that the Company makes certain assumptions regarding: (i) the expected volatility in the market price of its common stock; (ii) dividend yield; (iii) risk-free interest rates; and (iv) the period of time employees are expected to hold the award prior to exercise, referred to as the expected holding period. As a result, if the Company revises its assumptions and estimates, stock-based compensation expense could change materially for future grants.

For awards with performance conditions, if the achievement of the performance conditions is deemed probable, the Company recognizes compensation expense based on the grant date fair value of the award over the requisite service period. The Company reassesses the probability of achievement of the performance conditions each reporting period. For awards with market conditions, the Company recognizes compensation expense based on the grant date fair value of the award, using the Monte Carlo Model, over the requisite service period.

The Company estimates the level of forfeitures expected to occur based on its historical data and records compensation cost only for those awards that are ultimately expected to vest. See Note 9—Stock Incentive Plans and Stock-Based Compensation for further discussion.

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 36%, 28%, and 29%, respectively, of gross product sales for the year ended December 31, 2023 and represented 36%, 18%, and 38%, respectively, of the gross accounts receivable balance as of December 31, 2023. Customers A, B, and C accounted for 35%, 31% and 27%, respectively, of gross product sales for the year ended December 31, 2022 and represented 35%, 21%, and 39%, respectively, of the gross accounts receivable balance as of December 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.

Foreign Currency

Monetary assets and liabilities denominated in a foreign currency are remeasured into U.S. dollars at period-end exchange rates. Gains and losses from the remeasurement are included in Other income (expense), net in the consolidated statements of operations. For transactions settled during the applicable period, gains and losses are included in Other income (expense), net in the consolidated statements of operations. Certain amounts payable are denominated in currencies other than the U.S. dollar. The Company recorded a foreign currency loss within the Other income (expense), net on the consolidated statement of operations of $2.6 million, $0.7 million and $0.6 million for each of the years ended December 31, 2023, 2022, and 2021, respectively.

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

	December 31, 2023			
In thousands	Total	Level 1	Level 2	Level 3
Asset:				
U.S. Treasury Shares	$ 123,992	$ 123,992	$ —	$ —
Money Market Fund	99,226	99,226	—	—
Agency Securities	8,912	—	8,912	—
Repo Securities	3,250	—	3,250	—
Total	$ 235,380	$ 223,218	$ 12,162	$ —

	December 31, 2022			
In thousands	Total	Level 1	Level 2	Level 3
Asset:				
Money Market Fund	$ 81,870	$ 81,870	$ —	$ —
Commercial Paper	62,347	—	62,347	—
Corporate Bonds	28,416	—	28,416	—
Certificate of Deposit	9,100	—	9,100	—
Repo Securities	3,250	—	3,250	—
U.S. Treasury Shares	3,117	3,117	—	—
Agency Securities	1,554	1,554	—	—
Non-US Government	1,393	—	1,393	—
Asset Backed Securities	1,260	—	1,260	—
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 consolidated balance sheet. Those with remaining maturities in excess of 12 months are included in long-term investments on its 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 years ended December 31, 2023 and December 31, 2022 was a gain of less than $0.1 million and a loss of $0.4 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

The Company identifies a restructuring event as a program that is planned and controlled by management, and materially changes either the scope of the Company's business or the manner in which that business is conducted. The accounting for involuntary termination benefits that are provided pursuant to a one-time benefit arrangement are accounted for under *ASC 420 – Exit or Disposal Cost Obligations* whereas involuntary termination benefits that are part of an ongoing written or substantive plan are accounted for under *ASC 712 – Compensation – Nonretirement Postemployment Benefits.* The Company accrues a liability for termination benefits under ASC 712 when it is probable that a liability has been incurred and the amount can be reasonably estimated and under ASC 420 when the termination benefits are communicated.

In June 2023, the Company approved and subsequently announced on July 18, 2023, an Organizational Restructuring Plan, or ORP, to right-size and strengthen the Company. As part of the plan, the Company completed the elimination of its entire U.S. sales field force, as well as a reduction of approximately 30% of the non-sales positions. The Company maintained its managed care and trade organization to support U.S. commercial efforts. During the year ended December 31, 2023, the Company recognized approximately $11.0 million within restructuring expense on the consolidated statement of operations related to the reduction in force, substantially all of which are cash expenditures.

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. As a result of the ongoing assessment, the Company recognized $39.2 million and $18.1 million during the years ended December 31, 2023 and 2022, respectively, within cost of goods sold - restructuring inventory on the 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 June 6, 2022, the Company announced a Comprehensive Cost Reduction Plan, or CRP, which included an organizational restructuring plan to address the 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 year ended December 31, 2022, the Company recognized approximately $9.4 million within restructuring expense on the consolidated statement of operations related to the reduction in force, substantially all of which was cash expenditures.

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 was cash expenditures.

On September 22, 2021, the Company announced a Go-to-Market strategy for VASCEPA. As part of this strategy, the Company completed a reduction of its U.S. field force to approximately 300 sales representatives, enhanced managed care access and optimized VASCEPA prescriptions for cardiovascular risk reduction. During the year ended December 31, 2021, the Company recognized approximately $13.7 million in charges related to the reduction in force, substantially all of which were cash expenditures for one-time termination benefits and associated costs.

The following table sets forth the components of the Company's restructuring charges for the years ended December 31, 2023, 2022 and 2021:

	For the Year Ended December 31,		
In thousands	**2023**	**2022**	**2021**
Employee restructuring separation charges	$ 10,383	$ 9,310	$ 13,717
Vendor contract charges	589	4,216	—
Total restructuring expense	10,972	13,526	13,717
Restructuring inventory	39,228	18,078	—
Stock forfeitures	1,034	591	—
Total restructuring cash obligations incurred	$ 51,234	$ 32,195	$ 13,717

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
Restructuring cash obligations incurred	51,234
Payments	(37,837)
Balance at December 31, 2023	$ 13,589

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 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 internal-use software, 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. For the year ended December 31, 2023, the Company capitalized $0.3 million of costs associated with the implementation of internal-use software. 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 December 31, 2023, the intangible assets have an estimated weighted-average remaining useful life of 7.0 years. The carrying value as of December 31, 2023 and 2022 is as follows:

In thousands	December 31, 2023	December 31, 2022
Technology rights	$ 33,188	$ 32,859
Accumulated amortization	(13,884)	(11,079)
Intangible asset, net	$ 19,304	$ 21,780

Amortization expense for the years ended December 31, 2023 and 2022 was $2.8 million and $2.5 million, respectively. Estimated future amortization expense as of December 31, 2023 is as follows:

In thousands Year Ending December 31,	Amount
2024	$ 2,915
2025	2,915
2026	2,655
2027	2,546
2028	2,546
Thereafter	5,727
Total	$ 19,304

(4) Inventory

The Company capitalizes its purchases of saleable inventory of VASCEPA from suppliers that have been qualified by the U.S. FDA and other global regulatory agencies. Inventories as of December 31, 2023 and 2022 consist of the following:

In thousands	December 31, 2023	December 31, 2022
Raw materials	$ 155,128	$ 126,391
Work in process	5,373	52,297
Finished goods	175,730	213,664
Inventory [(1)]	$ 336,231	$ 392,352

(1) Total inventory consists of both current inventory and long-term inventory. During the year ended December 31, 2023, approximately $5.1 million of inventory was expensed through cost of goods sold for both product dating and non-product dating unsellable inventory. During the year ended December 31, 2022 approximately $9.6 million of finished goods were expensed through cost of goods sold related to unsellable inventory not related to product dating.

As of December 31, 2023 and 2022, the Company had $77.6 million and $163.6 million of long-term inventory, respectively, as consumption is expected beyond the Company's operating cycle of 12 months.

(5) Property, Plant and Equipment

Property, plant and equipment as of December 31, 2023 and 2022 consists of the following:

In thousands	Useful Life (in years)	December 31, 2023	December 31, 2022
Furniture and fixtures	5	$ 432	$ 1,633
Leasehold improvements	lesser of useful life or lease term	217	869
Software	3 - 5	617	617
Computer equipment	3 - 5	227	227
Property, plant and equipment		1,493	3,346
Accumulated depreciation and amortization		(1,379)	(2,472)
Property, plant and equipment, net		$ 114	$ 874

The Company provides for depreciation and amortization using the straight-line method by charges to operations in amounts that depreciate the cost of the fixed asset over its estimated useful life. Depreciation expense for the year ended December 31, 2023 was $0.2 million and for the years ended December 31 2022, and 2021 was $0.6 million, respectively. Upon retirement or sale of assets, the cost of the assets disposed and the related accumulated depreciation are removed from the consolidated balance sheet and any resulting gain or loss is credited or expensed to operations. Repairs and maintenance costs are expensed as incurred.

(6) Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following as of December 31, 2023 and 2022:

In thousands	December 31, 2023	December 31, 2022
Payroll and payroll-related expenses	$ 18,942	$ 20,302
Sales and marketing accruals	1,009	1,672
Accrued revenue allowances	145,034	134,869
Accrued restructuring	13,589	192
All other	25,600	35,643
Accrued expenses and other current liabilities	$ 204,174	$ 192,678

(7) 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.

Litigation – U.S. ANDAs

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

On May 22, 2020 and August 10, 2020, Hikma and Dr. Reddy's, respectively, received U.S. FDA approval to market its generic versions of VASCEPA. During the ANDA litigation, the Company reached agreements with Teva and Apotex, under which they received royalty-free license agreements to promote a generic version of icosapent ethyl in the U.S. under certain circumstances, one

of which circumstances was achieved when the Federal Circuit upheld the ruling by the Nevada Court and Hikma launched its generic version of icosapent ethyl. On September 11, 2020, and June 30, 2021, Teva and Apotex, respectively, received U.S. FDA approval to market their respective generic versions of icosapent ethyl. In November 2020, Hikma announced the price and launched its generic version of icosapent ethyl. In June 2021, Dr. Reddy's announced the price and launched its generic version of icosapent ethyl. In January 2022, Apotex announced the price and launched its generic version of icosapent ethyl. In September 2022, Teva announced the price and launched its generic version of icosapent ethyl for the 0.5-gram capsule and the 1.0 gram capsule in January 2023. All generic versions of icosapent ethyl as approved by the U.S. FDA pertains to the MARINE indication of VASCEPA, lowering of TG levels in patients with very high TG (>500 mg/dL). Current generic competition, together with past and on-going litigation related to such generic versions of icosapent ethyl are applicable to the U.S. only. The Company did not seek, nor is VAZKEPA approved in Europe for lowering of TG levels in patients with very high TG (>500 mg/dL).

The active pharmaceutical ingredient in VASCEPA is difficult and time consuming to manufacture, often requires considerable advanced planning and long-term financial commitment, including to manufacturing infrastructure such as dedicated facilities, to ensure sufficient capacity is available when needed. The Company has invested over a decade of resources and expenses to develop with individual members of its third-party, active pharmaceutical ingredient supply chain the technical knowhow, manufacturing processes and related regulatory approvals that have helped enable the Company's suppliers to supply the Company's need for clinical and commercial supply globally.

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

In January 2021, the Company expanded the scope of the VASCEPA CV risk reduction patent infringement lawsuit against Hikma to include a health care insurance provider in the United States, Health Net LLC, or Health Net. Through insurance coverage and economic incentives the Company alleged that Health Net has actively induced pharmacies to dispense, and patients to use, Hikma generic icosapent ethyl capsules in infringement of the related patents. In the complaint, the Company sought remedies including a permanent injunction against the unlawful inducement by Hikma and Health Net of infringing uses of the Hikma generic product, i.e., uses to reduce cardiovascular risk as detailed in the patents, and monetary damages in an amount sufficient to compensate the Company for such infringement. On January 4, 2022, the district court hearing the case granted Hikma's motion to dismiss. On October 13, 2022, the district court granted final judgement on the aspect of the litigation relating to the Company and Hikma. The Company has appealed the decision of the district court. On December 26, 2022, the Company entered into a settlement agreement with Health Net that resolved the litigation relating to the Company and Health Net. 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.

As has been a practice in the generic pharmaceutical industry, on April 27, 2021 and February 21, 2023, Dr. Reddy's and Hikma, respectively, filed complaints against the Company in the United States District Court for the District of New Jersey, Civil action No. 21-cv-10309 and No. 23-cv-01016, alleging various antitrust violations stemming from alleged anticompetitive practices related to the supply of active pharmaceutical ingredient of VASCEPA. The DRL complaints also includes a related state law tortious interference claim. Damages sought include recovery for alleged economic harm to Dr. Reddy's and to Hikma respectively, treble damages, other costs and fees and injunctive relief against the alleged violative activities. 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.

In March 2021, Amarin received a civil investigative demand, or CID, from the U.S. Federal Trade Commission and a subpoena from the New York Attorney General with respect to information on the same antitrust topic covered in the Dr. Reddy's litigation. Similarly, in June 2020, the Company received a CID from the U.S. Department of Justice, or the DOJ, informing Amarin that the DOJ is investigating whether aspects of its promotional speaker programs and copayment waiver program during the period from January 1, 2015 to the present violated the U.S. Anti-Kickback Statute and the U.S. Civil False Claims Act, in relation to the sale and marketing of VASCEPA by the Company and its previous co-marketing partner, Kowa Pharmaceuticals America, Inc. Amarin is cooperating with the government agencies regarding these two investigations, or the Investigations, and concluded document production and interrogatory responses in mid-2023. We cannot predict when these investigations will be resolved, the outcome of the investigations or their potential impact on the Company's business.

Amarin is named as a defendant in six antitrust class action lawsuits in the District Court for the District of New Jersey, as displayed in the table below. Each of the six antitrust class action lawsuits allege 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.

Lawsuits	Civil Action #	Direct/Indirect Purchasers
Uniformed Fire Officers Association Family Protection Plan Local 854	21-12061	Indirect Purchaser
Uniformed Fire Officers Association for Retired Fire Officers Family Protection Plan	21-12061	Indirect Purchaser
The International Union of Operating Engineers Locals 137, 137A, 137B, 137C, 137R	21-12416	Indirect Purchaser
KPH Healthcare Services, Inc.	21-12747	Direct Purchaser
Local 464A United Food and Commercial Workers Union Welfare Service Benefit Fund	21-13009	Indirect Purchaser
Teamsters Health & Welfare Fund of Philadelphia and Vicinity	21-13406	Indirect Purchaser

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.

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

Litigation – Other

On 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 Company's 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. In October 2022, the court consolidated the cases and appointed a lead plaintiff for the putative class. 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 and the motion remains pending. 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 alleged that the defendants failed to exercise appropriate diligence and due care in their conduct of the ANDA litigation. Based on those allegations, the complaint alleged that the defendants committed legal malpractice and sought 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 his 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). On June 30, 2023, all defendants moved to dismiss this case without prejudice. 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.

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 VASCEPA. 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.

The Company continues to negotiate with contract suppliers to align its supply arrangements with current and future global demand which may result in additional costs to the Company. As of the date of filing this Annual Report, the Company has a total of approximately $37.0 million in future contractual purchase obligations without consideration to ongoing discussions with other suppliers. In addition, the Company has total obligations of $186.5 million contingent on either certain suppliers obtaining regulatory approval in Europe or pricing reimbursement in certain European countries not occurring by June 30, 2024.

During 2023, the Company determined that it was probable that the Company would not be able to obtain pricing reimbursement in certain countries outlined within renegotiated supply agreements by June 30, 2024. The Company's reasonable estimate of the liability is a range between $8.0 million and $15.8 million, with no amount within that range a better estimate than any other amount; accordingly, an $8.0 million provision was recognized in cost of goods sold - restructuring inventory on the consolidated statement of operations. The ultimate resolution of the matter could result in up to an additional $7.8 million of the amount accrued.

On March 26, 2021, the EC approved the marketing authorization application for VAZKEPA. Under the 2004 share repurchase agreement with Laxdale upon receipt of pricing approval in Europe for the first indication for VASCEPA (or first indication of any product containing intellectual property acquired from Laxdale in 2004), the Company was obligated to make an aggregate stock or cash payment to the former shareholders of Laxdale (at the sole option of each of such former shareholders) of £7.5 million. On July 13, 2022 in connection with the United Kingdom's National Institute for Health and Care Excellence, or NICE's, final guidance for reimbursement of VAZKEPA and use across the National Health Service, or NHS, in England and Wales, representing receipt of marketing approval in Europe for the first indication for VAZKEPA, the Company became obligated to make the aggregate milestone payment of £7.5 million to Laxdale’s former shareholders (in either stock or cash at the election of each shareholder). As of December 31, 2023, the Company has settled the first European indication approval milestone through issuance of stock and cash payments based on the respective shareholder's election.

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 £5.0 million (approximately $6.4 million as of December 31, 2023) for the potential market approval.

The Company has no provision for any of these obligations, except the $8.0 million provision noted above, since the amounts are either not paid or payable as of December 31, 2023.

(8) Equity

Common Stock

On January 10, 2024, the Company announced plans to initiate a share repurchase program to purchase up to $50.0 million of the Company's ordinary shares held in the form of American Depository Shares. The implementation of the share repurchase program will require shareholder approval as well as UK High Court approval, as required under UK company law.

On July 13, 2022, in connection with the United Kingdom's National Institute for Health and Care Excellence, or NICE's, final guidance for reimbursement of VAZKEPA and use across the National Health Service, or NHS, in England and Wales, representing receipt of marketing approval in Europe for the first indication for VAZKEPA, the Company became obligated to make an aggregate milestone payment of £7.5 million to Laxdale's former shareholders (in either stock or cash at the election of each shareholder) under the 2004 purchase agreement among the Company and such former shareholders. One of the shareholders elected to receive payment in stock for its pro rata portion of the milestone payment, resulting in the issuance of 5,817,942 shares at a price of $1.41 per share in July 2022.

During the years ended December 31, 2023 and 2022, other than as described elsewhere in this Annual Report on Form 10-K, including in the Notes to Consolidated Financial Statements, the Company did not engage in any transactions involving its common stock. Refer to *Incentive Equity Awards* below for discussion of ordinary shares issued as a result of stock option exercises and the vesting of restricted stock units. Refer to *Note 9—Stock Incentive Plans and Stock Based Compensation* for discussion of shares issued under the Company’s employee stock purchase plan.

Incentive Equity Awards

The Company issues incentive equity awards, including incentive and non-qualified stock options and restricted stock units, under the Amarin Corporation plc 2020 Stock Incentive Plan, or the 2020 Plan, which is the successor to the Amarin Corporation plc 2011 Stock Incentive Plan, as amended, or the 2011 Plan, and the Amarin Corporation plc 2002 Stock Option Plan, as amended, or the 2002

Plan, and together with the 2020 Plan and 2011 Plan, the Plans. Refer to *Note 9—Stock Incentive Plans and Stock Based Compensation* for further information regarding the Company's incentive equity plans and awards.

The following table summarizes the aggregate number of stock options and restricted stock units, or RSUs, outstanding under the 2020 Plan as of December 31, 2023:

	December 31, 2023
Outstanding stock options	27,956,138
% of outstanding shares on a fully diluted basis	6%
Outstanding RSUs	11,983,101
% of outstanding shares on a fully diluted basis	3%

The following table represents equity awards activity during the years ended December 31, 2023 and 2022:

	For the Year Ended December 31,	
	2023	2022
Common shares issued for stock option exercises	1,239,763	33,303
Gross and net proceeds from stock option exercises	$ 1,882,001	$ 59,686
Common shares issued in settlement of vested RSUs	3,890,395	1,940,371
Shares retained for settlement of employee tax obligations ─ RSUs	1,187,251	500,064
Common shares issued in settlement of vested Performance-Based RSUs [(1)]	358,440	—
Shares retained for settlement of employee tax obligations ─ Performance-Based RSUs	143,120	—

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

During the years ended December 31, 2023 and 2022, the Company granted a total of 5,456,800 and 3,065,000 stock options, respectively, and 8,227,800 and 9,069,500 RSUs, respectively, to employees under the Plans. The RSUs typically vest annually over a three- or four-year period and the stock options typically vest quarterly over a four-year period. Also during 2023 and 2022, the Company granted a total of 1,368,800 and 1,919,500 RSUs, respectively, to employees under the Plans that vest upon the achievement of specified performance conditions.

In addition to the grants noted above, in connection with the implementation of a retention program in July 2023, the Company granted a total of 3,978,300 stock options to employees under the 2020 Plan. The options vest 50% on both January 1, 2024 and January 1, 2025, respectively. Also in July 2023, the Company granted 5,000,000 stock options to Patrick Holt in connection with his appointment as President and Chief Executive Officer, which will vest upon achievement of specified stock price conditions for the Company.

During the years ended December 31, 2023 and 2022, the Company granted a total of 3,853,025 and 1,973,124 stock options, respectively, and 1,392,257 and 1,597,955 RSUs, respectively, to members of the Company's Board of Directors under the Plans. The RSUs vest in equal installments over a three-year period upon the earlier of the anniversary of the grant date or the Company's annual general meeting of shareholders in such anniversary year. The stock options vest in full upon the earlier of the one-year anniversary of the grant date or the Company's annual general meeting of shareholders in such anniversary year. Upon termination of service to the Company or upon a change of control, each director shall be entitled to a payment equal to the fair market value of one share of Amarin common stock per award vested or granted, respectively, which is required to be made in shares.

(9) Stock Incentive Plans and Stock-Based Compensation

On March 16, 2020, the Company's Board of Directors, upon the recommendation of the Remuneration Committee, adopted, subject to shareholder approval, the 2020 Plan which was subsequently approved by the Company's shareholders on July 13, 2020 at the Annual General Meeting of Shareholders. The 2020 Plan is the successor to the Company's 2011 Plan, which was set to expire on July 12, 2021, and the Company's 2002 Plan, the Plans.

The 2020 Plan allows the Company to grant stock options, both incentive and non-qualified options, to employees and Directors, restricted stock units to employees and unrestricted shares to Directors. The maximum number of the Company's Ordinary Shares of £0.50 each or any ADS's, as to be issued under the 2020 Plan shall not exceed the sum of (i) 20,000,000 shares and (ii) the number of Shares that remained available for grants under the Company's 2011 Plan as of July 13, 2020. If any award granted and outstanding under the Plans expires or is forfeited, surrendered, canceled or otherwise terminated, the shares may be made available for subsequent

grants under the 2020 Plan. The 2020 Plan is administered by the Remuneration Committee of the Company's Board of Directors and expires on July 13, 2030.

Stock Options

Under the terms of the Plans, stock options typically vest over a four-year period and expire after a 10-year term. The stock options are granted at an exercise price equal to the closing price of the Company's American Depositary Shares on the grant date. The following table summarizes all stock option activity for the year ended December 31, 2023:

In thousands (except per share amounts and years)	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding as of January 1, 2023	19,182	$ 5.80		
Granted	18,363	1.27		
Forfeited	(8,221)	4.85		
Expired	(128)	7.54		
Exercised	(1,240)	1.50		
Outstanding as of December 31, 2023	27,956	3.21	7.3 years	$ 131
Exercisable as of December 31, 2023	12,333	5.72	4.4 years	$ -
Vested and expected to vest as of December 31, 2023	27,114	3.35	6.6 years	$ 113
Available for future grant as of December 31, 2023	22,984			

The weighted average grant date fair value of stock options granted during the years ended December 31, 2023, 2022, and 2021 was $1.27, $2.56, and $5.12, respectively. The total grant date fair value of options vested during the years ended December 31, 2023, 2022, and 2021 was $8.2 million, $16.6 million, and $21.1 million, respectively. Included within the above table is the 5,000,000 market-based stock option award with a weighted average grant date fair value of $0.37.

During the years ended December 31, 2023, 2022 and 2021, the Company received proceeds from the exercise of options of $1.9 million, $0.1 million, and $2.9 million, respectively. The total intrinsic value of options exercised during the years ended December 31, 2023, 2022, and 2021 was $0.4 million, nominal and $4.9 million, respectively, calculated as the difference between the quoted stock price of the Company's common stock as of the reporting date and the exercise prices of the underlying awards.

As of December 31, 2023, options have $11.7 million of unrecognized stock-based compensation expense with such expense expected to be recognized over a weighted-average period of approximately 2.8 years.

The fair value of stock options on the date of grant was estimated using the Black-Scholes option pricing model except for the market-based option awards which used the Monte Carlo option pricing model. Use of a valuation model requires management to make certain assumptions with respect to selected model inputs, which include:

- *Risk free rate*: The risk-free interest rate is based on zero-coupon U.S. Treasury securities with a maturity term approximating the expected life of the option at the date of grant.
- *Expected dividend yield*: No dividend yield has been assumed as the Company does not currently pay dividends on its common stock and does not anticipate doing so in the foreseeable future.
- *Expected option life:* The expected life was determined using the simplified method based on the term and vesting period.
- *Expected volatility:* Expected stock price volatility for the Black-Scholes model was calculated based on the historical volatility of the Company's common stock over the expected life of the option. For the Monte Carlo model, expected stock price volatility was calculated based on the historical volatility of both the Company's common stock and comparable company's common stock over the expected life of the option.

For 2023, 2022, and 2021, the Company used the following assumptions to estimate the fair value of share-based payment awards under the Black-Scholes model:

	2023	2022	2021
Risk-free interest rate	3.59% - 4.72%	1.64% - 4.35%	0.53% - 1.36%
Expected dividend yield	0.00%	0.00%	0.00%
Expected option life (years)	6.25	6.25	6.25
Expected volatility	101% - 104%	96% - 101%	96% - 99%

The Company used the following assumptions to estimate the fair value of share-based payment awards under the Monte Carlo model in 2023:

	2023
Risk-free interest rate	4.06% - 4.09%
Expected dividend yield	0.00%
Expected option life (years)	9
Expected volatility	42.5% - 43.00%

Employee stock options generally require future service and vest ratably over a four-year service period and are settled by the issuance of new common shares. The grant date fair value of the stock options, net of an estimated forfeiture rate is amortized straight-line over the awards' vesting periods or respective requisite service periods and is adjusted for actual forfeitures over such period. The Company recorded compensation expense in relation to stock options of $6.8 million, $14.8 million and $23.0 million for the years ended December 31, 2023, 2022, and 2021, respectively.

Restricted Stock Units

The restricted stock units vest based upon either a time-based service condition, a performance condition, or both. The grant date fair value of the restricted stock unites, net of the estimated forfeiture rate, is amortized straight-line over the vesting periods or requisite service periods and is adjusted for actual forfeitures over such period. For any awards with a performance condition, the probability that any performance criteria will be achieved is assessed by management and compensation expense for such awards is only recorded to the extent that the attainment of the performance criteria is deemed to be probable.

The following table presents the restricted stock unit activity for the year ended December 31, 2023:

In thousands (except per share amounts)	Shares	Weighted Average Grant Date Fair Value
Outstanding as of January 1, 2023	14,461	3.98
Granted	11,048	1.73
Vested	(4,249)	3.91
Forfeited	(9,057)	2.85
Expired	(220)	16.87
Outstanding as of December 31, 2023	11,983	$ 1.70

The Company recorded compensation expense in relation to restricted stock units of $9.8 million, $11.4 million and $13.9 million, for the years ended December 31, 2023, 2022, and 2021, respectively. The total grant date fair value of restricted stock units vested during the years ended December 31, 2023, 2022, and 2021 was $16.3 million, $14.3 million and $23.8 million, respectively. As of December 31, 2023, restricted stock units have $14.9 million of unrecognized stock-based compensation expense with such expense to be recognized over a weighted-average period of approximately 1.8 years.

The following table presents the stock-based compensation expense related to stock-based awards for the years ended December 31, 2023, 2022, and 2021:

In thousands	2023	2022	2021
Research and development	$ 4,187	$ 4,465	$ 4,327
Selling, general and administrative	12,493	22,339	32,305
Restructuring	(1,034)	(591)	306
Stock-based compensation expense	$ 15,646	$ 26,213	$ 36,938

Employee Stock Purchase Plan

On March 13, 2017, the Board adopted, subject to shareholder approval, the Amarin Corporation plc 2017 Employee Stock Purchase Plan, or the ESPP, which was approved by the Company's shareholders on May 15, 2017. The ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Internal Revenue Code. The maximum fair market value of stock which can be purchased by a participant in a calendar year is $25,000.

Under the ESPP, an aggregate of 3,000,000 ordinary shares (each ordinary share to be represented by one ADS) are reserved and available for issuance, which were registered with the SEC on August 2, 2017, for sale to eligible employees. Subject to certain exclusions, any employee of the Company's U.S. subsidiary, Amarin Pharma, Inc., who works at least 20 hours per week and has been employed for at least six months as of the first day of the applicable offering period is eligible to participate in the ESPP. Eligible employees may authorize payroll deductions of up to 15 percent of their base pay to be withheld to purchase ordinary shares, subject to terms and limitations of the plan, at a price equal to 85 percent of the lower of the fair market values of the Company's ordinary shares as of the beginning or the end of six-month offering periods.

For the offering periods ended on the last business day on or before each of May 31, 2023 and November 30, 2023, the Company issued 205,861 shares and 113,749 shares, respectively, at a purchase price of $1.01 per share and $0.66 per share, respectively.

For the offering periods ended on the last business day on or before each of May 31, 2022 and November 30, 2022, the Company issued 265,214 shares and 191,482 shares, respectively, at a purchase price of $1.45 per share and $1.15 per share, respectively.

For the offering periods ended on the last business day on or before each of May 31, 2021 and November 30, 2021, the Company issued 226,402 shares and 172,884 shares, respectively, at a purchase price of $3.86 per share and $3.06 per share, respectively.

As of December 31, 2023, 1,041,967 shares were reserved for future issuance under the ESPP.

(10) Income Taxes

The Company recognizes interest and penalties related to uncertain tax positions within the provision for income taxes. The total amount of unrecognized tax benefits that would affect the Company's effective tax rate if recognized is $8.9 million and $8.2 million as of December 31, 2023 and 2022, respectively. The Company recognized interest related to uncertain tax positions of $0.7 million and $0.5 million for the years ended December 31, 2023 and 2022, respectively. No penalties have been recognized in conjunction with these positions.

The following is a reconciliation of the total amounts of unrecognized tax benefits for the years ended December 31, 2023, 2022 and 2021:

In thousands	2023	2022	2021
Beginning uncertain tax benefits	$ 18,715	$ 22,040	$ 24,034
Prior year—increases	—	—	16
Prior year—decreases	(2,261)	(9,107)	(2,248)
Current year—increases	2,204	5,782	238
Ending uncertain tax benefits	$ 18,658	$ 18,715	$ 22,040

The Company files income tax returns in the United States, Ireland and United Kingdom, or UK. The Company remains subject to tax examinations in the following jurisdictions as of December 31, 2023:

Jurisdiction	Tax Years
United States—Federal	2018-2023
United States—State	2018-2023
Ireland	2019-2023
United Kingdom	2022-2023

The Company does not expect any gross liabilities to expire in 2024 based on statutory lapses or audits.

The components of (loss) income from operations before taxes were as follows for the years ended December 31, 2023, 2022 and 2021:

In thousands	2023	2022	2021
United States	$ 15,881	$ 5,358	$ 10,222
Ireland and United Kingdom	(85,177)	(112,527)	(4,368)
Other	15,626	3,364	5,437
Total (loss) / income before taxes	$ (53,670)	$ (103,805)	$ 11,291

The provision for income taxes shown in the accompanying consolidated statements of operations consists of the following for the years ended December 31, 2023, 2022 and 2021:

In thousands	2023	2022	2021
Current:			
United States—Federal	$ 1,597	$ 562	$ 2,690
United States—State	243	573	716
Foreign	3,602	863	156
Total current	$ 5,442	$ 1,998	$ 3,562
Deferred:			
United States—Federal	9,927	(3,721)	5,222
United States—State	(934)	284	(3,057)
Foreign	(15,408)	(1,646)	(1,619)
Change in valuation allowance	6,415	5,083	(546)
Total deferred	$ —	$ —	$ —
Provision for income taxes	$ 5,442	$ 1,998	$ 3,562

The provision for income taxes differs from the amount computed by applying the statutory income tax rate to income before taxes due to the following for the years ended December 31, 2023, 2022 and 2021:

In thousands	2023	2022	2021
Benefits from taxes at statutory rate	$ (13,418)	$ (25,952)	$ 2,823
Rate differential	8,042	9,141	(4,416)
Change in valuation reserves	6,415	5,083	(546)
Nondeductible employee compensation	31	2,344	5,249
Stock option/RSU windfall	4,500	3,569	81
ISO disqualifying disposition windfall	—	—	(219)
Research and development credits	(376)	(958)	(1,170)
Tax return to provision adjustments	4,187	424	(8,372)
Foreign exchange	(2,921)	7,859	4,109
Permanent and other	141	(1,542)	863
Uncertain tax positions	780	(3,290)	5,160
Foreign-derived intangible income	(1,939)	(2,935)	—
Loss of tax attributes	—	8,255	—
Provision for income taxes	$ 5,442	$ 1,998	$ 3,562

The Company is subject to a corporate tax rate in Ireland of 25% for non-trading activities and 12.5% for trading activities. For the years ended December 31, 2023, 2022, and 2021, the Company applied the statutory corporate tax rate of 25% for Amarin Corporation plc, reflecting the non-trading tax rate in Ireland. However, for Amarin Pharmaceuticals Ireland Limited, a wholly-owned subsidiary of Amarin Corporation plc, the Company applied the 12.5% Irish trading tax rate. In the table above, the Company used Amarin Corporation plc's 25% tax rate as the starting point for the reconciliation since it is the parent entity of the business.

In April 2016, the Company adopted ASU No. 2016-09, *Compensation-Stock Compensation (Topic 718): Improvements to Share-Based Payment Accounting* which changes the accounting for certain aspects of share-based payments to employees. One aspect of the standard requires that excess tax benefits and deficiencies that arise upon vesting or exercise of share-based payments be recognized as an income tax benefit and expense in the income statement. Previously, such amounts were recognized as an increase and decrease in additional paid-in capital. This aspect of the standard was adopted prospectively, and accordingly the provisions for income taxes for the years ended December 31, 2023, 2022 and 2021 includes nil, $0.6 million and $0.1 million of excess tax benefits, respectively, arising from share-based payments during the period.

The income tax effect of each type of temporary difference comprising the net deferred tax asset as of December 31, 2023 and 2022 is as follows:

In thousands	December 31, 2023	December 31, 2022
Deferred tax assets:		
Net operating losses	$ 154,086	$ 136,862
Stock-based compensation	9,929	11,616
Tax credits	2,409	2,639
Capitalized R&D	—	4,723
Lease liability	1,971	2,583
Other reserves and accrued liabilities	7,916	11,895
Gross deferred tax assets	176,311	170,318
Less: valuation allowance	(171,793)	(165,378)
Total deferred tax assets	4,518	4,940
Deferred tax liabilities:		
Depreciation and amortization	(3,050)	(3,337)
Lease asset	(1,468)	(1,603)
Total deferred tax liabilities	(4,518)	(4,940)
Net deferred tax assets	$ —	$ —

The Company assesses whether it is more-likely-than-not that the Company will realize its deferred tax assets. The Company determined that it was more-likely-than-not that the Irish, U.S., Germany, and Israeli net operating losses and the related deferred tax assets would not be realized in future periods and a full valuation allowance has been provided for all periods.

The following table reflects the activity in the valuation allowance for the years ended December 31, 2023 and 2022:

In thousands	2023	2022
Beginning valuation allowance	$ 165,378	$ 160,295
Increase as reflected in income tax expense	3,494	12,942
Foreign exchange	2,921	(7,859)
Ending valuation allowance	$ 171,793	$ 165,378

During 2023, the Company recorded adjustments to its deferred tax accounts related to the impact of foreign exchange rate changes and to reconcile the financial statement accounts to the amounts expected to result in future income and deductions under local law, primarily as it relates to Irish net operating losses and deferred taxes for stock compensation. These adjustments were fully offset with valuation allowances based on the Company's position with respect to the realizability of its recorded deferred tax assets.

The Company has combined U.S. and non-U.S. net operating loss carryforwards of $959.9 million, which do not expire. The total net operating loss carryforwards increased by approximately $125.6 million from the prior year primarily as a result of current year loss generated by the Company's U.S. and non-U.S. subsidiaries, the impact of foreign exchange rate changes and adjustments to reconcile to the amount reported on the filed 2021 foreign tax returns. In addition, the Company has U.S. Federal tax credit carryforwards of $8.6 million and state tax credit carryforwards of $3.5 million. These amounts exclude the impact of any unrecognized tax benefits and valuation allowances. These carryforwards, which will expire between 2025 and 2043, may be used to offset future taxable income, if any.

As of December 31, 2023, there are no earnings that have been retained indefinitely for reinvestment by foreign subsidiary; therefore, no provision has been made for income taxes that would be payable upon the distribution of such earnings or the recovery of the Company's investment in its subsidiaries as the amount of the related unrecognized deferred income tax liability is zero.

The Company's and its subsidiaries' income tax returns are periodically examined by various taxing authorities. The Company is currently under audit by the IRS for the Company's 2018 U.S. income tax return and by the New York Department of Finance for the years 2018 and 2019. 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 the Company's consolidated financial position or results of operations.

(11) Defined Contribution Plan

The Company makes available a 401(k) plan for its U.S. employees. Under the 401(k) plan, employees may make contributions which are eligible for a discretionary percentage match, in cash, as defined in the 401(k) plan and determined by the Board of Directors. The

Company recognized $2.7 million, $1.7 million and $1.9 million of related compensation expense for the years ended December 31, 2023, 2022 and 2021, respectively.

(12) 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 45 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 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. For the year ended December 31, 2023, the Company recognized $15.1 million related to a change in estimate primarily for the Medicaid rebate provision as a result of a change in the percentage of business within the Medicaid segment, with a related reduction in net loss by $15.1 million in the year ended December 31, 2023. Excluding this change in estimate, net loss per share basic and diluted for the year ended December 31, 2023 would have been $(0.18).

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 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 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 years ended December 31, 2023 and 2022:

In thousands	Trade Allowances	Rebates, Chargebacks and Discounts	Product Returns	Other Incentives	Total
Balance as of January 1, 2022	**$ 86,636**	**$ 184,756**	**$ 8,089**	**$ 2,745**	**$ 282,226**
Provision related to current period sales	96,340	676,816	2,347	26,612	802,115
Provision related to prior period sales	—	592	—	—	592
Credits/payments made for current period sales	(54,952)	(548,783)	—	(24,671)	(628,406)
Credits/payments made for prior period sales	(83,398)	(177,288)	(1,690)	(2,630)	(265,006)
Balance as of December 31, 2022	**44,626**	**136,093**	**8,746**	**2,056**	**191,521**
Provision related to current period sales	90,806	726,119	2,199	16,561	835,685
Provision related to prior period sales	(897)	(16,337)	(250)	106	(17,378)
Credits/payments made for current period sales	(71,972)	(593,584)	(1,744)	(14,658)	(681,958)
Credits/payments made for prior period sales	(43,729)	(109,258)	(1,219)	(2,163)	(156,369)
Balance as of December 31, 2023	**$ 18,834**	**$ 143,033**	**$ 7,732**	**$ 1,902**	**$ 171,501**

Such net product revenue allowances and reserves are included within accrued expenses and other current liabilities within the consolidated balance sheets, with the exception of trade allowances and chargebacks, which are included within accounts receivable, net as discussed 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. During the three months ended June 30, 2023, the Company adjusted the measure of performance and recognized an additional $5.0 million and $5.3 million of license revenue relating to Eddingpharm (Asia) Macao Commercial Offshore Limited, or Edding, and HLS Therapeutics Inc., or HLS, respectively. Excluding this change in estimate, net loss per share basic and diluted for the year ended December 31, 2023 would have been $(0.17). Refer to *Note 8—Development, Commercialization and Supply Agreements* for further details.

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. Upfront 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.

(13) Development, Commercialization and Supply Agreements

In-licenses

Mochida Pharmaceutical Co., Ltd.

In June 2018, the Company entered into a collaboration with Mochida related to the development and commercialization of drug products and indications based on the active pharmaceutical ingredient in VASCEPA, the omega-3 acid, EPA, 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 U.S. 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 U.S. 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 up-front 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, 2022 and 2021, 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 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 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 the right to sublicense development and commercialization of 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 upfront 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 was 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 and under the MARINE indication in Mainland China in the second quarter of 2023. Following approval of VASCEPA in Mainland China under the MARINE indication, the Company received a non-refundable $5.0 million milestone payment. In October 2023, Edding submitted its CTA with respect to the REDUCE-IT indication for VASCEPA to the Chinese regulatory authority. Following the CTA submission, the Company recognized a non-refundable $3.0 million milestone.

In addition to the non-refundable, upfront and regulatory milestone payments described above, the Company is entitled to receive certain regulatory and sales-based milestone payments of up to an additional $145.0 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 $25.0 million. As of

December 31, 2023 the Company has recognized $9.0 million relating to milestone achievements. Achievement of regulatory approval for a third indication is not probable. The achievement of 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 upfront consideration received, the $1.0 million milestone payment received related to the successful submission of the CTA for the MARINE indication, the $5.0 million milestone payment received related to the approval of VASCEPA under the MARINE indication and the $3.0 million milestone payment related to the submission of the CTA for the REDUCE-IT 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 second quarter of 2023, Edding received regulatory approval in China under the MARINE indication and pursuit of additional indications outside of the REDUCE-IT indication is not probable. As a result, the Company reevaluated the performance period and determined that completion of the remaining performance obligations was estimated to be by the end of December 2025. The effect of this change in estimate from the previously received upfront payment and prior year milestone payments was an increase of $5.0 million in licensing revenue and a related reduction in net loss by $5.0 million for the year ended December 31, 2023. In addition, the Company recognized $3.9 million related to the milestone payment received in the second quarter for the MARINE indication approval and the remaining $1.1 million will be recognized over the remaining performance period through December 2025. The change in estimate resulted in the remaining performance period decreasing from 11 years to three years for recognizing the remaining deferred revenue.

During the years ended December 31, 2023 and 2022, the Company recognized $12.9 million and $0.6 million, respectively, as licensing revenue related to the upfront and milestone payments received in connection with the Edding agreement. From contract inception through December 31, 2023 and 2022, the Company recognized $20.6 million and $7.7 million, respectively, as licensing revenue under the DCS Agreement concurrent with the input measure of support hours provided by the Company 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 $4.4 million and $9.3 million is recorded in deferred revenue as of December 31, 2023 and 2022, respectively, on the consolidated balance sheets and as of December 31, 2023 will be recognized as revenue over the remaining period of two years.

The Company recognized net product revenue of $1.8 million and $0.2 million for the years ended December 31, 2023 and 2022, respectively, related to sales to Edding.

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 upfront 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	N/A
Bahrain	April 2021	April 2022	N/A
Kuwait	December 2021	March 2023	September 2023
Saudi Arabia	March 2022	June 2023	September 2023

The Company recognized net product revenue of approximately $3.4 million and $1.0 million as of December 31, 2023 and 2022, respectively, related to sales to Biologix.

HLS Therapeutics, Inc.

In September 2017, the Company entered into an agreement with HLS, a company incorporated under the laws of Canada, to register, commercialize and distribute VASCEPA in Canada. Under the agreement, HLS is 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 upfront 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, upfront 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 upfront 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 second quarter of 2023, the Company concluded support for regulatory activities and pursuit of additional indications was deemed to be not probable. As a result, the Company reevaluated the performance period and determined that all remaining performance obligations were satisfied as of June 30, 2023, resulting in a decrease of the previous performance period of eight years. The effect of this change in estimate was the remaining transaction price of $5.3 million being recognized in licensing revenue and a related reduction in net loss by $5.3 million during the year ended December 31, 2023 from the previously received upfront payment and prior year milestone payments.

During the years ended December 31, 2023 and 2022, the Company recognized $5.6 million and $0.7 million, respectively, as licensing revenue related to upfront and milestone payments received in connection with the HLS agreement. From the contract's inception through December 31, 2023 and 2022, the Company has recognized $13.7 million and $8.2 million, respectively. 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. As of December 31, 2022 the remaining transaction price of $5.6 million is recorded in deferred revenue on the consolidated balance sheets. The Company fully recognized the transaction price as of December 31, 2023.

The Company recognized net product revenue of $3.1 million and $2.9 million for the years ended December 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 reevaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

During the year ended December 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).

Lotus Pharmaceuticals

In July 2023, the Company entered into a distribution agreement with Lotus Pharmaceuticals, or Lotus, to commercialize and distribute VAZKEPA in South Korea and nine countries in Southeast Asia. The Company received an up-front payment of $0.3 million and is eligible to receive event-related and product-related milestone payments. The Company will be responsible for supplying finished product to Lotus at a pre-defined supply price.

The Company assessed this arrangement in accordance with Topic 606 and concluded that the contract counterparty, Lotus, 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 South Korea and Southeast Asian territories.

The transaction price includes the $0.3 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 reevaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

During the year ended December 31, 2023, the Company recognized $0.3 million as licensing revenue related to the upfront payment received in connection with the Lotus agreement (none in 2022).

The following table presents changes in the balances of the Company's contract assets and liabilities for years ended December 31, 2023 and 2022:

In thousands	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
Year ended December 31, 2023:				
Contract assets	$ —	$ —	$ —	$ —
Contract liabilities:				
Deferred revenue	$ 15,346	$ 8,090	$ (18,586)	$ 4,850
Year ended December 31, 2022:				
Contract assets	$ —	$ —	$ —	$ —
Contract liabilities:				
Deferred revenue	$ 16,709	$ 6	$ (1,369)	$ 15,346

During the years ended December 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	Twelve Months Ended December 31,	
Revenue recognized in the period from:	**2023**	**2022**
Amounts included in contract liability at the beginning of the period	$ 1,892	$ 1,366
Performance obligations satisfied in previous periods	$ 16,182	$ 2

(15) 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 consolidated financial statements.

On February 5, 2019, the Company entered into a lease agreement for new office space in Bridgewater, New Jersey, or the Lease. The Lease commenced on August 15, 2019, or the Commencement Date, for an 11-year period, with two five-year renewal options. Subject to the terms of the Lease, Amarin will have a one-time option to terminate the agreement effective on the first day of the 97th month after the Commencement Date upon advance written notice and a termination payment specified in the Lease. Under the Lease, the Company paid monthly rent of approximately $0.1 million for the first year following the Commencement Date, and such rent increases by a nominal percentage every year following the first anniversary of the Commencement Date. In addition, Amarin receives certain abatements subject to the limitations in the 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 five-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 two-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 continually enters into leases agreements for various vehicles with terms ranging from month to month up to 36 months.

The operating lease liability is $10.6 million and $11.6 million and the operating lease right-of-use asset is $8.3 million and $9.1 million, as of December 31, 2023 and 2022, respectively.

The lease expense for the years ended December 31, 2023, 2022 and 2021 is approximately $3.2 million, $2.8 million and $2.2 million, respectively.

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

	Undiscounted lease payments ($000s)
2024	$ 2,967
2025	2,292
2026	2,181
2027	1,964
2028	1,978
2029 and thereafter	3,273
Total undiscounted payments	$ 14,655
Discount Adjustments	$ (4,048)
Current operating lease liability	1,870
Long-term operating lease liability	$ 8,737

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 Year Ended December 31, 2023
Interest income from sales-type leases	$ 61
Operating lease income	912
Loss recognized at commencement date of sales type lease	(61)
Total	$ 912

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

	Sales-Type Leases	Operating Leases
2024	$ 117	$ 1,006
2025	119	1,029
2026	122	1,051
2027	125	1,073
2028	127	1,096
2029 and thereafter	218	1,878
Total	$ 828	$ 7,133

Exhibit 10.43

October 9, 2023

Jonathan Noah Provoost
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Dear Jonathan,

On behalf of Amarin Corporation plc (the "Company"), I am pleased to confirm our offer to employ you as Executive Vice President, Chief Legal and Compliance Officer. The initial terms and conditions of your employment, should you accept this offer, are set forth below in this letter agreement (the "Agreement"),

1. **Position**: Executive Vice President, Chief Legal and Compliance Officer is a full-time position as an officer of the Company. You will report to the Company's Chief Executive Officer (the "CEO") and to the Company's Board of Directors (the "Board"), having such powers and duties as may from time to time be prescribed by the CEO and/or the Board. It is understood and agreed that, while you render services to the Company, you will not engage in any other full or part-time employment activities, devoting your business time (except for permitted vacation and reasonable periods of illness or other incapacity) and best efforts, business judgment, skill, and knowledge to the advancement of the Company and interests of the Company. Notwithstanding the foregoing sentence to the contrary, you shall be permitted to (i) serve on corporate, civic, or charitable boards or committees of non-profit organizations, (to the extent there are no conflicts), (ii) lecture, speak, or attend industry-related or academic conferences or events, and (iii) manage personal investments (including, without limitation, passive real estate investments, unrelated business investments, and investments in publicly traded companies; provided, such investments are that of a passive investor of less than 5% (five percent) of any class of securities of a publicly traded entity), so long as such activities do not interfere with your duties as set forth in this Agreement (herein, "Permitted Activities").

In addition to your role as Executive Vice President, Chief Legal and Compliance Officer of the Company, you acknowledge and agree that you may be required, without additional compensation, to perform duties for certain affiliated entities of the Company, including without limitation Amarin Pharma, Inc., the Company's wholly owned subsidiary, and to accept any reasonable office or position with any such affiliate as the Company's Board of Directors may require, including, but not limited to, service as an officer or director of any such affiliate. Amarin Pharma, Inc. will maintain and distribute employment-related records. The duties of the Company set forth herein may be discharged by Amarin Corporation plc or Amarin Pharma, Inc.

2. **Work Location:** Your principal place of employment will be the Company's U.S. offices, which are currently located in Bridgewater, New Jersey, subject to business travel requirements. Notwithstanding the foregoing to the contrary, you may provide services from other locations as mutually agreed to by the CEO and you; provided that, the performance of your duties from any remote location does not interfere with the diligent exercise of your duties as set forth in this Agreement.

3. **Start Date**: Unless otherwise agreed, your first day of employment will be November 15, 2023, or such earlier date as may be mutually determined. The actual first day of your employment will be referred to herein as the "Start Date."

4. **Salary**: The Company will pay you an initial base salary at the annual rate of $465,000, subject to periodic review and adjustment at the discretion of the Company, which shall be eligible for adjustment during the next review period for 2025. Currently our policy is to make salary payments semi-monthly. Your base salary in effect at any given time is referred to herein as the "Base Salary."

5. **Annual Bonus**: Commencing with respect to work performed in calendar year 2024, you will be eligible to receive an annual performance bonus. The Company will target the bonus at up to 50% of your Base Salary for the applicable year. The actual bonus is discretionary and will be subject to the Company's assessment of your performance, as well as business conditions at the Company. The bonus also will be subject to your employment for the full period covered by the bonus, approval by and adjustment at the discretion of the Company's Board of Directors or an authorized committee thereof, and the terms of any applicable bonus plan. The Company may also make adjustments in the targeted amount of your annual performance bonus. Any bonus awarded to you will be paid by March 15 of the year following the bonus year to which such bonus relates.

6. **Special Bonus**: In consideration of the forfeiture of your 2023 bonus by your former employer, you will receive a one-time bonus totaling $100,000 (less appropriate taxes) to be paid on or about February 28, 2024 (and in any event no later than March 15, 2024), provided that you remain employed by the Company on such date; provided further that if you resign your employment other than for Good Reason or if the Company terminates your employment for Cause (as “Good Reason” and “Cause” are defined in Severance Plan described in Section 10 below) prior to the one year anniversary date of your Start Date, you will be required to repay the Company the full $100,000 within 10 days following the Date of Termination (as defined below).

7. **Benefits**: You and your dependents will be eligible to participate in the employee benefits and insurance programs generally made available to the Company's full-time U.S. employees, including health, life, disability, and dental insurance. Other benefits, such as the 401K, Employee Stock Purchase Plan, LifeLock and Executive Disability do have a waiting period component. You will be eligible for up to 18 days of paid time off or such other amount determined by the Company, which shall accrue and in other respects be administered in accordance with the Company's U.S. paid time off policy, as in effect from time to time. The Company reserves the right to modify, amend or cancel any of its benefit plans or programs at any time. You will be reimbursed for all necessary and reasonable business expenses you incur while carrying out your duties on behalf of the Company; provided such reimbursement shall be conditioned on you following the Company's U.S. reimbursement policies and claims procedure, including by providing reasonable documentation of such expenses. The Company shall reimburse you for costs, fees, and expenses incurred by you to maintain your current licenses to practice law, as well as, but not limited to dues for one (1) national and one (1) state bar association membership, costs for continuing legal education credits, other costs associated with the states in which you are licensed, and pay for you to obtain any in-house counsel registrations which may be required in the future; provided that, such costs, fees, and expenses are incurred, reported, and substantiated in accordance with the Company's customary practices and policies for reimbursement of business-related expenses and applicable federal tax laws.

8. **Equity Participation**: Subject to the approval of the Company's Board of Directors, and subject to the terms and conditions set forth in Amarin Corporation plc's 2020 Stock Incentive Plan and the applicable equity award agreements (collectively, the "Equity Documents"), including, without limitation, with respect to vesting, following the Start Date you will be awarded (i) an option to purchase 800,000 of the Company's ordinary shares, which will have an exercise price equal to the closing market price on date of grant (the "Option") and be subject to time-based vesting.

9. **At-will Employment**, **Accrued Obligations**: Your employment is "at will," meaning you or the Company may terminate it at any time for any or no reason, subject to the terms of the Severance Plan. Similarly, the terms of employment outlined in this Agreement are subject to change at any time. The last date of your employment

with the Company is referred to herein as the "Date of Termination." In the event of the termination of your employment for any reason, the Company shall pay you the "Accrued Obligations," defined as (i) your Base Salary through the Date of Termination, (ii) an amount equal to the value of your accrued unused paid time off days, if any, and (iii) the amount of any business expenses properly incurred by you on behalf of the Company prior to any such termination and not yet reimbursed, if any.

10. **Severance Benefits**: As an Executive Vice President, you are an "Eligible Executive" under the Company's Executive Severance and Change in Control Plan, effective as of January 28, 2021 (as may be amended, suspended or terminated in accordance with the terms therein, the "Severance Plan").

11. **Taxes; Section 409A**: All forms of compensation referred to in this Agreement are subject to reduction to reflect applicable withholdings and payroll taxes and other deductions required by law. You hereby acknowledge that the Company does not have a duty to design its compensation policies in a manner that minimizes tax liabilities. All in-kind benefits provided and expenses eligible for reimbursement under this Agreement shall be provided by the Company or incurred by you during the time periods set forth in this Agreement. All reimbursements shall be paid as soon as administratively practicable, but in no event shall any reimbursement be paid after the last day of the taxable year following the taxable year in which the expense was incurred. The amount of in-kind benefits provided or reimbursable expenses incurred in one taxable year shall not affect the in-kind benefits to be provided or the expenses eligible for reimbursement in any other taxable year. Such right to reimbursement or in-kind benefits is not subject to liquidation or exchange for another benefit. The parties intend that this Agreement will be administered to comply with or satisfy an exemption from Section 409A of the Internal Revenue Code of 1986, as amended from time to time (the “Code”). To the extent that any provision of this Agreement is ambiguous as to its compliance with Section 409A of the Code, the provision shall be read in such a manner so that all payments hereunder comply with Section 409A of the Code.

12. **Nondisclosure, Developments and Noncompetition Agreement:** As a condition of your employment, you are required to enter into the enclosed Nondisclosure, Developments and Noncompetition Agreement, the terms of which are incorporated by reference into this Agreement; provided, however, and notwithstanding anything to the contrary in the Nondisclosure, Developments and Noncompetition Agreement, it will not be enforced in a way that would restrict your right to practice law.

13. **Representation Regarding Other Obligations**: This offer is conditioned on your representation that you are not subject to any confidentiality, noncompetition agreement or any other similar type of restriction that may affect your ability to devote full time and attention to your work at the Company. If you have entered into any agreement that may restrict your activities on behalf of the Company, please provide me with a copy of the agreement as soon as possible. You agree that in your work for the Company, you will not disclose or make use of any information in violation of any agreements with or rights of any such previous employer or other party, and you will not bring to the premises of the Company any copies or other tangible embodiments of non-public information belonging to or obtained from any such previous employment or other party.

14. **Other Conditions**: The Company's offer of employment is contingent on the completion of references checks and a background investigation that are satisfactory to the Company (as determined by the Company), your submission of satisfactory proof of your identity and your legal authorization to work in the United States, and a satisfactory Company paid initial-employment drug screen, in each case to the extent not already completed and as requested by the Company.

15. **Entire Agreement, Amendment and Enforcement**: This Agreement, together with the Nondisclosure, Developments and Noncompetition Agreement and the Equity Documents, constitutes the complete agreement between you and the Company, contains all of the terms of your employment with the Company and supersedes any prior agreements, representations or understandings (whether written, oral or implied) between you and the Company. This Agreement may be amended or modified only by a written instrument signed by you and by a duly authorized representative of the Company. Except as may be provided in the Equity Documents, the terms of this Agreement and the resolution of any disputes as to the meaning, effect, performance or validity of this Agreement or arising out of, related to, or in any way connected with, this Agreement, your employment with the Company or any other relationship between you and the Company (the "Disputes") will be governed by the laws of the State of New Jersey, excluding laws relating to conflicts or choice of law. You and the Company submit to the exclusive personal jurisdiction of the federal and state courts located in the State of New Jersey in connection with any Dispute or any claim related to any Dispute.

16. **Assignment**: Neither you nor the Company may make any assignment of this Agreement or any interest in it, by operation of law or otherwise, without the prior written consent of the other; provided, however, that the Company may assign its rights and obligations under this Agreement without your consent to one of its affiliates or to any person with whom the Company shall hereafter effect a reorganization, consolidate with, or merge into or to whom it transfers all or substantially all of its properties or assets. This Agreement shall inure to the benefit of and be binding upon you and the Company, and each of our respective successors, executors, administrators, heirs and permitted assigns.

17. **Severability**. If any portion or provision of this Agreement shall to any extent be declared illegal or unenforceable by a court of competent jurisdiction, then the remainder of this Agreement, or the application of such portion or provision in circumstances other than those as to which it is so declared illegal or unenforceable, shall not be affected thereby, and each portion and provision of this Agreement shall be valid and enforceable to the fullest extent permitted by law.

18. **Counterparts**: This Agreement may be executed in separate counterparts. When both counterparts are signed, they shall be treated together as one and the same document. PDF copies of signed counterparts shall be equally effective as originals.

We are excited about the opportunity to work with you at Amarin. If you have any questions about this information, please do not hesitate to call. Otherwise, please confirm your acceptance of this offer of employment by signing this Agreement and the nondisclosure, Developments and Noncompetition Agreement and returning both to me no later than October 16, 2023.

AMARIN CORPORATION PLC

For itself and on behalf of Amarin Pharma, Inc.

Signed: **__/s/ Patrick Holt_____**
Name:

Dated: __10/10/2023_____

I accept the offer of employment under the terms and conditions stated above.

Signed: _/s/ Jonathan Provoost_____
Name:

Dated: _____10/10/2023_____

Enclosures: Attachment
Nondisclosure, Developments and Noncompetition Agreement

EXHIBIT 21.1

Subsidiaries of the Registrant as of December 31, 2023

Name	Jurisdiction
Amarin Pharmaceuticals Ireland Limited	Ireland
Amarin Pharma, Inc.	United States
Ester Neurosciences Limited	Israel
Amarin Switzerland GmbH	Switzerland
Amarin Germany GmbH	Germany
Amarin France SAS	France
Amarin UK Limited	United Kingdom
Amarin Italy S.r.l	Italy
Amarin Switzerland GmbH Sucursal Espana	Spain
Amarin Switzerland GmbH Austrian branch	Austria
Amarin Belgium, branch of Amarin Switzerland GmbH	Belgium
Amarin Denmark, filial af Amarin Switzerland GmbH	Denmark
Amarin Switzerland GmbH, Suomen sivuliike	Finland
Amarin Switzerland GmbH Greek branch	Greece
Amarin Switzerland GmbH Dutch branch	Netherlands
Amarin Switzerland GmbH Norwegian branch	Norway
Amarin Switzerland GmbH, Sucursal em Portugal	Portugal
Amarin Switzerland GmbH Sweden filial	Sweden

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement on Form F-1 No. 333-163704 of Amarin Corporation plc;
(2) Registration Statements on Form S-8 Nos. 333-146839, 333-143358, 333-132520, 333-110704, 333-101775, 333-168055, 333-168054, 333-176877, 333-183160, 333-205863, 333-219644, 333-180180, 333-84152, 333-240321, 333-266611 and 333-273592 of Amarin Corporation plc; and
(3) Registration Statement on Form S-3 No. 333-273591 of Amarin Corporation plc

of our reports dated February 29, 2024, with respect to the consolidated financial statements of Amarin Corporation plc, and the effectiveness of internal control over financial reporting of Amarin Corporation plc, included in this Annual Report (Form 10-K) of Amarin Corporation plc for the year ended December 31, 2023.

/s/ Ernst & Young LLP

Iselin, New Jersey
February 29, 2024

EXHIBIT 31.1

CERTIFICATION

I, Patrick Holt, certify that:

1. I have reviewed this Annual Report on Form 10-K 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(s) 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 controls over financial reporting, or caused such internal controls 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(s) 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: February 29, 2024

/s/ Patrick Holt

Patrick Holt
President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION

I, Tom Reilly, certify that:

1. I have reviewed this Annual Report on Form 10-K 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(s) 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(s) 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: February 29, 2024

/s/ Tom Reilly

Tom Reilly
Executive 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 (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Patrick Holt, President and Chief Executive Officer (Principal Executive Officer) of Amarin Corporation plc (the "Company"), and Tom Reilly, Executive 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 Annual Report on Form 10-K for the period ended December 31, 2023, to which this Certification is attached as Exhibit 32.1 (the "Annual 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 Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company at the end of such year.

/s/ Patrick Holt

Date: February 29, 2024

Patrick Holt
President and Chief Executive Officer (Principal Executive Officer)

/s/ Tom Reilly

Date: February 29, 2024

Tom Reilly
Executive Vice President and Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

This certification accompanies the Form 10-K 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-K), irrespective of any general incorporation language contained in such filing.

EXHIBIT 97.1

AMARIN CORPORATION PLC
COMPENSATION RECOVERY POLICY

Amarin Corporation plc, a public limited company incorporated under the laws of England and Wales (the "Company"), has adopted a Compensation Recovery Policy (this "Policy") as described below.

1. Overview

The Policy sets forth the circumstances and procedures under which the Company shall recover Erroneously Awarded Compensation from Covered Persons (as defined below) in accordance with rules issued by the United States Securities and Exchange Commission (the "SEC") under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and the Nasdaq Stock Market. Capitalized terms used and not otherwise defined herein shall have the meanings given in Section 3 below.

2. Compensation Recovery Requirement

In the event the Company is required to prepare a Financial Restatement, the Company shall recover reasonably promptly all Erroneously Awarded Compensation with respect to such Financial Restatement.

3. Definitions

a. "Applicable Recovery Period" means the three completed fiscal years immediately preceding the Restatement Date for a Financial Restatement. In addition, in the event the Company has changed its fiscal year: (i) any transition period of less than nine months occurring within or immediately following such three completed fiscal years shall also be part of such Applicable Recovery Period and (ii) any transition period of nine to 12 months will be deemed to be a completed fiscal year.

b. "Applicable Rules" means any rules or regulations adopted by the Exchange pursuant to Rule 10D-1 under the Exchange Act and any applicable rules or regulations adopted by the SEC pursuant to Section 10D of the Exchange Act.

c. "Board" means the Board of Directors of the Company.

d. "Committee" means the Remuneration Committee of the Board or, in the absence of such committee, a majority of independent directors serving on the Board.

e. "Covered Person" means any Executive Officer. A person's status as a Covered Person with respect to Erroneously Awarded Compensation shall be determined as of the time of receipt of such Erroneously Awarded Compensation regardless of the person's current role or status with the Company (e.g., if a person began service as an Executive Officer after the beginning of an Applicable Recovery Period, that person

would not be considered a Covered Person with respect to Erroneously Awarded Compensation received before the person began service as an Executive Officer, but would be considered a Covered Person with respect to Erroneously Awarded Compensation received after the person began service as an Executive Officer where such person served as an Executive Officer at any time during the performance period for such Erroneously Awarded Compensation).

f. "Effective Date" means October 2, 2023.

g. "Erroneously Awarded Compensation" means the amount of any Incentive-Based Compensation received by a Covered Person on or after the Effective Date and during the Applicable Recovery Period that exceeds the amount that otherwise would have been received by the Covered Person had such compensation been determined based on the restated amounts in a Financial Restatement, computed without regard to any taxes paid. Calculation of Erroneously Awarded Compensation with respect to Incentive-Based Compensation based on stock price or total shareholder return, where the amount of Erroneously Awarded Compensation is not subject to mathematical recalculation directly from the information in a Financial Restatement, shall be based on a reasonable estimate of the effect of the Financial Restatement on the stock price or total shareholder return upon which the Incentive-Based Compensation was based, and the Company shall maintain documentation of the determination of such reasonable estimate and provide such documentation to the Exchange in accordance with the Applicable Rules. Incentive-Based Compensation is deemed received when the Financial Reporting Measure is attained, not when the actual payment, grant or vesting occurs.

h. "Exchange" means the Nasdaq Stock Market LLC.

i. "Executive Officer" means any person who served the Company in any of the following roles at any time during the performance period applicable to Incentive-Based Compensation and received Incentive-Based Compensation after beginning service in any such role (regardless of whether such Incentive-Based Compensation was received during or after such person's service in such role): the president, principal financial officer, principal accounting officer (or if there is no such accounting officer the controller), any vice president in charge of a principal business unit, division or function (such as sales, administration or finance), any other officer who performs a policy making function or any other person who performs similar policy making functions for the Company. Executive officers of parents or subsidiaries of the Company may be deemed Executive Officers if they perform such policy making functions for the Company.

j. "Financial Reporting Measures" mean measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial

statements, any measures that are derived wholly or in part from such measures (including, for example, a non-GAAP financial measure), and stock price and total shareholder return.

k. "Financial Restatement" means a restatement of previously issued financial statements of the Company due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required restatement to correct an error in previously-issued financial statements that is material to the previously-issued financial statements or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

l. "Incentive-Based Compensation" means any compensation provided, directly or indirectly, by the Company or any of its subsidiaries that is granted, earned or vested based, in whole or in part, upon the attainment of a Financial Reporting Measure, including, for example, annual cash bonuses paid under the Company's management incentive plan that are granted, earned, or vested based, in whole or in part, upon the attainment of a Financial Reporting Measure, any other special cash bonuses that are granted, earned, or vested based, in whole or in part, upon the attainment of a Financial Reporting Measure and annual, new hire, promotion-based, or special performance-based equity awards that are granted, earned, or vested based, in whole or in part, upon the attainment of a Financial Reporting Measure.

m. "Restatement Date" means, with respect to a Financial Restatement, the earlier to occur of: (i) the date the Board concludes, or reasonably should have concluded, that the Company is required to prepare the Financial Restatement or (ii) the date a court, regulator or other legally authorized body directs the Company to prepare the Financial Restatement.

4. Exception to Compensation Recovery Requirement

The Company may elect not to recover Erroneously Awarded Compensation pursuant to this Policy if the Committee determines that recovery would be impracticable, and one or more of the following conditions, together with any further requirements set forth in the Applicable Rules, are met: (i) the direct expense paid to a third party, including outside legal counsel, to assist in enforcing this Policy would exceed the amount to be recovered, and the Company has made a reasonable attempt to recover such Erroneously Awarded Compensation; (ii) recovery would cause the Company to violate a law of England and Wales that was adopted prior to November 28, 2022, and the Company obtains an opinion of England and Wales counsel that recovery would result in a violation of such country's law and provides the opinion to the Exchange; or (iii) recovery would likely cause an otherwise tax-qualified retirement plan to fail to be so qualified under applicable regulations.

5. Tax Considerations

The Company is entitled to recover the gross amount of any Erroneously Awarded Compensation that is received by a Covered Person (i.e., the amount the Covered Person received, or was entitled to receive, before any deductions for tax withholding or other payments). For example, if a Covered Person was awarded a $100,000 cash bonus and received $60,000 after 40% was withheld for taxes, and it was determined that the amount awarded should only have been $80,000, the Covered Person would be required to return $20,000 to the Company.

6. Method of Compensation Recovery

The Committee shall determine, in its sole discretion, the method for recovering Erroneously Awarded Compensation hereunder, which may include, without limitation, any one or more of the following:

a. requiring reimbursement of cash Incentive-Based Compensation previously paid;

b. seeking recovery of any gain realized on the vesting, exercise, settlement, sale, transfer or other disposition of any equity-based awards;

c. cancelling or rescinding some or all outstanding vested or unvested equity-based awards;

d. adjusting or withholding from unpaid compensation or other set-off;

e. cancelling or offsetting against planned future grants of equity-based awards; and/or

f. any other method permitted by applicable law or contract.

Notwithstanding the foregoing, a Covered Person will be deemed to have satisfied such person's obligation to return Erroneously Awarded Compensation to the Company if such Erroneously Awarded Compensation is returned in the exact same form in which it was received; provided that equity withheld to satisfy tax obligations will be deemed to have been received in cash in an amount equal to the tax withholding payment made.

7. Policy Interpretation

This Policy shall be interpreted in a manner that is consistent with the Applicable Rules and any other applicable law. The Committee shall take into consideration any applicable interpretations and guidance of the SEC in interpreting this Policy, including, for example, in determining whether a financial restatement qualifies as a Financial Restatement hereunder. To the extent the Applicable Rules require recovery of Incentive-Based Compensation in additional circumstances

besides those specified above, nothing in this Policy shall be deemed to limit or restrict the right or obligation of the Company to recover Incentive-Based Compensation to the fullest extent required by the Applicable Rules.

8. Policy Administration

This Policy shall be administered by the Committee; provided, however, that the Board shall have exclusive authority to authorize the Company to prepare a Financial Restatement. In doing so, the Board may rely on a recommendation of the Audit Committee of the Board. The Committee shall have such powers and authorities related to the administration of this Policy as are consistent with the governing documents of the Company and applicable law. The Committee shall have full power and authority to take, or direct the taking of, all actions and to make all determinations required or provided for under this Policy and shall have full power and authority to take, or direct the taking of, all such other actions and make all such other determinations not inconsistent with the specific terms and provisions of this Policy that the Committee deems to be necessary or appropriate to the administration of this Policy. The interpretation and construction by the Committee of any provision of this Policy and all determinations made by the Committee under this policy shall be final, binding and conclusive.

9. Compensation Recovery Repayments not Subject to Indemnification

Notwithstanding anything to the contrary set forth in any agreement with, or the organizational documents of, the Company or any of its subsidiaries, Covered Persons are not entitled to indemnification for Erroneously Awarded Compensation or for any losses arising out of or in any way related to Erroneously Awarded Compensation recovered under this Policy.

Adopted as of [October __,] 2023