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, 2021

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.)**

77 Sir John Rogerson's Quay, Block C,
Grand Canal Docklands, 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. ☑

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, 2021 was approximately $1,710.3 million, based upon the closing price on the NASDAQ Global Market reported for such date.

396,737,811 shares were outstanding as of February 25, 2022, including 396,540,984 shares held as American Depositary Shares (ADSs), each representing one Ordinary Share, 50 pence par value per share, and 196,827 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 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 offices are located at 77 Sir John Rogerson's Quay, Block C, Grand Canal Docklands, 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 Spaces Grafenauweg 8, 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 on Form 10-K, 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 lead product, VASCEPA® (icosapent ethyl) was first approved by the United States Food and Drug Administration, or U.S. FDA, for use as an adjunct to diet to reduce triglyceride, or TG, levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia, or the MARINE indication. We launched VASCEPA in the United States, or U.S., in January 2013. On December 13, 2019 the U.S. FDA approved another 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 the EU, for VAZKEPA, hereinafter along with the U.S. brand name VASCEPA, collectively referred to as VASCEPA, which is the first and only EC approved therapy to reduce cardiovascular risk in high-risk statin-treated patients with elevated TG levels. On September 13, 2021, we launched VAZKEPA in Germany, representing our first European launch. On April 22, 2021, we announced that we received marketing authorization from the Medicines and Healthcare Products Regulatory Agency, or MHRA, for VAZKEPA in England, Wales and Scotland to reduce cardiovascular risk through MHRA's new 'reliance' route following the end of the Brexit transition period.

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

United States

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

Since our inception, we have devoted substantial resources to our research and development efforts, most significantly our VASCEPA cardiovascular outcomes trial, REDUCE-IT. We announced topline results from REDUCE-IT on September 24, 2018. On November 10, 2018, we presented REDUCE-IT primary 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% relative risk reduction, or RRR, to a high degree of statistical significance ($p<0.001$), in first occurrence of major adverse cardiovascular events, or MACE, in the intent-to-treat patient population with use of VASCEPA 4 grams/day as compared to placebo. REDUCE-IT also showed a 26% RRR in its key secondary composite endpoint of cardiovascular death, heart attacks and stroke ($p<0.001$). On March 18, 2019, we publicly presented the total cardiovascular events results, and the method of calculating such

events, of the REDUCE-IT study at the American College of Cardiology's 68th Annual Scientific Session and such results and methods were concurrently published in the *Journal of the American College of Cardiology*. VASCEPA reduced total events (first and subsequent events) by 30% compared to placebo, reflecting that for every 1,000 patients treated for five years with VASCEPA versus placebo in this trial, approximately 159 MACE could be prevented with VASCEPA.

Since commercial launch of VASCEPA in January 2013, we had promoted VASCEPA based on the MARINE clinical trial data as reflected in the first U.S. FDA-approved label for VASCEPA. In August 2015, we and our co-promotion partner began communicating promotional information beyond MARINE clinical trial data to targeted healthcare professionals. Such qualified communications were made pursuant to the August 7, 2015 federal district court declaration and related March 2016 settlement allowing truthful and non-misleading promotion of the U.S. FDA-reviewed and agreed effects of VASCEPA demonstrated in the ANCHOR clinical trial, discussed further below. This promotion also included information related to the then current state of scientific research about the potential of VASCEPA to reduce the risk of cardiovascular disease, including REDUCE-IT data and previously other peer-reviewed scientific publications of available data. The ANCHOR clinical trial of VASCEPA demonstrated the favorable effects of VASCEPA on TGs and related lipid, lipoprotein and inflammation parameters in patients on statin therapy and persistent high TGs.

After results of REDUCE-IT were available in September 2018 and demonstrated that VASCEPA is effective in lowering the rate of major adverse cardiovascular events in statin-treated patients with CV risk factors, we expanded the size of our U.S. direct sales force and continued to expand promotion of VASCEPA. After publication of the primary results of the REDUCE-IT study in *The New England Journal of Medicine* and scientific presentation of REDUCE-IT results at the 2018 Scientific Sessions of the AHA on November 10, 2018, we updated and expanded our communication of REDUCE-IT results to include the publication and the peer-reviewed information presented in an effort to further ensure that our communications remained truthful and non-misleading. Starting December 13, 2019, we began promoting based on the label expansion from the REDUCE-IT indication. We employ various medical affairs and marketing personnel to support our commercialization of VASCEPA.

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

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

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

We have continued to monitor the effect of COVID-19 and its impact on patient visits to doctors. Our level and type of promotion has varied during the pandemic based on the determination of whether the cost was justified in light of COVID-19's impact at a given time. We anticipate that at-risk patients will increasingly resume visiting their doctors for non-urgent medical care after they are vaccinated for COVID-19, however, we cannot accurately predict when this resumption in visits to doctors will occur and, because many patients have multiple medical issues, we cannot predict the degree to which healthcare professionals will be proactive in seeking to reduce cardiovascular risk in at-risk patients when these patients resume visiting their doctors. The timing is likely to vary by geography. We resumed on a very limited basis, a direct-to-patient campaign in January 2021, including television-based promotion, digital and social media promotion to continue to grow consumer awareness of VASCEPA. In June 2021, we launched an educational campaign, *It's Clear to Me Now*, to help physicians and patients learn more about the differentiation between VASCEPA and fenofibrates for CV risk reduction. The differentiation is important for physicians and patients as the U.S. FDA removed use with

statins for CV risk reduction from the fenofibrates' label based on a failed CV risk outcomes trial. In September 2021, we announced our Go-to-Market strategy in the U.S. to optimize provider engagement and drive demand for VASCEPA and contains three key strategic priorities:

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

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

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

Europe

In December 2019, we announced that the European Medicines Agency, or EMA, validated the marketing authorization application seeking approval for VAZKEPA. The validation confirmed the submission was sufficiently complete for the EMA to begin its review. In August 2020, we announced our plans to launch VAZKEPA in major markets in Europe through our own new European sales and marketing team. Such an approach allows us to retain substantially all of the economic potential of VAZKEPA in Europe and helps ensure that VAZKEPA would get the highest level of priority and focus. On January 28, 2021, the Committee for Medicinal Products for Human Use, or CHMP, of the EMA adopted a positive opinion, recommending that a marketing authorization be granted to our drug icosapent ethyl in the EU for the reduction of risk of cardiovascular events in patients with high cardiovascular risk. On March 26, 2021, the EC granted approval of the marketing authorization application in the EU for VAZKEPA which is the first and only EC approved therapy to reduce cardiovascular risk in high-risk statin-treated patients with elevated TG levels. The EC approval provides ten years of market protection in the EU, and we have been issued a patent that expires in 2033 with additional pending applications that could extend exclusivity into 2039. On September 13, 2021, we launched VAZKEPA in Germany, representing our first European launch. On April 22, 2021, we announced that we received marketing authorization from the MHRA for VAZKEPA in England, Wales and Scotland to reduce cardiovascular risk through MHRA's new 'reliance' route following the end of the Brexit transition period.

In Europe, launch of VAZKEPA in individual countries is gated by timing of achieving product reimbursement on a country-by-country basis as is typical for new drugs. In seeking market access, we have filed ten dossiers in European countries, including in all of the largest countries in Europe, and expect to file additional dossiers in Europe and select other parts of the world in the first half of 2022. In most European countries, securing product reimbursement is a requisite to launching. In certain countries, such as Denmark, individual patient reimbursement is allowed prior to national, general organization reimbursement. In all countries, securing adequate reimbursement is a requisite for commercial success of any therapeutic. The time required to secure reimbursement tends to vary from country to country and cannot be reliably predicted at this time, however, we expect to obtain access to several European markets during 2022. While we believe that we have strong arguments regarding the cost effectiveness of VAZKEPA, the success of such reimbursement negotiations will be critical to achieve the commercial potential of VAZKEPA in Europe. Additionally, we are continuing to grow our European staff by hiring Market access and Medical affairs teams, among others, across Europe.

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

are launched. As we are building this model, our teams have faced increased access restrictions beginning in the middle of November 2021 due to the severe increase of COVID-19 in Germany.

In order to launch impactfully in other countries throughout Europe we continue to build, in each country, a core team of experienced professionals and a highly capable commercial team involved with pre-launch planning and other commercial preparation activities and are leveraging third-party relationships for various support activities. In Europe, patients at high risk for cardiovascular disease tend, in comparison to the United States, to be treated more often by specialists, such as cardiologists rather than by physicians who are general practitioners. Privacy laws and other factors impact the availability of data to inform European commercial operations at an individual physician level. Generally, less data is available and at reduced frequencies as compared to the United States. However, this greater concentration of at-risk patients being treated by specialists in Europe should allow for more efficient promotion in Europe than in the United States.

Rest of World

China

In February 2015, we entered into a Development, Commercialization and Supply Agreement, or the DCS Agreement, with Eddingpharm (Asia) Macao Commercial Offshore Limited, or Edding, related to the development and commercialization of VASCEPA in Mainland China, Hong Kong, Macau and Taiwan, or the China Territory. Under the DCS Agreement, Edding is solely responsible for development and commercialization activities in the China Territory and associated expenses. Additionally, Edding is required to conduct clinical trials in the China Territory to secure regulatory approval in certain territories. Edding, with our support, commenced a pivotal Phase 3 clinical trial of VASCEPA aimed to support the regulatory approval of the first indication of VASCEPA in a patient population with severe hypertriglyceridemia in Mainland China. Additional clinical development efforts are necessary in certain segments of this market. In November 2020, we announced statistically significant positive topline results from the Phase 3 clinical trial of VASCEPA conducted by Edding. The study, which investigated VASCEPA as a treatment for patients with very high triglycerides (≥500 mg/dL), met its primary efficacy endpoint as defined in the clinical trial protocol and demonstrated a safety profile similar to placebo. Importantly, the VASCEPA 4 gram per day dose in this study appeared to be well-tolerated with a safety profile similar to placebo. There were no treatment-related serious adverse events in this study. On February 9, 2021, we announced that the regulatory review processes for approval of VASCEPA in Mainland China and Hong Kong have commenced. The National Medical Products Administration, or NMPA, has accepted for review the new drug application for VASCEPA, submitted by Edding, based on the results from the Phase 3 clinical trial and the results from our prior studies of VASCEPA. We expect to receive a decision from the NMPA in Mainland China in the second half of 2022. The Hong Kong Department of Health is evaluating VASCEPA based on current approvals in the United States and Canada. The review process in Hong Kong is expected to conclude in the second half of 2022. If Edding is not able to effectively develop and commercialize VASCEPA in the China Territory, we may not be able to generate revenue from the DCS Agreement resulting from the sale of VASCEPA in the China Territory.

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. Under the terms of the distribution agreement, we granted to Biologix a non-exclusive license to use our trademarks in connection with the importation, distribution, promotion, marketing and sale of VASCEPA in the Middle East and North Africa territory. Biologix 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 2018	April 2021	—
Bahrain	April 2021	—	—
Kuwait	December 2021	—	—

VASCEPA is under registration in additional countries in the MENA region. Commercialization across the Middle East and North Africa is subject to similar risks as in the China Territory.

Canada

In September 2017, we entered into an agreement with HLS Therapeutics Inc., or HLS, to register, commercialize and distribute VASCEPA in Canada. Under the agreement, HLS is responsible for regulatory and commercialization activities and associated costs. We are responsible for providing assistance towards local filings, supplying finished product under negotiated supply terms, and maintaining intellectual property. In December 2019, following priority review designation, HLS received 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 an extended regulatory exclusivity designation and commercial launch began in February 2020. In July 2020, the Canadian Agency for Drugs and Technologies in Health recommended that VASCEPA be reimbursed by participating public drug plans for statin-treated patients with established cardiovascular diseases and elevated triglycerides. HLS also received notification by the Patented Medicine Prices Review Board that, further to its review, VASCEPA's price did not trigger the investigation criteria for excessive pricing. If HLS is not able to effectively commercialize VASCEPA in Canada, we may not be able to generate revenue from the agreement as a result of the sale of VASCEPA in Canada. VASCEPA has the benefit of data protection afforded through Health Canada until the end of 2027, in addition to separate patent protection with expiration dates that could extend into 2039.

Other

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

Impact of COVID-19

As of December 31, 2021, according to U.S. Centers for Disease Control and Prevention, or CDC, data, approximately 60% of the U.S. population has been fully vaccinated, which does not include a booster shot, and approximately 75% of the U.S. population has received at least one dose of a vaccine. While according to CDC data, the population's vaccination rate has increased, the number of new cases increased at the end of 2021 and into early 2022, driven by the Omicron variant.

Our ability to directly promote VASCEPA to healthcare professionals has been limited due to appropriate social distancing practices associated with COVID-19 and by patients electing to forego visiting their doctors for non-urgent medical examinations and/or choosing to not get blood tests which the results of these tests provide useful information to the treatment of cardiovascular risk. These limitations have had a significant impact on slowing VASCEPA prescription and revenue growth. Although some of these restrictions were lifted throughout parts of 2021, in light of the increase in cases in the fourth quarter of 2021 due to the Omicron variant and despite the prevalence of the vaccines, many restrictions have been put back in place and access remains variable and challenging due to COVID-19. While COVID-19 continues to impact our promotion of VASCEPA, we have seen signs of improvement in access to face-to-face interactions with healthcare providers.

In the United States, prior to the recent surge at the end of 2021, at-risk patients increasingly resumed visiting their doctors for non-urgent medical care after they are vaccinated for COVID-19 and we anticipate that to continue when the current surge in cases decreases. We continued to adjust our promotional initiatives throughout 2021 and plan to adjust throughout 2022, including pursuing increased face-to-face interactions with health care professionals and expanding various forms of direct-to-patient promotion based on COVID-19 protocols that are in place.

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

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

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

Clinical Trials

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

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.

In August 2011, we reached agreement with the U.S. FDA on a special protocol assessment, or SPA, agreement for the design of the REDUCE-IT cardiovascular outcomes study. An SPA is an evaluation by the U.S. FDA of a protocol with the goal of reaching an agreement that the Phase 3 trial protocol design, clinical endpoints, and statistical analyses are acceptable to support regulatory approval. The U.S. FDA agreed that, based on the information we submitted to the agency, the design and planned analysis of the REDUCE-IT study adequately addressed the objectives necessary to support a regulatory submission. An SPA is generally binding upon the U.S. FDA unless a substantial scientific issue essential to determining safety or efficacy of the drug is identified after the testing begins.

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 September 2011, we engaged a clinical research organization, or CRO, and began initial trial and clinical site preparation for REDUCE-IT. In December 2011, we announced that the first patient was dosed in the study. 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 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 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-C75 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 5-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.

The U.S. FDA granted Priority Review designation to our March 2019 supplemental new drug application, or sNDA, seeking an expanded indication for VASCEPA in the United States based on the positive results of the REDUCE-IT study. The U.S. FDA grants Priority Review designation to applications for drugs that, if approved, have the potential to offer significant improvements in the effectiveness and safety of the treatment of serious conditions when compared to standard applications. In November 2019, the U.S. FDA held an Endocrinologic and Metabolic Drugs Advisory Committee, or EMDAC, meeting to review the REDUCE-IT sNDA. The EMDAC voted unanimously (16-0) to recommend approval of an indication and label expansion for VASCEPA to reduce cardiovascular events in high-risk patients based on the REDUCE-IT results. 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 on Form 10-K, 26 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 2021 through the date of the filing of this Annual Report on Form 10-K as listed below:

- The Polish Cardiac Society Working Group on Cardiovascular Pharmacotherapy, or SFSN PTK, published a consensus statement on the management of dyslipidemia. The statement by SFSN PTK recommends 4g of EPA, icosapent ethyl, daily in combination with statins for patients with TG levels 135–499 mg/dL in the high- and very-high-risk categories. The statement mentions that in REDUCE-IT, 2g of icosapent ethyl, or IPE, twice daily in combination with a statin significantly reduced the risk of CV events and lowered TG levels. SFSN PTK acknowledges that icosapent ethyl is not approved for use in Poland, and data from REDUCE-IT cannot be extrapolated to other doses and formulation of omega-3s.
- The Diabetes CardioRenal Metabolic Diseases, or DCRM, Task Force published practice recommendations for the management of DCRM. The practice recommendation recommends icosapent ethyl, for the primary prevention of myocardial infarction, coronary artery disease, or stroke in patients with diabetes and for secondary prevention of these

events in those with and without diabetes. DCRM further states that based on evidence from REDUCE-IT, adding IPE to statin therapies further reduces the risk of atherosclerotic cardiovascular disease, or ASCVD, events in patients with TG levels 135–500 mg/dL (1.5–5.7 mmol/L) who have ASCVD or diabetes plus 2 major ASCVD risk factors.

- The AHA issued a scientific statement on the comprehensive management of CV risk factors for adults with type 2 diabetes. The AHA statement recommends patients with diabetes and ASCVD or patients with diabetes at high risk for ASCVD with serum TG levels of 135–500 mg/dL despite maximally tolerated statin therapy, and addressing contributory factors including lifestyle modification, prescription IPE at a dose of 4 grams/day should be considered given the 30% additional CV risk reduction in the REDUCE-IT trial. AHA further states that for primary prevention in type 2 diabetes, a moderate-intensity statin should be considered based on age, absolute ASCVD risk, or the presence of risk-enhancing factors. Non-statin therapies including ezetimibe, PCSK9 inhibitors, IPE, bile acid resins, and fibrates should be considered after thorough evaluation of risk, LDL-C level after optimal statin therapy, and presence of hypertriglyceridemia.

During 2021, 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:

STROKE

The REDUCE-IT STROKE analyses were presented at the International Stroke Conference 2021, which was held virtually from March 17 to March 19, 2021. The REDUCE-IT STROKE analyses examined stroke rates across the enrolled patient population, who were required to be treated with statins and other conventional therapies, and all patients had either established cardiovascular disease or diabetes and had other cardiovascular risk factors such as elevated triglyceride levels. Event rates for time to first fatal or nonfatal stroke were 2.4% for VASCEPA vs. 3.3% for placebo for a relative risk reduction of 28%. Ischemic stroke time to first event rates were 2.0% for VASCEPA vs. 3.0% for placebo for a relative risk reduction of 36%. Hemorrhagic stroke occurred at low rates with no significant difference for VASCEPA vs. placebo. The REDUCE-IT STROKE abstract received the prestigious Paul Dudley White International Scholar Award, recognizing the authors with the highest ranked abstract across the United States at the International Stroke Conference 2021.

HEART FAILURE

During the American College of Cardiology's 70th Annual Scientific Session, which was held virtually from May 15 to May 17, 2021, we presented new REDUCE-IT HEART FAILURE analyses. The REDUCE-IT HEART FAILURE analyses examined the effects of icosapent ethyl on the incidence of the new heart failure by achieved on-treatment serum EPA levels in REDUCE-IT patients. New heart failure and new heart failure requiring hospitalization were prespecified tertiary endpoints and were not significant in the overall patient population. *Post hoc* analyses were conducted based on estimated average on-treatment EPA levels in patients in the icosapent ethyl group with available EPA measurements, as compared to patients in the placebo group with available EPA measurements; these analyses showed that new heart failure and new heart failure requiring hospitalization may be reduced in patients who achieve serum EPA levels higher than approximately 150 µg/mL, though this needs to be tested prospectively.

PRIOR MI

Data on the effect of VASCEPA on patients with prior heart attacks, known as myocardial infarction, or MI, at risk for major adverse cardiovascular events were delivered in a Late Breaking Science Presentation at ESC Congress 2021, which was held virtually from August 27 to August 30, 2021. The Late Breaking Science Presentation included both prespecified and *post hoc* analyses of patients who had prior MI from the REDUCE-IT study, prior to trial randomization, to determine if treatment with VASCEPA reduced further ischemic events in those subjects. Icosapent ethyl 4 gram/day significantly reduced first and total primary endpoints of 5-point major adverse cardiovascular event, comprised of CV death, MI, stroke, coronary revascularization, and hospitalization for unstable angina by 26% and 35%, respectively in patients with prior MI.

PRIOR PAD

During a Rapid Fire Oral Session Presentation at the AHA Scientific Sessions 2021, which took place virtually from November 13 to November 15, 2021, data was presented on VASCEPA in patients with prior peripheral artery diseases, or PAD, at risk for major adverse cardiovascular event. The Rapid Fire Oral Session presentation included both prespecified and *post hoc* analyses of patients who had PAD prior to randomization in the REDUCE-IT study to determine if treatment with VASCEPA reduced further ischemic events in those subjects. Icosapent ethyl 4 gram/day significantly reduced first and subsequent primary endpoints by 32% in patients with PAD.

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

The MARINE trial, the then largest study ever conducted with the omega-3 fatty acid ethyl EPA in treating patients with very high triglycerides (≥500 mg/dL), was a Phase 3, multi-center, placebo-controlled, randomized, double-blind, 12-week study. Patients were randomized into three treatment arms for treatment with VASCEPA 4 gram/day, 2 gram/day or placebo. Patient enrollment in this trial began in December 2009, and enrollment and randomization was completed in August 2010 at 229 patients. The primary endpoint in the trial was the percentage change in triglyceride level from baseline compared to placebo after 12 weeks of treatment. The MARINE study primary endpoint was required to meet a stringent level of statistical significance of 1% ($p < 0.01$) in our SPA agreement with the U.S. FDA.

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.

In a pre-specified secondary analysis in the subgroup of patients with baseline triglyceride > 750 mg/dL, representing 39% of all patients, the effect of VASCEPA in reducing triglyceride levels compared to placebo was 45% for 4 grams and 33% for 2 grams, both statistically significant ($p = 0.0001$ for 4 grams and $p= 0.0016$ for 2 grams, respectively). The median baseline triglyceride levels in this subgroup were 1052 mg/dL, 902 mg/dL and 948 mg/dL for placebo, 4-gram and 2-gram groups, respectively. Twenty-five percent of patients in this trial were also on background statin therapy. These patients had greater median reduction in triglyceride levels, which was also statistically significant.

Importantly, the significant reduction in triglycerides was not associated with a statistically significant increase in median LDL-C compared to placebo at either dose (-2.3% for the 4-gram group and +5.2% for the 2-gram group [both p=NS]). In addition, there was a statistically significant decrease in median non-HDL-C (total cholesterol less so-called “good cholesterol”) compared to placebo with both of the VASCEPA-treated groups (-18% for the 4-gram group [$p < 0.001$] and -8% for the 2-gram group [$p < 0.05$]).

The MARINE trial results also included statistically significant reductions compared to placebo in several important lipid and inflammatory biomarkers, including apo B (apolipoprotein B) (8.5%), Lp-PLA2 (lipoprotein-phospholipase A2) (13.6%), VLDL-C (very low-density lipoprotein cholesterol) (28.6%), Total Cholesterol (16.3%), and hsCRP (high-sensitivity C-reactive protein) (36.0%) at the 4-gram dose. For these achieved endpoints, p-values were <0.01 for most and <0.05 for all. Apo B (apolipoprotein B) is believed to be a sensitive biomarker of cardiovascular risk and may be a better predictor of cardiovascular risk than LDL-C. Lp-PLA2 is an enzyme found in blood and atherosclerotic plaque; high levels have been implicated in the development and progression of atherosclerosis. In a *post hoc* analysis of MARINE study data, VASCEPA 4 grams/day and 2 grams/day statistically significantly reduced ApoC-III levels by 25.1% ($p < 0.0001$) and 14.3% ($p=0.0154$) versus placebo, respectively. In the MARINE trial, patients treated with 4 grams per day of VASCEPA experienced a significant reduction in median placebo-adjusted lipoprotein particle concentrations of total LDL and small LDL. When looking at lipoprotein particle concentrations and sizes as measured with nuclear magnetic resonance spectroscopy, VASCEPA 4 grams per day, compared with placebo, significantly reduced median total LDL particle count by 16.3% ($p=0.0006$), which is an important factor in atherogenesis. LDL particle count and apo B are important risk markers for the prediction of cardiovascular events. Small LDL particle count, which is a common risk factor for cardiovascular events in patients with diabetes, was reduced by 25.6% ($p<0.0001$) compared with placebo. VASCEPA 2 grams per day, compared with placebo, significantly reduced median small LDL particle count by 12.8% ($p <0.05$) and reduced median total LDL particle count by 1.1% (NS). LDL particle size did not change significantly for the 2 or 4 gram per day doses.

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. No patient discontinued treatment of VASCEPA during this study due to VASCEPA-related adverse events. No significant changes in fasting blood glucose, hemoglobin A1C, vital signs, electrocardiograms, or liver or kidney function were observed with either VASCEPA dose.

Patients enrolled in the MARINE trial were given the option to be treated with VASCEPA for a period of up to 40 weeks after their last dose in the double-blind portion of the trial. Once participants completed the randomized, double blind, placebo-controlled 12-week MARINE registration trial, patients in all three randomized groups (4 grams, 2 grams and placebo) were offered the opportunity to participate in the open label extension, or OLE, phase. Patients in the OLE phase received 4 grams per day of VASCEPA for a period of up to an additional 40 weeks. As is typical of such extension phases, the OLE phase was not a controlled trial, as differentiated from the randomized, double blind, placebo-controlled 12-week MARINE registration trial. In the OLE phase, participants were not randomized at entry, VASCEPA administration was open label (and thus not blinded), and no placebo group was maintained. Also, once patients entered in the OLE phase, investigators were free to add or modify other lipid-altering nutritional, lifestyle and drug treatment regimens. Given the lack of randomization, the open-label design, the addition of various other lipid-altering drugs and changes to doses of existing lipid-altering drugs, as well as the lack of placebo control, neither we nor our independent advisors were able to draw efficacy conclusions from the data. However, we have concluded that the MARINE OLE phase revealed no new safety signals after an additional 40 weeks of exposure to VASCEPA, whether used alone or in combination with other lipid-altering regimens.

The ANCHOR Trial

The ANCHOR trial was a multi-center, placebo-controlled, randomized, double-blind, 12-week pivotal study in patients with high triglycerides (≥200 and <500 mg/dL) who were also receiving optimized statin therapy. Patients were randomized into three arms for treatment with VASCEPA 4 gram/day, 2 gram/day or placebo. Patient enrollment in this trial began in January 2010, and enrollment and randomization was completed in February 2011 at 702 patients. The primary endpoint in the trial was the percentage change in triglyceride level from baseline compared to placebo after 12 weeks of treatment.

In April 2011, we reported topline results from the ANCHOR trial. The ANCHOR trial met its primary endpoint at doses of 4 grams and 2 grams per day with median placebo-adjusted reductions in triglyceride levels of 21.5% ($p<0.0001$ value) for 4 grams and 10.1% ($p=0.0005$) for 2 grams. The median baseline triglyceride levels were 259 mg/dL, 265 mg/dL and 254 mg/dL for the patient groups treated with placebo, 4 grams and 2 grams of VASCEPA per day, respectively. The analysis of subgroups by baseline triglyceride tertiles showed that higher baseline triglycerides resulted in greater triglyceride reductions.

One of the trial's secondary endpoints was to demonstrate a lack of elevation in LDL-C, the primary target of cholesterol lowering therapy. The trial's non-inferiority criterion for LDL-C was met at both VASCEPA doses. The upper confidence boundaries for both doses were below the pre-specified +6% LDL-C threshold limit. At the 4-gram dose the upper confidence boundary was below zero (-1.7%) and at the 2-gram dose the upper confidence boundary was close to zero (0.5%). For the 4 grams per day group, LDL-C decreased significantly by 6.2% from baseline versus placebo, demonstrating superiority over placebo ($p=0.0067$). For the 2-gram group, LDL-C decreased by 3.6% from baseline versus placebo ($p=0.0867$), which is not a statistically significant decrease.

Other secondary efficacy endpoints included the median placebo-adjusted percent change in non-high-density lipoprotein cholesterol, or non-HDL-C, apolipoprotein B, or apo B, and lipoprotein-associated phospholipase A2 (Lp-PLA2). The 4-gram dose was associated with statistically significant reductions in non-HDL-C (13.6%, $p<0.0001$), apo B (9.3%, $p<0.0001$), Lp-PLA2 (19%, $p<0.0001$) and high-sensitivity C-reactive protein, or hsCRP, (22%, $p<0.001$), at week 12 compared to placebo. One published analysis showed that the VASCEPA 4-gram daily dose in the ANCHOR study also significantly decreased levels of the inflammatory marker oxidized low-density lipoprotein relative to placebo by 13% ($p < 0.0001$). In a separate, *post hoc* analysis of study data, VASCEPA 4 g/day statistically significantly reduced ApoC-III levels by 25.1% in MARINE ($p < 0.0001$) and by 19.2% in ANCHOR ($p < 0.0001$) versus placebo.

VASCEPA was well tolerated in the ANCHOR trial with a safety profile comparable to placebo and there were no treatment-related serious adverse events observed. No significant changes in fasting blood glucose, hemoglobin A1C, vital signs, electrocardiograms, or liver or kidney function were observed with either VASCEPA dose. The safety results from the ANCHOR trial are included in the first U.S. FDA-approved label for VASCEPA.

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

U.S. FDA acknowledged at the time that the design of the REDUCE-IT study was such that results of that cardiovascular outcomes study should address their lack of confidence in serum triglycerides as a surrogate marker for reducing cardiovascular risk.

In May 2015, we and a group of independent physicians filed a lawsuit in federal court to permit us to promote to healthcare professionals the use of VASCEPA in patients with mixed dyslipidemia so long as the promotion is truthful and non-misleading. This use reflected recognized medical practice but was not covered by the then-current, U.S. FDA-approved labeling for the drug. Historically, the U.S. FDA has considered promotion of drug uses not covered by U.S. FDA-approved labeling to be illegal off-label promotion, even if such promotion is truthful and non-misleading. In August 2015, we were granted preliminary relief in the form of a declaratory judgment in this lawsuit. The court declaration permits us to promote to healthcare professionals the U.S. FDA-reviewed and agreed effects of VASCEPA demonstrated in the ANCHOR clinical trial and presentation of the current state of scientific research related to the potential (and now demonstrated effect) of VASCEPA to reduce the risk of cardiovascular disease including through use of peer-reviewed scientific publications of available data. In August 2015, we began to communicate promotional information beyond the MARINE indication to healthcare professionals in the United States as permitted by this court declaration and in March 2016, the parties obtained court approval of negotiated settlement terms under which the U.S. FDA and the U.S. government agreed to be bound by the court's conclusions from the August 2015 declaration that we may engage in truthful and non-misleading speech promoting the off-label use of VASCEPA and that certain statements and disclosures that we proposed to make to healthcare professionals were truthful and non-misleading. 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. Pursuant to U.S. FDA approval in December 2019 of the label for VASCEPA to reduce persistent cardiovascular risk beyond maximally tolerated statin therapy, our promotion of ANCHOR clinical trial results was de-prioritized as such results became less important.

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.

Since VASCEPA was made commercially available in 2013, more than seventeen million estimated normalized total prescriptions of VASCEPA have been reported by Symphony Health.

Clinical Study in China

In addition to the studies of VASCEPA we conducted, our partner in China, Edding, completed a Phase 3 study of VASCEPA in China, the study design of which was similar to, but larger than, our MARINE study. In November 2020, we announced statistically significant positive topline results from this study. The study, which investigated VASCEPA as a treatment for patients with very high triglycerides (≥500 mg/dL), met its primary efficacy endpoint as defined in the clinical trial protocol and demonstrated a safety profile similar to placebo. Importantly, the VASCEPA 4 gram per day dose in this study appeared to be well-tolerated with a safety profile similar to placebo. There were no treatment-related serious adverse events in this study. On February 9, 2021, we announced that the regulatory review processes for approval of VASCEPA in Mainland China and Hong Kong have commenced. The NMPA has accepted for review the new drug application for VASCEPA, submitted by Edding, based on the results of this clinical study and the results from our prior studies of VASCEPA. We expect to receive a decision from the NMPA in Mainland China in the second half of

2022. The Hong Kong Department of Health is evaluating VASCEPA based on current approvals in the United States and Canada. The review process in Hong Kong is expected to conclude in the second half of 2022.

COVID-19

Based on our current understanding of the biological effects of a COVID-19 infection, including that patients at high risk of cardiovascular disease are at higher risk of mortality and severe effects from a COVID-19 infection, and based on data related to the mechanism of action and effects of VASCEPA in lowering cardiovascular risk in certain high-risk patients, we believe that VASCEPA could play a beneficial clinical role in helping patients infected by the virus. We are currently providing study drug product and limited financial support to investigators in multiple pilot studies designed to better understand the potential of VASCEPA and this potentially beneficial role. The clinical effects of VASCEPA are multi-factorial. Multiple mechanisms of action associated with VASCEPA from clinical and mechanistic studies support the rationale to study its effects in patients with the COVID-19 infection. Additional postulated mechanisms that might play a role in the use of VASCEPA in the patients infected with COVID-19 include potential antiviral/antimicrobial effects, fibrosis and cardiac damage mitigation in animal models and anti-inflammatory effects (acute) in pulmonary/lung tissue.

On December 12, 2020, we announced at the National Lipid Association Scientific Sessions 2020 the positive clinical results from the first study of VASCEPA in COVID-19 infected outpatients, CardioLink-9. A total of 100 COVID-19 positive and symptomatic patients were enrolled in the randomized, open-label trial. The primary biomarker endpoint of the study was within-group changes in high-sensitivity C-reaction protein, or hsCRP, a measure of inflammation and within-group changes in D-dimer were also examined. VASCEPA administration resulted in a 25% reduction in hsCRP ($p=0.011$) as well as a reduction in D-dimer ($p=0.048$). In addition to these biomarker changes, assessment was made of COVID-19 symptom changes from baseline to 14 days in the influenza patient-reported outcome, or FLU-PRO, score. VASCEPA administration resulted in a significant 52% reduction of the total FLU-PRO prevalence score as compared to a 24% reduction in the usual care group, with reductions across individual score domains. More study is needed to demonstrate the effects of VASCEPA on COVID-19 infected outpatients.

On August 31, 2021, we announced at the ESC Congress 2021 the clinical results from the PREPARE-IT-1 study, which was an investigator-initiated trial of approximately 2,000 COVID-19 negative, high-risk healthcare and other public workers in Argentina investigating the effects of VASCEPA on reducing COVID-19 infections and subsequent clinical events associated with COVID-19. The results of PREPARE-IT-1 did not meet the primary and/or other endpoints studied. On November 16, 2021, we announced at the AHA Scientific Sessions 2021 the clinical results from the PREPARE-IT-2 study, which was an investigator-initiated trial to evaluate the efficacy of icosapent ethyl to reduce hospitalizations or death in approximately 2,000 patients in Argentina with a positive diagnosis for COVID-19. The results of PREPARE-IT-2 did not meet the primary and/or other endpoints studied.

We are supporting an additional ongoing pilot study, MITIGATE, by providing study drug product and limited financial support to investigators with results anticipated in 2022. The MITIGATE clinical trial is investigating the effects of VASCEPA on laboratory-confirmed viral upper respiratory infection rates, clinical impact and outcomes, especially with COVID-19, in 1,500 adults with established ASCVD who are at increased risk for severe illness from COVID-19. Our personnel remain blinded to the efficacy and safety data until after the study is completed. Upon completion, and once the results are known, we will evaluate the next steps.

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. Epadel has been approved and available by prescription in Japan for over a decade. In 2013, the Japan Ministry of Health approved Epadel for over-the-counter sales. JELIS provided supportive but not conclusive data that EPA drug therapy may reduce major coronary events. JELIS results cannot be generalized to populations outside of Japan due to limitations in the study's design. Due to the limitation of JELIS, further study was needed through the REDUCE-IT study to determine the clinical benefit, if any, of EPA therapy in statin-treated patients with elevated triglyceride levels in a patient population beyond that studied in JELIS.

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.

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.

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.

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—2021 Update* from the AHA, CVD is the underlying cause of death in approximately one out of every three deaths – one death approximately every 36 seconds. Approximately 127 million adults in the United States live with one or more types of cardiovascular disease with an estimated 1 million new or recurrent coronary events and 795,000 new or recurrent strokes occurring each year. Combining the rates of cardiovascular death, stroke and heart attack, one major adverse cardiovascular event occurs in the United States every 13 seconds. An estimated 28 million adults ≥20 years of age have high total serum cholesterol levels (≥240 mg/dL), and an estimated 70 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, with direct medical costs projected to reach $749.0 billion and indirect costs estimated to reach $368.0 billion.

In addition to cholesterol, lipoproteins such as LDL also carry fats in the form of triglycerides. Hypertriglyceridemia, or HTG, refers to a condition in which patients have high levels of triglycerides in the bloodstream and has been reported to be both an independent risk factor for, and potential cause of, cardiovascular disease. Triglyceride levels provide important information as a marker associated with the risk for heart disease and stroke.

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.

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.

It is estimated that more than 50 million adults in the United States have elevated triglyceride levels ≥150 mg/dL. Additionally, approximately 2 to 3 million adults in the United States have very high triglyceride levels (≥500 mg/dL), the condition for which VASCEPA received its annual 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. This may mean that patients on prior statin therapy who are thought to be intolerant to statins, approximately 10% - 20% of patients with prior statin use, may be eligible for VASCEPA. 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.

Mixed dyslipidemia refers to a condition in which patients have a combination of two or more lipid abnormalities including elevated triglycerides, low HDL-C, and/or elevated LDL-C. Both hypertriglyceridemia and mixed dyslipidemia are components of a range of lipid disorders collectively referred to as dyslipidemia. Dyslipidemia has been linked to atherosclerosis, commonly referred to as hardening of the arteries.

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 have done so since we began clinical development of VASCEPA prior to the drug's marketing approval by the U.S. FDA in 2012. We rely on contract manufacturers in each step of our commercial and clinical product supply chain. These steps include API, manufacturing, encapsulation of the active pharmaceutical ingredient, or 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.

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 U.S. FDA has approved several international large-scale API manufacturers, global encapsulation leaders and multiple U.S.-based packagers for use in the manufacturing of VASCEPA. All of our manufacturing facilities were approved by the U.S. FDA following successful preapproval inspections and they remain active manufacturers of VASCEPA under U.S. FDA authority. The EMA has approved one European-based packager for use in the manufacturing of VAZKEPA for the European markets.

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. A limited number of other manufacturers have the ability, scale, know-how, sufficient supply chain capability and suitable, industrial-scale facilities to produce ethyl-EPA to the required level of purity. We have worked with our suppliers to build required scale, quality and cost-efficiency needed to meet our current and anticipated future market requirements. We are working with our suppliers on capacity expansion plans anticipating approval of VASCEPA in China and potentially other countries in addition to the increased demand for VASCEPA in the United States that we plan to create from our Go-to-Market strategy and other promotional initiatives. 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.

Similar to the 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 launch in Europe.

Production of VASCEPA, from sourcing of starting 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.

Some of our agreements with our API suppliers are exclusive and include minimum purchase commitments. During 2021, we fully met the aggregate minimum purchase requirements in our supply agreements. Under the supply agreements, we can purchase more than the minimum requirements. Certain of these agreements contemplate phased capacity expansion aimed at creating sufficient volumes to meet anticipated demand for VASCEPA. Certain of these agreements contain provisions for reduced payments (fractional API cost) for unmet annual volume requirements.

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 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. 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 sales and marketing companies, and specialized cardiovascular treatment companies. With generic versions of VASCEPA launched in the U.S. by Hikma in November 2020, Dr. Reddy's in June 2021 and Apotex in January 2022, with the potential for further generic versions being launched, it may not be viable for us to invest in market education to grow the market and our ability to maintain current promotional efforts and attract favorable commercial terms in several aspects of our business will likely be adversely affected as we face increased generic competition, or if we launch our own generic version of VASCEPA.

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

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

AstraZeneca conducted a long-term outcomes study to assess Statin Residual Risk Reduction With EpaNova in HiGh Cardiovascular Risk PatienTs With Hypertriglyceridemia, or STRENGTH. The study was a randomized, double-blind, placebo-controlled (corn oil), parallel group design that is believed to have enrolled approximately 13,000 patients with hypertriglyceridemia and low HDL and high risk for cardiovascular disease randomized 1:1 to either corn oil plus statin or Epanova plus statin, once daily. On January 13, 2020, following the recommendation of an independent Data Monitoring Committee, AstraZeneca decided to close the STRENGTH trial due to its low likelihood of demonstrating benefit to patients with mixed dyslipidemia who are at increased risk of cardiovascular disease. Full data from the STRENGTH trial was presented at the AHA's Scientific Sessions in November 2020 confirming that Epanova failed to meet the primary endpoint of CV risk reduction, and published in Journal of the American Medical Association, 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. Kowa Research Institute has publicly estimated study completion in May 2022, and if successful, U.S. regulatory approval is estimated in mid-2023.

During 2018, two outcomes studies were completed of omega-3 mixtures which both failed to achieve their primary endpoints of cardiovascular risk reduction and two meta-analyses were published showing that omega-3 mixtures are not effective in lowering cardiovascular risk. Results of these failed outcomes studies and analysis, while not done with VASCEPA, may negatively affect sales

of VASCEPA. For example, results of VITamin D and OmegA-3 TriaL, or VITAL, as announced immediately before the presentation of REDUCE-IT results at the 2018 Scientific Sessions of the AHA on November 10, 2018, failed to achieve its primary endpoint of lowering cardiovascular events. VITAL was an NIH funded randomized double-blind, placebo-controlled, 2x2 factorial trial of 2000 IU per day of vitamin D3 and 1 gram per day of omega-3 fatty acid mixture supplementation (Lovaza) for the primary prevention of cancer and cardiovascular disease in a nationwide USA cohort of 25,874 adults not selected for elevated cardiovascular or cancer risk.

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

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

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

We are also aware of other pharmaceutical companies that are developing products that, if successfully developed, approved and marketed, would compete with VASCEPA. It is not fully clear at this time what the impact of COVID-19 will be on each of these programs.

Matinas BioPharma, Inc., or Matinas, is developing an omega-3-based therapeutic (MAT9001) for the treatment of severe hypertriglyceridemia and mixed dyslipidemia. In the fourth quarter of 2014, Matinas filed an investigational new drug application, or IND, with the U.S. FDA to conduct a human study in the treatment of severe hypertriglyceridemia and, in June 2015, Matinas announced topline results for its head-to-head comparative short duration pharmacokinetic and pharmacodynamic study of MAT9001 versus VASCEPA in patients under conditions inconsistent with the U.S. FDA-approved label for VASCEPA and presented results based on biomarker modification without outcomes data. In September 2017, Matinas announced that it will be seeking a partner company to develop and commercialize MAT9001. In March 2019, Matinas announced that net proceeds from a public offering of common stock would be used for development activities for MAT9001. In March 2020, Matinas announced that it completed the clinical dosing for a comparative clinical bridging bioavailability study and the in-life portion of a 90-day comparative toxicology study in the first quarter of 2020. Both studies were conducted to support a planned 505(b)(2) registration pathway. In March 2020, Matinas also initiated an additional Phase 2 head-to-head pharmacokinetic and pharmacodynamic study, ENHANCE-IT, against VASCEPA in patients with elevated triglycerides (150-499 mg/dL), while the study was paused in the first quarter of 2020 due to the COVID-19 pandemic, enrollment resumed in June and was completed in August 2020. In the first quarter of 2021, Matinas announced topline results from the ENHANCE-IT study, stating that LYPDISO, or MAT9001, did not meet statistical significance over VASCEPA on the primary endpoint of percent change from baseline to end of treatment in triglycerides in the pharmacodynamic, or PD, population. A key secondary endpoint in ENHANCE-IT was the measurement of eicosapentaenoic acid levels in the blood, which is regarded as a key surrogate marker in determining cardiovascular risk reduction. In ENHANCE-IT, plasma EPA concentrations were significantly higher with LYPDISO versus VASCEPA, with a 46% relative percentage increase in the change from baseline EPA level versus VASCEPA. Matinas has announced that the results from ENHANCE-IT suggest potential for LYPDISO as a drug for cardiovascular risk reduction and announced that it is pursuing external partnerships to further develop LYPDISO for cardiovascular outcomes indication. As a result, Matinas no longer plans to pursue an indication for the treatment of severe HTG, instead focusing on the broader cardiovascular risk reduction indication.

In June 2018, NeuroBo Pharmaceuticals, Inc. (previously named Gemphire Therapeutics) announced positive topline results from a Phase 2b trial, or INDIGO-1, of its drug candidate, Gemcabene, in patients with severe hypertriglyceridemia. Gemcabene is an oral, once-daily pill for a number of hypercholesterolemic populations and severe hypertriglyceridemia. In August 2018, the U.S. FDA requested that Gemphire conduct an additional long-term toxicity study before commencing any further clinical testing, thereby

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

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

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

VASCEPA also faces competition from dietary supplement manufacturers marketing omega-3 products as nutritional supplements. Such products are classified as food, not as prescription drugs or as over-the-counter drugs, by the U.S. FDA in the United States. Most regulatory regimes outside the United States are similar in this regard. Some of the promoters of such products have greater resources than us and are not restricted to the same standards as are prescription drugs with respect to promotional claims or manufacturing quality, consistency and subsequent product stability. 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 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.

In CV outcomes trials, therapies that reduce TG levels and had other favorable effects on classically studied lipid and lipoprotein parameters, such as extended-release niacin and fibrates, did not met their primary CV endpoints to reduce risk when taken with contemporary medical therapy, including statins. Specifically, cardiovascular outcomes trials, ACCORD Lipid, AIM-HIGH, and HPS2-THRIVE, while not designed to test the effect of lowering TG levels in patients with high TG levels after statin therapy, each failed to demonstrate incremental cardiovascular benefit of adding a second lipid-altering drug (fenofibrate or formulations of niacin), despite raising HDL-C and reducing TG levels, among statin-treated patients with well-controlled LDL-C. As a result, in 2015, the U.S. FDA updated both the Trilipix® (a fenofibrate) and extended-release niacin product labeling and removed combination use with statin therapy in mixed dyslipidemia patients as an indication due to a failed outcomes trial. No head-to head, randomized, well-controlled studies have been conducted to compare the clinical effects of VASCEPA with other U.S. FDA-approved TG-lowering therapies.

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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 by the EMA through the centralized marketing authorization procedure process 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. Companies that market drugs for off-label uses or indications have been subject to related costly litigation, criminal penalties and civil liability under the FDCA and the False Claims Act. However, recent case law has called into question the extent to which government in the United States, including the U.S. FDA, can, and is willing to seek to, prevent truthful and non-misleading speech related to off-label uses of U.S. FDA-approved products such as VASCEPA.

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

U.S. FDA-approved labeling of VASCEPA) or the peer-reviewed research related to VASCEPA and the potential for cardiovascular risk reduction.

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

In March 2016, we settled this litigation under terms by which the U.S. FDA and the U.S. government agreed to be bound by the conclusions from the federal court order that we may engage in truthful and non-misleading speech promoting the off-label use of VASCEPA and that certain statements and disclosures that we proposed to make to healthcare professionals were truthful and non-misleading. As part of the settlement, given, as expressed in the court's opinion, that the dynamic nature of science and medicine is that knowledge is ever-advancing and that a statement that is fair and balanced one day may become incomplete or otherwise misleading in the future as new studies are done and new data is acquired, we agreed that we bear the responsibility to ensure that our communications regarding off-label use of VASCEPA remain truthful and non-misleading, consistent with the federal court ruling.

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. 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. 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. For example, three-year exclusivity may be granted 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. For example, we received such three-year regulatory exclusivity in connection with the recent 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.

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

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 was superseded by the current Clinical Trials Directive 2001/20/EC, or the new Regulation, issued on January 31, 2022 and overhauled the system of approvals for clinical trials. Specifically, the new Regulation, which will be 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 new 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. 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 United Kingdom, which comprises Great Britain and Northern Ireland, has left the EU, Great Britain will no longer be covered by centralized marketing authorizations, while under the Northern Ireland Protocol centralized marketing authorizations will continue to be recognized in Northern Ireland. All medicinal products with a current centralized marketing authorization were automatically converted to Great Britain marketing authorizations on January 1, 2021. For a period of two years from January 1, 2021, the MHRA may rely on a decision taken by the EC on the approval of a new marketing authorization in the centralized procedure, in order to quickly grant a Great Britain marketing authorization despite a separate application being required.

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 drug 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 drug 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 completely independent data package of pharmaceutical tests, preclinical tests and clinical trials.

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 2003/94/EC, 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 drugs, including industry-sponsored continuing medical education and advertising directed toward the prescribers of drugs and/or the general public, are strictly regulated in the EU. Direct-to-consumer advertising of prescription medicines is prohibited across the EU.

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.

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. These rules, with exceptions, became effective January 19, 2021. 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.

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) and teaching hospitals, as well as ownership and investment interests held in the company by physicians and their immediate family members. Effective January 1, 2022, applicable manufacturers are also required to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives.

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 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.

In the event we decide to conduct clinical trials or continue to enroll subjects in our ongoing or future clinical trials, we may be subject to additional privacy restrictions. The collection, use, storage, disclosure, transfer, or other processing of personal data regarding individuals in the EEA including personal health data, is subject to the GDPR, which became effective on May 25, 2018. 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, obtaining consent of the individuals to whom the personal data relates, providing 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 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. In addition, the GDPR includes restrictions on cross-border data transfers. 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. Further, since the United Kingdom's exit of the EU, often referred to as Brexit, companies have to now comply with the GDPR and also the United Kingdom GDPR, or UK GDPR, which, together with the amended UK Data Protection Act of 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR, for example of fines up to the greater of €20 million (£17.5 million) or 4% of global turnover. In addition, 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.

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 CMS 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.

On December 2, 2020, the HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, or PBMs, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between PBMs and manufacturers. Implementation of this change and new safe harbors for point-of-sale reductions in price for prescription pharmaceutical products and PBM service fees are currently under review by the current U.S. presidential administration and may be amended or repealed. Further, on December 31, 2020, CMS published a new rule, effective January 1, 2023, requiring manufacturers to ensure the full value of co-pay assistance is passed on to the patient or these dollars will count toward the Average Manufacturer Price and Best Price calculation of the drug. On May 21, 2021, PhRMA sued the HHS in the U.S. District Court for the District of Columbia, to stop the implementation of the rule claiming that the rule contradicts federal law surrounding Medicaid rebates. It is unclear how the outcome of this litigation will affect the rule. We cannot predict how the implementation of and any further changes to this rule will affect our business.

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. In particular, there have been and continue to be a number of initiatives at the United States federal and state levels that seek to reduce healthcare costs. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, imposed new requirements for the distribution and pricing of prescription drugs for Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities which will provide coverage of outpatient prescription drugs. Part D plans include both stand-alone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans. Unlike Medicare Part A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for our products for which we receive marketing approval. However, any negotiated prices for our products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payers often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payers. In addition, there has been renewed interest in amending the Social Security Act to allow Medicare to negotiate prices for prescription drugs covered under Medicare Part B. If this were to be enacted by Congress and signed by the President, the prices we obtain for our products covered under Part B could be lower than the prices we might otherwise obtain, and it could exert a similar lowering pressure on payments from non-governmental payers.

The Agency for Healthcare Research and Quality, or AHRQ, established by the MMA and provided additional funding by the American Recovery and Reinvestment Act of 2009, conducts comparative effectiveness research on different treatments for the same illness. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payers, it is possible that comparative effectiveness research demonstrating benefits in a competitor's product could adversely affect the sales of our product candidates. If third-party payers do not consider our products to be cost-effective compared to other available therapies, they may not cover our products as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, was enacted, which has substantially changed the way healthcare is financed by both governmental and private insurers and has significantly impacted the pharmaceutical industry. Among the provisions of the ACA of greatest importance to the pharmaceutical and biotechnology industry are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic products, apportioned among these entities according to their market share in certain government healthcare programs, that began in 2011;
- expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;

- expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs and revising the definition of "average manufacturer price," or AMP, for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices;
- addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- expanded the types of entities eligible for the 340B drug discount program;
- established the Medicare Part D coverage gap discount program by requiring manufacturers to provide a 50% point-of-sale-discount, which was increased to 70% by the Bipartisan Budget Act of 2018 (as of January 1, 2019), off the negotiated price of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D;
- increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organization;
- establishes annual fees and taxes on manufacturers of certain branded prescription drugs;
- a licensure framework for follow-on biologic products;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- establishment of a Center for Medicare and Medicaid Innovation at the Centers for Medicare & Medicaid Services to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending that began on January 1, 2011.

Certain provisions of the ACA have yet to be implemented and others have been subject to judicial challenges, as well as efforts to repeal or replace them or to alter their interpretation or implementation. Prior to the Biden administration, on October 13, 2017, former President Trump signed an Executive Order terminating the cost-sharing subsidies that reimburse insurers under the ACA. The former Trump administration concluded that cost-sharing reduction, or CSR, payments to insurance companies required under the ACA have not received necessary appropriations from Congress and announced that it will discontinue these payments immediately until those appropriations are made. Several state Attorney Generals filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. On August 14, 2020, the U.S. Court of Appeals for the Federal Circuit ruled in two separate cases that the federal government is liable for the full amount of unpaid CSRs for the years preceding and including 2017. For CSR claims made by health insurance companies for the years 2018 and later, further litigation will be required to determine to amounts due, if any. Further, on June 14, 2018, the U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than $12.0 billion in ACA risk corridor payments to third-party payors who argued the payments were owed to them. On April 27, 2020, the U.S. Supreme Court reversed the U.S. Court of Appeals for the Federal Circuit's decision and remanded the case to the U.S. Court of Federal Claims, concluding that the government has an obligation to pay these risk corridor payments under the relevant formula.

Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA such as the Tax Cuts and Jobs Act enacted on December 22, 2017, or the Tax Act, which included a provision that decreased the tax-based shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code of 1986, commonly referred to as the "individual mandate," to $0, effective January 1, 2019. On December 14, 2018, a federal district court in Texas ruled the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the Fifth Circuit U.S. Court of Appeals held that the individual mandate is unconstitutional, and remanded the case to the lower court to reconsider its earlier invalidation of the full ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an Executive Order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The Executive Order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, re-examining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results. We continue to evaluate the effect that the ACA and its possible repeal and replacement could have on our business.

Further, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. The Bipartisan Budget Act of 2018 among other things, amended the Medicare statute, effective January 1, 2019, to close the coverage gap

in most Medicare drug plans, commonly referred to as the "donut hole." On December 20, 2019, President Trump signed into law the Further Consolidated Appropriations Act (H.R. 1865), which repeals the "Cadillac" tax on certain high-cost employer-sponsored insurance plans, the health insurance provider tax based on market share, and the medical device excise tax on non-exempt medical devices. It is impossible to determine whether similar taxes could be instated in the future. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

It is unclear how the ACA and its implementation, as well as efforts to repeal, replace, or invalidate, the ACA or its implementing regulations, or portions thereof, and other legislative changes adopted since, will affect our business. It is possible that the ACA will continue to exert pressure on pharmaceutical pricing, especially under the Medicare and Medicaid programs, and may also increase our regulatory burdens and operating costs. Additional legislative changes, regulatory changes, and judicial challenges related to the ACA remain possible. We will continue to evaluate the effect that the ACA as well as its possible repeal, replacement, or invalidation, in whole or in part, has on our business.

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. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost effectiveness of our products. Even with studies, our products may be considered less safe, less effective or less cost effective than other products, and third-party payors may not provide coverage and reimbursement for our product candidates, in whole or in part. Reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the U.S. FDA or comparable foreign regulatory authorities. Product candidates may not be considered medically necessary or cost effective. 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.

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 drug and the same indication as in the U.S., tend to be significantly lower.

A decision by a third-party payor not to cover a product could reduce physician utilization once the product is approved and have a material adverse effect on sales, results of operations and financial condition. Additionally, a third-party payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor. 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.

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. For example, on August 2, 2011, the Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic. Following the temporary suspension, a 1% payment reduction will occur beginning April 1, 2022 through June 30, 2022, and the 2% payment reduction will resume on July 1, 2022. These cuts reduce reimbursement payments related to our products, which could potentially negatively impact our revenue.

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. 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, which is based on the average manufacturer price and Medicaid rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate program. There have been several changes to the 340B drug pricing program, which imposes ceilings on prices that drug manufacturers can charge for medications sold to certain health care facilities. On December 27, 2018, the District Court for the District of Columbia invalidated a reimbursement formula change under the 340B drug pricing program, and CMS subsequently altered the FY's 2019 and 2018 reimbursement formula on specified covered outpatient drugs, or SCODs. The court ruled this change was not an "adjustment" which was within the Secretary's discretion to make but was instead a fundamental change in the reimbursement calculation. However, most recently, on July 31, 2020, the U.S. Court of Appeals for the District of Columbia Circuit overturned the district court's decision and found that the changes were within the Secretary's authority. On September 14, 2020, the plaintiffs-appellees filed a Petition for Rehearing En Banc, i.e., before the full court, but was denied on October 16, 2020. Plaintiffs-appellees filed a petition for a writ of certiorari at the U.S. Supreme Court on February 10, 2021. On Friday July 2, 2021, the Supreme Court granted the petition. 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. 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.

Recently, there have been several U.S. Congressional inquiries and proposed and adopted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, President Biden signed an Executive Order on July 9, 2021 affirming the administration's policy to (i) support legislative reforms that would lower the prices of prescription drug and biologics, including by allowing Medicare to negotiate drug prices, imposing inflation caps and supporting the development and market entry of lower-cost generic drugs and biosimilars; and (ii) support the enactment of a public health insurance option. Among other things, the Executive Order also directs HHS to provide a report on actions to combat excessive pricing of prescription drugs, to enhance the domestic drug supply chain, to reduce the price that the Federal government pays for drugs, and to address price gouging in the industry; and directs the U.S. FDA to work with states and Indian Tribes that propose to develop section 804 Importation Programs in accordance with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and the U.S. FDA's implementing regulations. The U.S. FDA released such implementing regulations on September 24, 2020, which went into effect on November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, CMS issued an Interim Final Rule implementing the Most Favored Nation, or MFN, Model under which Medicare Part B reimbursement rates will be calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. On December 29, 2021, CMS rescinded the Most Favored Nations rule. Further, authorities in Canada have passed rules designed to safeguard the Canadian drug supply from shortages. If implemented, importation of drugs from Canada may materially and adversely affect the price we receive for any of our products. Additionally, on December 2, 2020, HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Pursuant to the court order, the removal and addition of the aforementioned safe harbors were delayed and recent legislation imposed a moratorium on implementation of the rule until January 1, 2026. Although a number of these and other proposed measures may require authorization

through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that it will continue to seek new legislative measures to control drug costs.

In addition, on May 30, 2018, the Right to Try Act was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for U.S. FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining U.S. FDA permission under the U.S. FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. For example, the State of California enacted legislation that requires notice for exceeding specified limits on annual drug price increases and other legislation that seeks to limit the use of co-pay cards in certain situations.

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. 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 123 patent applications in

the United States that have been either issued or allowed and more than 30 additional patent applications are pending in the United States. Such 123 allowed and issued applications include the following:

- one issued U.S. patent directed to a pharmaceutical composition of VASCEPA in a capsule that expires in 2030;
- 61 U.S. patents covering or related to the use of VASCEPA in either the MARINE or ANCHOR populations that have terms that expire in 2030 or later;
- 27 U.S. patents covering or related to the use of VASCEPA in the REDUCE-IT population with terms expiring in 2033 or later;
- three additional US patents directed to a pharmaceutical composition comprised of free fatty acids with a term that expires in 2030;
- five additional patents related to the use of a pharmaceutical composition comprised of free fatty acids to treat the ANCHOR patient population with a term that expires in 2030 or later;
- two additional patents related to the use of a pharmaceutical composition comprised of free fatty acids to treat the MARINE patient population with a term that expires in 2030;
- three additional patents related to the use of a pharmaceutical composition comprised of free fatty acids to treat the REDUCE-IT population expiring 2033;
- four additional patents related to a pharmaceutical composition comprised of free fatty acids and uses thereof to treat both the MARINE and ANCHOR patient populations with a term that expires in 2030;
- one additional patent related to the use of a pharmaceutical composition comprised of re-esterified EPA triglyceride to treat the REDUCE-IT population expiring 2033;
- four additional patents related to a formulation of EPA/DHA and uses thereof with a term that expires in 2030;
- two additional patents related to the use of VASCEPA to treat obesity with a term that expires in 2034;
- one additional patent related to the use of VASCEPA to treat prostate cancer with a term that expires in 2037;
- four additional patents covering a pharmaceutical composition comprised of EPA and a hydroxyl compound with a term that expires in 2034; and
- five additional patents covering a new combination therapy comprised of EPA and another drug.

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

We are the owner of the above-listed patents. We are also the exclusive licensee of certain patents owned by others covering products in development.

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

We may be dependent in some cases upon third-party licensors to pursue filing, prosecution and maintenance of patent rights or applications owned or controlled by those parties, including, for example, under our collaboration with Mochida. It is possible that third parties will obtain patents or other proprietary rights that might be necessary or useful to us. In cases where third parties are first to invent a particular product or technology, or first to file after various provisions of the America Invents Act of 2011 went into effect

on March 16, 2013, it is possible that those parties will obtain patents that will be sufficiently broad so as to prevent us from utilizing such technology or commercializing our current and future products.

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

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

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

Human Capital Management

As of December 31, 2021, we had approximately 560 full-time employees located in ten countries. 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 the success of the business. 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.

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. In our hiring, promotion, compensation, retention and other employment practices, we regularly evaluate whether women and minority populations are being treated equally. We seek ways to continually improve in this area. While we acknowledge and support the benefits of diversity, individual hiring and promotion decisions are made irrespective of personal characteristics such as race, disability, gender, sexual orientation, religion, or age.

	2021 Workforce Diversity Representation (U.S. Only)	
	Gender	**Race**
Executive Leadership	20%	10%
Management	45%	30%
Sales Professionals and Other Associates	64%	30%

In the above table, executive leadership is defined as positions of vice president and above. Management is defined as positions of director, manager or equivalent roles.

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 communications and 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. 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. 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.

COVID-19

Very high in our priorities during the COVID-19 pandemic is the health and safety of our employees, their families, and the community. For example, on March 15, 2020, we suspended field based, face-to-face interactions with healthcare providers and moved to remote work for our office-based employees. We were one of the first pharmaceutical companies to announce such an action, which was taken to promote safety. We attempt to balance this very high priority with the high importance of the work we are doing to reduce the incidence of at-risk patients having strokes, heart attacks and other major adverse cardiovascular events, the prevalence of which are high, while also evaluating whether our lead drug, VASCEPA, can be used to lower the rate of COVID-19 infections or help mitigate the symptoms of COVID-19. The vast majority of our employees are paid based on fixed salaries and their compensation has not been reduced as a result of COVID-19. For hourly employees, we have been flexible in ensuring that, when necessary, they are able to work remotely to avoid significant reduction, if any, in their hours and level of compensation. We have implemented a hybrid workplace model for our offices throughout the world. We continue to monitor the effects of COVID-19 around the world and will continue to adjust our activities as needed for the health and safety of our workforce, partners and communities.

Organizational Structure

At March 1, 2022, 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. Amarin Neuroscience Limited was liquidated in January 2021.

Available Information

Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, 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 and commercialization in Europe and other major markets. In the United States, VASCEPA is facing increasing competition from generic versions of the drug. In Europe, VAZKEPA recently launched in Germany following approval from the central regulatory authority and we are in the process of obtaining relevant pricing approvals in various countries; however, we may not be successful in obtaining such approvals in a timely manner, or at all and, even if successfully obtained, we may not be successful in commercializing VAZKEPA in Europe or elsewhere.
- In the United States, we face increasing competition from generic drug companies in the near term and our revenues and results of operations could be materially and adversely affected.
- Factors outside of our control make it more difficult for VASCEPA to achieve a level of market acceptance by physicians, patients, healthcare payors and others in the medical community necessary to meet expectations for commercial success.
- The continued scale, scope and duration of business interruptions caused by the ongoing COVID-19 pandemic and related recovery efforts are uncertain as the impact of the pandemic continues to cause negative effects on our business.
- Our current and planned commercialization efforts, including our recently implemented Go-to-Market strategy, may not be successful in increasing sales of VASCEPA in the United States and developing sales internationally.
- Our promotion and supply of VASCEPA is subject to regulatory scrutiny and associated risk.
- We may not be able to compete effectively against our competitors' pharmaceutical products.
- VASCEPA is a prescription-only omega-3 fatty acid product. Omega-3 fatty acids are also marketed by other companies as non-prescription dietary supplements. As a result, VASCEPA is subject to non-prescription competition and consumer substitution.
- The commercial value of VASCEPA outside the United States may be smaller than we anticipate, including adequacy of product reimbursement which can vary from country to country. If we are unable to realize product reimbursement rates at reasonable levels, or at all, patient access to VASCEPA may be limited.
- Our supply of product for the commercial market and clinical trials is dependent upon relationships with third-party manufacturers and suppliers.
- Our dependence on third parties in the distribution channel from our manufacturers to patients subject us to risks that limit our profitability and could limit our ability to supply VASCEPA to large market segments.
- Our commercialization of VASCEPA outside the United States is substantially dependent on third parties and other circumstances outside our control.
- We are dependent on patents, proprietary rights and confidentiality to protect the commercial value and potential of VASCEPA.
- Our issued patents may not prevent competitors from competing with VASCEPA, even if we are successful in enforcing our patent rights.
- There can be no assurance that any of our pending patent applications relating to VASCEPA or its use will issue as patents.

The summary risk factors described above should be read together with the text of the full risk factors below and in the other information set forth in 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. In the United States, VASCEPA is facing increasing competition from generic versions of the drug. In Europe, VAZKEPA recently launched in Germany following approval from the central regulatory authority and we are in the process of obtaining relevant pricing approvals in various countries; however, we may not be successful in obtaining such approvals in a timely manner or at all and even if successfully obtained, we may not be successful in commercializing VAZKEPA in Europe or elsewhere.

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

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

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

We have been developing VASCEPA on our own in Europe for the approved cardiovascular risk reduction indication and are exploring possible strategic collaborations in smaller markets within Europe and in other major markets. We currently have multiple partners for the development and commercialization of VASCEPA in select geographies and intend to assess potential partners to commercialize VASCEPA in other parts of the world. For example, we have strategic collaborations for the development and commercialization of VASCEPA in Canada, the Middle East and Greater China. However, we cannot make any guarantees as to the success of these efforts or that our beliefs about the value potential are accurate, and if commercialization plans for VASCEPA do not meet expectations in major markets such as the United States and Europe, our business and prospects could be materially and adversely affected.

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

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

ability to effectively shift our resources to the development of alternative products, or do so in a timely manner, without suffering material adverse effects on our business. As a result, the lack of alternative markets and products we develop could constrain our ability to generate revenues and achieve profitability.

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

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

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

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

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

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

We believe that VASCEPA is difficult to manufacture and that building capacity to manufacture VASCEPA is time-consuming and expensive. These factors may limit the amount of VASCEPA supply available to generic companies, as we believe to be experienced by Hikma and Dr. Reddy. We do not have direct visibility into the supply levels of any of the generic companies and we rely on our own experience together with information from third parties, which information may not be reliable. The generic companies could potentially find or develop sources of qualified VASCEPA supply that are not known to us and that are more efficient or less expensive than our sources. Furthermore, generic companies could potentially convince our suppliers to prioritize supply to the generic companies ahead of any applicable contractual commitments to supply us. While we anticipate that our suppliers will honor their commitments to us, if generic competitors are successful in gaining an advantage in the supply chain, manufacturing and supply with respect to VASCEPA will suffer and consequentially VASCEPA prescriptions will likely decrease. In addition, we may need to litigate with such suppliers to protect our rights, which can be costly and distracting to management. Such circumstances could have a material and adverse impact on our revenues and results of operations directly in the United States and potentially outside of the United States as well if supply costs and availability are affected or promotion and education programs reduced.

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

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

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

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

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

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

Our ability to generate meaningful revenues of VASCEPA outside of the United States is dependent on the availability and extent of coverage and reimbursement from third-party payers. In many markets around the world, these payers, 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, payers are becoming more restrictive regarding the use of biopharmaceutical products and scrutinizing the prices of these products while requiring a higher level of clinical evidence to support the benefits such products bring to patients and the broader healthcare system. These pressures are intensified where our products are subject to competition, including from biosimilars.

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

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

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

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

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

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

In September 2018, we announced topline results from the REDUCE-IT®, or Reduction of Cardiovascular Events with EPA—Intervention Trial cardiovascular outcomes study of VASCEPA. In November 2018, we announced the primary results of our REDUCE-IT cardiovascular outcomes study confirming 25% relative risk reduction for the topline primary endpoint result with multiple robust demonstrations of efficacy, including 20% reduction in cardiovascular death. REDUCE-IT was a multinational, prospective, randomized, double-blind, placebo-controlled study, enrollment for which started in November 2011. REDUCE-IT investigated the effects of VASCEPA on CV risk in statin-treated adults with well-controlled LDL-C 41-100 mg/dL (median baseline LDL-C: 75 mg/dL) and other CV risk factors, including persistent elevated TG 150-499 mg/dL (median baseline TG: 216 mg/dL). REDUCE-IT topline results showed the trial met its primary endpoint demonstrating an approximately 25% relative risk reduction, to

a high degree of statistical significance ($p<0.001$), in MACE in the intent-to-treat patient population with use of VASCEPA 4 grams/day as compared to placebo. MACE events were defined as a composite of cardiovascular death, nonfatal myocardial infarction (MI), nonfatal stroke, coronary revascularization, or unstable angina requiring hospitalization. This result was supported by robust demonstrations of efficacy across multiple secondary endpoints. VASCEPA was well tolerated in REDUCE-IT with a safety profile generally consistent with clinical experience associated with omega-3 fatty acids and current U.S. FDA-approved labeling.

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

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

- the impact of and outcome of pending patent litigation;
- the commercialization and pricing of any current or potential generic versions of VASCEPA;
- the perceived efficacy and safety of VASCEPA by prescribing healthcare professionals and patients, as compared to no treatment and as compared to alternative treatments in various at-risk patient populations;
- peer review of different elements of REDUCE-IT results over time;
- continued review and analysis of the results of REDUCE-IT by regulatory authorities internationally;
- our ability to offer VASCEPA for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the scope, effectiveness and strength of product education, marketing and distribution support, including our sales and marketing team and the success of our omnichannel platform;
- publicity concerning VASCEPA or competing products;
- our ability to continually promote VASCEPA in the United States consistent with and outside of U.S. FDA-approved labeling and the related perception thereof;
- sufficient third-party coverage or reimbursement for VASCEPA and its prescribed uses, on-label and off-label;
- natural disasters, including pandemics such as COVID-19 and political unrest that could inhibit our ability to promote VASCEPA regionally and that could negatively affect product demand by creating obstacles for patients to seek treatment and fill prescriptions;
- new policies or laws affecting VASCEPA sales, such as state and federal efforts to affect drug pricing and provide or remove healthcare coverage that includes reimbursement for prescription drugs; and
- the actual and perceived efficacy of the product and the prevalence and severity of any side effects and warnings in VASCEPA's approved labeling internationally.

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

prescriptions in patient populations that go beyond U.S. FDA labeling, U.S. FDA-approved labeling that is more closely tied to the patient population studied in a clinical trial could limit use generally and could make reimbursement more difficult.

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

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

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

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

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

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

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

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

In addition, the same set of data can sometimes be interpreted to reach different conclusions. For example, Health Canada approved an indication based on REDUCE-IT data that was different in certain respects than that approved by U.S. FDA and by the EC in Europe. It is possible the scope of subsequent regulatory approvals, if any, could likewise differ based on the same data. Conflicting interpretations of data, or new data, could impact public and medical community perception of the totality of the efficacy and safety data from REDUCE-IT.

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

- the magnitude of the treatment benefit and related risks on the primary composite endpoint, its components, secondary endpoints and the primary and secondary risk prevention cohorts;
- consideration of which components of the composite or secondary endpoints have the most clinical significance;
- the consistency of the primary and secondary outcomes;
- the consistency of findings across cohorts and important subgroups;
- safety considerations and risk/benefit considerations (such as those related to adverse events, including bleeding and atrial fibrillation generally and in different sub-populations);
- consideration of REDUCE-IT results in the context of other clinical studies;
- consideration of the cumulative effect of VASCEPA in studied patients; and
- study conduct and data quality, integrity and consistency, including aspects such as analyses regarding the placebo used in REDUCE-IT and other studies of VASCEPA and its impact, if any, on the reliability of clinical data.

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

Ongoing clinical trials or new clinical data involving VASCEPA and similar moderate-to-high doses of eicosapentaenoic acid or icosapent ethyl could influence public perception of VASCEPA's clinical profile and the commercial and regulatory prospects of VASCEPA.

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

For example, the Randomized Trial for Evaluation in Secondary Prevention Efficacy of Combination Therapy–Statin and EPA (RESPECT-EPA; UMIN Clinical Trials Registry number, UMIN000012069) is a study examining Japanese patients with chronic coronary artery disease receiving LDL-C lowering treatment by statin therapy. Patients will be randomized to either a control group (standard treatment) or EPA group (standard treatment plus 1.8 grams/day of eicosapentaenoic acid), to examine the effects of a different formulation of icosapent ethyl than VASCEPA on the incidence of cardiovascular events. The relationship between the ratio of EPA to arachidonic acid and incidence of events will also be examined. Results from this study are expected in the second half of 2022, though the study and results are not under the Company's control and may be delayed as a result of COVID-19 impacts.

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

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

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

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

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

Given the dynamics related to COVID-19, we cannot predict when we will be able to substantially resume and sustain our business efforts. While we have supplemented traditional face-to-face interactions with virtual outreach, including our omnichannel platform, these efforts may not be as successful as in-person interactions. Specifically, access to healthcare professionals through digital or other channels, may not be as productive as in-person interactions in promoting use of VASCEPA. In the United States, in July 2020 we launched our first ever direct-to-consumer promotional campaign regarding VASCEPA demonstrating results in lowering cardiovascular risk in patients with persistent cardiovascular risk in high risk patients. In September 2020, we launched a new, nationwide television advertisement campaign in connection with our expanded promotional campaign which was further complemented by additional digital, point-of-care and other forms of healthcare professional and patient educational outreach. As the impact of COVID-19 on much of the United States worsened in the fourth quarter of 2020, we suspended television-based promotion of VASCEPA as we determined that the cost was not sufficiently justified in light of the COVID-19 pandemic on patient visits to doctors. During 2021 we invested in a limited direct-to-consumer campaign, including television-based, digital and social media promotions to continue to grow consumer awareness of VASCEPA and launched an educational campaign, *It's Clear to Me Now*, to help physicians and patients learn more about the differentiation between VASCEPA and fenofibrates for CV risk reduction. Such efforts are costly and there can be no assurance that they will result in an increase in VASCEPA prescriptions and sales in the near future, or at all.

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

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

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

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

While we believe we are now permitted under applicable law to more broadly promote VASCEPA, the U.S. FDA-approved labeling for VASCEPA did not change as a result of this litigation and settlement, and neither government nor other third-party coverage or reimbursement to pay for the off-label use of VASCEPA promoted under the court declaration was required. In addition to claims classically considered to be on-label based on our expanded label for VASCEPA based on the REDUCE-IT results, we proactively communicate information related to VASCEPA in a manner that we believe is truthful and non-misleading and thus protected under the freedom of speech clause of the First Amendment to the United States Constitution.

Promotional activities in the biotechnology and pharmaceutical industries generally are subject to considerable regulatory scrutiny and, even though we have the benefit of a final settlement in this litigation, our efforts may be subject to enhanced scrutiny to ensure that our promotion remains within the scope covered by the settlement. For example, under the settlement, we remain responsible for ensuring our speech is truthful and non-misleading, which is subject to a considerable amount of judgment. We, the U.S. FDA, the U.S. government, our competitors and other interested parties may not agree on the truthfulness and non-misleading nature of our promotional materials. Federal and state governments or agencies may also seek to find other means to prevent our promotion of unapproved truthful and non-misleading information about VASCEPA.

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

If our promotional activities or other operations are found to be in violation of any law or governmental regulation through existing or new interpretations, we may be subject to prolonged litigation, penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Also, if governmental parties or our competitors view our claims as

misleading or false, we could be subject to liability based on fair competition-based statutes, such as the Lanham Act. Any allegations that our promotional activities are not truthful or misleading, even allegations without merit, could cause reputational harm and adversely affect our ability to operate our business and our results of operations.

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

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 will increase. Many of these and other existing or potential competitors may have substantially greater financial, technical and human resources than we do and may be better equipped to develop, manufacture and market products. These companies may develop and introduce products and processes competitive with, more efficient than or superior to ours. In addition, other technologies or products may be developed that have an entirely different approach or means of accomplishing the intended purposes of our products, which might render our technology and products noncompetitive or obsolete.

Our competitors include large, well-established pharmaceutical and generic companies, specialty and generic pharmaceutical sales and marketing companies, and specialized cardiovascular treatment companies. With generic versions of VASCEPA launched in the U.S. by Hikma in November 2020, Dr. Reddy's in June 2021 and Apotex in January 2022, with the potential for further generic versions being launched, it may not be viable for us to invest in market education to grow the market and our ability to maintain current promotional efforts and attract favorable commercial terms in several aspects of our business will likely be adversely affected as we face increased generic competition, or if we launch our own generic version of VASCEPA.

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

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

AstraZeneca conducted a long-term outcomes study to assess Statin Residual Risk Reduction With EpaNova in HiGh Cardiovascular Risk PatienTs With Hypertriglyceridemia, or STRENGTH. The study was a randomized, double-blind, placebo-controlled (corn oil), parallel group design that is believed to have enrolled approximately 13,000 patients with hypertriglyceridemia and low HDL and high risk for cardiovascular disease randomized 1:1 to either corn oil plus statin or Epanova plus statin, once daily. On January 13, 2020, following the recommendation of an independent Data Monitoring Committee, AstraZeneca decided to close the STRENGTH trial due to its low likelihood of demonstrating benefit to patients with mixed dyslipidemia who are at increased risk of cardiovascular disease. Full data from the STRENGTH trial was presented at the AHA's Scientific Sessions in November 2020 confirming that Epanova failed to meet the primary endpoint of CV risk reduction, and published in Journal of the American Medical Association (JAMA) in December 2020. In addition, in March 2017, Kowa Research Institute (a subsidiary of the Japanese company Kowa Co., Ltd) initiated a Phase 3 cardiovascular outcomes trial titled PROMINENT examining the effect of pemafibrate (experimental name K-877) in reducing cardiovascular events in Type II diabetic patients with hypertriglyceridemia. Kowa Research Institute has publicly estimated study completion in May 2022, and if successful, U.S. regulatory approval is estimated in mid-2023.

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

Likewise, in 2018, results from A Study of Cardiovascular Events iN Diabetes (ASCEND) trial were released and showed negligible results for omega-3 fatty acid mixtures 1 gram daily. ASCEND was a British Heart Foundation funded 2x2 factorial design, randomized study to assess whether aspirin 100 mg daily versus placebo and separately, omega-3 fatty acid mixtures 1 gram daily

versus placebo, reduce the risk of cardiovascular events in a nationwide United Kingdom, or UK, cohort of over 15,000 individuals with diabetes who do not have ASCVD.

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

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

Matinas BioPharma, Inc., or Matinas, is developing an omega-3-based therapeutic (MAT9001) for the treatment of severe hypertriglyceridemia and mixed dyslipidemia. In the fourth quarter of 2014 Matinas filed an IND with the U.S. FDA to conduct a human study in the treatment of severe hypertriglyceridemia and, in June 2015, the company announced topline results for its head-to-head comparative short duration pharmacokinetic and pharmacodynamic study of MAT9001 versus VASCEPA in patients under conditions inconsistent with the U.S. FDA-approved label for VASCEPA and presented results based on biomarker modification without outcomes data. In September 2017, Matinas announced that it will be seeking a partner company to develop and commercialize MAT9001. In March 2019, Matinas announced that net proceeds from a public offering of common stock would be used for development activities for MAT9001. In March 2020, Matinas announced that it completed the clinical dosing for a comparative clinical bridging bioavailability study and the in-life portion of a 90-day comparative toxicology study in the first quarter of 2020. Both studies were conducted to support a planned 505(b)(2) registration pathway. In March, Matinas also initiated an additional Phase 2 head-to-head pharmacokinetic and pharmacodynamic study, ENHANCE-IT, against VASCEPA in patients with elevated triglycerides (150-499 mg/dL), while the study was paused in the first quarter of 2020 due to the COVID-19 pandemic, enrollment resumed in June and was completed in August 2020. In the first quarter of 2021, Matinas announced topline results from the ENHANCE-IT study, stating that LYPDISO, or MAT9001, did not meet statistical significance over VASCEPA on the primary endpoint of percent change from baseline to end of treatment in triglycerides in the PD population. A key secondary endpoint in ENHANCE-IT was the measurement of eicosapentaenoic acid levels in the blood, which is regarded as a key surrogate marker in determining cardiovascular risk reduction. In ENHANCE-IT, plasma EPA concentrations were significantly higher with LYPDISO versus VASCEPA, with a 46% relative percentage increase in the change from baseline EPA level versus VASCEPA. Matinas has announced that the results from ENHANCE-IT suggest potential for LYPDISO as a drug for cardiovascular risk reduction and announced that it is pursuing external partnerships to further develop LYPDISO for cardiovascular outcomes indication. As a result, Matinas no longer plans to pursue an indication for the treatment of severe HTG, instead focusing on the broader cardiovascular risk reduction indication.

In June 2018, NeuroBo Pharmaceuticals, Inc. (previously named Gemphire Therapeutics) announced positive topline results from a Phase 2b trial, or INDIGO-1, of its drug candidate, Gemcabene, in patients with severe hypertriglyceridemia. Gemcabene is an oral, once-daily pill for a number of hypercholesterolemic populations and severe hypertriglyceridemia. In August 2018, the U.S. FDA requested that Gemphire conduct an additional long-term toxicity study before commencing any further clinical testing, thereby effectively placing Gemcabene on clinical hold. In March 2020, NeuroBo announced the completion of the requested studies, and in May 2020 the company announced that it received written communication from the U.S. FDA that the clinical development program for Gemcabene remains on partial clinical hold for severe HTG. In June 2019, Gemphire announced top-line clinical results from a Phase 2 trial in Familial Partial Lipodystrophy (FPL)/NASH in which Gemcabene safely met the primary endpoint in a sub-set of patients. Phase 3 studies for homozygous familial hypercholesterolemia, or HoFH, heterozygous familial hypercholesterolemia, or HeFH, and non-familial hypercholesterolemia in ASCVD patients are planned. NeuroBO is currently assessing Gemcabene as an acute treatment for COVID-19.

Afimmune Ltd. has an oral, small molecule drug candidate, epeleuton (DS-102), in development for a number of conditions of the liver, lung, and metabolic system, including hypertriglyceridemia and cardiovascular risk reduction, Phase 2 clinical trials are currently ongoing for non-alcoholic fatty liver disease, or NAFLD, chronic obstructive pulmonary disease, or COPD, and planned for hypertriglyceridemia and Type 2 diabetes (TRIAGE), in the United States. In November 2019, Afimmune Ltd. announced positive results from an exploratory Phase 2 study of epeleuton in patients with NAFLD in which the molecule decreased triglycerides,

improved glycemic control, and decreased markers of inflammation. In August 2020, Afimmune reported Ph2a study results of epeleuton in patients with NAFLD. Although epeleuton failed to meet the primary endpoint to demonstrate effects on liver enzyme elevation, it demonstrated significant reduction of triglycerides, HbA1c and potential for CV risk reduction. In September 2020, Afimmune announced the start of TRIglyceride And Glucose control with Epeleuton in Metabolic Syndrome Patients, or TRIAGE, a Phase IIb study of epeleuton in patients with high triglycerides and type 2 diabetes to assess the safety and efficacy of orally administered epeleuton capsules vs placebo in the treatment of hypertriglyceridemia and type 2 diabetes. Results are expected in the third quarter of 2022.

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

VASCEPA also faces competition from dietary supplement manufacturers marketing omega-3 products as nutritional supplements. Such products are classified as food, not as prescription drugs or as over-the-counter drugs, by the U.S. FDA in the United States. Most regulatory regimes outside the United States are similar in this regard. Some of the promoters of such products have greater resources than us and are not restricted to the same standards as are prescription drugs with respect to promotional claims or manufacturing quality, consistency and subsequent product stability. 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 U.S. FDA's stringent regulatory oversight, as significant advantages versus omega-3 dietary supplements regardless of clinical study results and other scientific data.

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

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

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

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

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

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

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

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

The paragraph IV notice is required to contain a detailed factual and legal statement explaining the basis for the applicant's opinion that the proposed product does not infringe our patents, that the relevant patents are invalid, or both. After receipt of a valid notice, the branded product manufacturer has the option of bringing a patent infringement suit in federal district court against any generic company seeking approval for its product within 45 days from the date of receipt of each notice. If such a suit is commenced within this 45-day period, the Hatch-Waxman Amendments provide for a 30-month stay on U.S. FDA's ability to give final approval to the proposed generic product, which period begins on the date the paragraph IV notice is received. Generally, during a period of time in which generic applications may be submitted for a branded product based on a product's regulatory exclusivity status, if no patents are listed in the Orange Book before the date on which a complete ANDA application for a product (excluding an amendment or supplement to the application) is submitted, an ANDA application could be approved by U.S. FDA without regard to a stay. For products entitled to five-year exclusivity status, the Hatch-Waxman Amendments provide that an ANDA application may be submitted after four years following U.S. FDA approval of the branded product if it contains a certification of patent invalidity or non-infringement to a patent listed in the Orange Book. In such a case, the 30-month stay runs from the end of the five-year exclusivity period. Statutory stays may be shortened or lengthened if either party fails to cooperate in the litigation and it may be terminated if the court decides the case in less than 30 months. If the litigation is resolved in favor of the ANDA applicant before the expiration of the 30-month period, the stay will be immediately lifted and the U.S. FDA's review of the application may be completed. Such litigation is often time-consuming and costly, and may result in generic competition if such patents are not upheld or if the generic competitor is found not to infringe such patents.

In addition to the ANDA patent litigation described above, we could face patent litigation related to the patents filed in the Orange Book related to the REDUCE-IT study. A three-year period of exclusivity under the Hatch-Waxman Amendments is generally granted for a drug product that contains an active moiety that has been previously approved, such as when the application contains reports of new clinical investigations (other than bioavailability studies) conducted by the sponsor that were essential to approval of the application. Accordingly, we received three-year exclusivity in connection with the approval of our sNDA for REDUCE-IT study results. Such three-year exclusivity protection precludes, unless otherwise agreed, the U.S. FDA from approving a marketing application for an ANDA, a product candidate that the U.S. FDA views as having the same conditions of approval as VASCEPA (for example, the same indication and/or other conditions of use), or a 505(b)(2) NDA submitted to the U.S. FDA with VASCEPA as the reference product until December 13, 2022, three years from the date of U.S. FDA approval of the REDUCE-IT sNDA. While this three-year exclusivity would generally prevent such an approval based on our REDUCE-IT indication during such time, it does not preclude tentative or final approval of an ANDA based on our MARINE indication. The U.S. FDA may accept and commence review of such REDUCE-IT-related applications during the three-year exclusivity period. Such three-year exclusivity grant does not prevent a company from challenging the validity of REDUCE-IT patents during such period. This three-year form of exclusivity may also not prevent the U.S. FDA from approving an NDA that relies only on its own data to support the change or innovation. Regulatory exclusivity is in addition to exclusivity afforded by issued patents related to VASCEPA.

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

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

Generally, if an ANDA filer meets the approval requirements for a generic version of VASCEPA to the satisfaction of the U.S. FDA under its ANDA, U.S. FDA may grant tentative approval to the ANDA during a Hatch-Waxman 30-month stay period and during the Hatch-Waxman 36-month regulatory exclusivity period. A tentative approval is issued to an ANDA applicant when its application is approvable prior to the expiration of any exclusivities applicable to the branded, reference listed drug product. A tentative approval does not allow the applicant to market the generic drug product and postpones the final ANDA approval until applicable exclusivity protections have expired.

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

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

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

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

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

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

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

VASCEPA is a prescription-only omega-3 fatty acid product. Omega-3 fatty acids are also marketed by other companies as non-prescription dietary supplements. As a result, in the U.S. VASCEPA is subject to non-prescription competition and consumer substitution. This dynamic also exists in markets outside the United States.

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

Also, for over a decade, subject to certain limitations, the U.S. FDA has expressly permitted dietary supplement manufacturers that sell supplements containing the omega-3 fatty acids EPA and/or DHA to make the following qualified health claim directly to consumers: Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease. Such companies are not, however, permitted, based on U.S. FDA enforcement activity, to make claims that suggest or imply treatment of cardiovascular disease.

These factors enable dietary supplements to compete with VASCEPA to a certain degree. Although we have taken steps to address these competitive issues, and plan to continue to do so vigorously, we may not be successful in such efforts.

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

Similarly, on August 30, 2017, we filed a lawsuit with the United States International Trade Commission, or the ITC, against manufacturers, importers, and distributors of products containing synthetically produced omega-3 products in ethyl ester or re-esterified triglyceride form that contain more EPA than DHA or any other single component for use in or as dietary supplements. The lawsuit sought an investigation by the ITC regarding potentially unfair methods of competition and unfair acts involving the importation and sale of articles in the United States that injure or threaten injury to a domestic industry. In October 2017, the ITC determined to not institute our requested investigation. We appealed this determination to the U.S. Federal Circuit, but that court upheld ITC's determination. On July 30, 2019, we filed a petition with the U.S. Supreme Court seeking to appeal the Federal Circuit decision, which petition was denied on December 9, 2019, ending this litigation. We have also engaged with U.S. FDA on the topic of synthetically produced omega-3 products through the citizen's petition process and otherwise.

In addition, to the extent the net price of VASCEPA after insurance and offered discounts is significantly higher than the prices of commercially available omega-3 fatty acids marketed by other companies as dietary supplements (through that lack of coverage by insurers or otherwise), physicians and pharmacists may recommend these retail alternatives instead of writing or filling prescriptions for VASCEPA or patients may elect on their own to take commercially available omega-3 fatty acids. Also, insurance plans may increasingly impose policies that directly or indirectly favor supplement use over VASCEPA. While VASCEPA is priced comparatively with, or in some cases lower than, many competing treatments, particularly when taking into account insurance coverage, such pricing might not be sufficient for healthcare providers or patients to elect VASCEPA over alternative treatments that may be perceived as less expense or more convenient to access. If healthcare providers or patients favor dietary supplements over prescribing VASCEPA, we may be constrained in how we price our product or VASCEPA's market acceptance may be less than expected, which would have a negative impact on our revenues and results of operations.

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

There can be no assurance as to the market for VASCEPA outside the United States. For example, despite having received EC approval to commercialize VAZKEPA in Europe and as we expect to obtain, through our partner Edding, marketing approval for VASCEPA in Mainland China, Hong Kong, Macau and Taiwan, or the China Territory, applicable regulatory agencies may impose restrictions on the product's conditions for use, distribution or marketing and in some cases may impose ongoing requirements for post-market surveillance, post-approval studies or clinical trials.

Further, securing adequate reimbursement is critical for commercial success of any therapeutic and pricing and reimbursement levels of medications in markets outside the United States can be unpredictable and vary considerably on a country-by-country basis. In some foreign countries, including major markets in Europe, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with individual governmental authorities can take six to 12 months or longer after the receipt of regulatory marketing approval for a product. The time required to secure reimbursement tends to vary from country to country and cannot be reliably predicted at this time. In certain European countries, securing product reimbursement is a requisite to commercial launch. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a pharmacoeconomic study that compares the cost-effectiveness of VASCEPA to other available therapies. Such pharmacoeconomic studies can be costly and the results uncertain. Our business could be harmed if reimbursement of our products is unavailable, delayed or limited in scope or amount or if pricing is set at unsatisfactory levels. If the pricing and reimbursement levels of VASCEPA are lower than we anticipate, then affordability of, and market access to, VASCEPA may be adversely affected and thus market potential in these territories would suffer.

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

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

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

With respect to sales and marketing activities, advertising and promotional materials must comply with U.S. FDA rules in addition to other applicable federal and local laws in the United States and in other countries. The result of our First Amendment litigation and settlement may cause the government to scrutinize our promotional efforts or otherwise monitor our business more closely. Industry-sponsored scientific and educational activities also must comply with U.S. FDA and other requirements. In the United States, the distribution of product samples to physicians must comply with the requirements of the U.S. Prescription Drug Marketing Act. Manufacturing facilities remain subject to U.S. FDA inspection and must continue to adhere to the U.S. FDA's pharmaceutical current good manufacturing practice requirements, or cGMPs. Application holders must obtain U.S. FDA approval for product and manufacturing changes, depending on the nature of the change. In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are subject to periodic unannounced inspections by the U.S. FDA and state agencies for compliance with cGMP requirements.

We also are subject to the federal transparency requirements under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, enacted in March 2010, which require manufacturers of certain drugs, devices, biologics, and medical supplies to report to the Centers for Medicare & Medicaid Services, or CMS, information related to payments and other transfers of value to physicians and teaching hospitals and physician ownership and investment interests. We may also be subject, directly or indirectly through our customers and partners, to various fraud and abuse laws, including, without limitation, the U.S. Anti-Kickback Statute, U.S. FCA, and similar state laws, which impact, among other things, our proposed sales, marketing, and scientific/educational grant programs. We participate in the U.S. Medicaid Drug Rebate Program, the Federal Supply Schedule, or FSS, of the U.S. Department of Veterans Affairs, or the VA, and other government drug programs, and, accordingly, are subject to complex laws and regulations regarding reporting and payment obligations. We must also comply with requirements to collect and report adverse events and product complaints associated with our products. Our activities are also subject to U.S. federal and state consumer protection and unfair competition laws, non-compliance with which could subject us to significant liability. Similar requirements exist in many of these areas in other countries.

Depending on the circumstances, failure to meet post-approval requirements can result in criminal prosecution, fines or other penalties, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, or refusal to allow us to enter into supply contracts, including government contracts. We may also be held responsible for the non-compliance of our partners, such as our former co-promotion partner Kowa America. As discussed above, in June 2020, we received a CID from the DOJ informing us that the DOJ is investigating whether aspects of our promotional speaker programs and copayment waiver programs during the period from January 1, 2015 to the present violated the U.S. Anti-Kickback Statute and the U.S. FCA in relation to the sale and marketing of VASCEPA by us and our previous co-marketing partner, Kowa America. The New York State attorney general similarly issued a subpoena to us regarding the same subject matter on which the FTC CID is focused. The inquiries require us to produce documents and answer written questions, or interrogatories, relevant to specified time periods. We are cooperating with the government. We cannot predict when these investigations will be resolved, the outcome of the investigations or their potential impact on our business. Such investigations can be lengthy, costly and could materially affect and disrupt our business. If the government determines that we have violated the U.S. Anti-Kickback Statute, the FCA or antitrust regulations, we could be subject to significant civil and criminal fines and penalties. In addition, even if we comply with U.S. FDA and other requirements, new information regarding the safety or effectiveness of a product could lead the U.S. FDA to modify or withdraw a product approval. Newly discovered or developed safety or effectiveness data may require changes to a drug's approved labeling and marketing, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Adverse regulatory action, whether pre- or post-approval, can potentially lead to product liability claims and increase our product liability exposure. We must also compete against other products in qualifying for coverage and reimbursement under applicable third-party payment and insurance programs.

In addition, all of the above factors may also apply to any regulatory approval for VASCEPA obtained in territories outside the United States. In Europe, for example, restrictions regarding off-label promotion are in some ways more stringent than in the United States, including restrictions covering certain communications with shareholders. Given our inexperience with marketing and commercializing products outside the United States, in certain territories we may need to rely on third parties, such as our partners in Canada, China and the Middle East, to assist us in dealing with any such issues and we will have limited or no control over such partners.

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

Our ability to commercialize VASCEPA or any future products successfully, alone or with collaborators, will depend in part on the extent to which coverage and reimbursement for the products will be available from government and health administration authorities, private health insurers and other third-party payors. The continuing efforts of the U.S. and foreign governments, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce healthcare costs may adversely affect our ability to set prices for our products which we believe are fair, and our ability to generate revenues and achieve and maintain profitability. Refer to "*Business - United States Healthcare Reform and Legislation"* and "*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. For example, proposals are being considered to expand the use of dietary supplements in addition to or in place of drugs in government and private payor plans. In addition, cost control initiatives could decrease the price that we or any potential collaborators could receive for any of our future products and could adversely affect our profitability.

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

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

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

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

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

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

Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by us, governmental or regulatory agencies and the courts. In the case of our Medicaid pricing data, if we become aware that our reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected data for up to three years after those data originally were due. Such restatements and recalculations increase our costs for complying with the laws and regulations governing the Medicaid Drug Rebate program and could result in an overage or underage in our rebate liability for past quarters. Price recalculations also may affect the ceiling price at which we are required to offer our products under the 340B program or could require us to issue refunds to 340B covered entities.

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

In order to be eligible to have our products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies and grantees, as noted above, we participate in the VA's FSS pricing program. As part of this program, we are obligated to make our products available for procurement on an FSS contract under which we must comply with standard government terms and conditions and charge a price that is no higher than the statutory Federal Ceiling Price, or FCP, to four federal agencies (the VA, U.S. Department of Defense, or DOD, Public Health Service, and the U.S. Coast Guard). The FCP is based on the Non-Federal Average Manufacturer Price, or Non-FAMP, which we calculate and report to the VA on a quarterly and annual basis. Pursuant to applicable law, knowing provision of false information in connection with a Non-FAMP filing can subject a manufacturer to significant penalties for each item of false information. These obligations also contain extensive disclosure and certification requirements.

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

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

In the U.S., Europe and other regions globally, sales of pharmaceutical drugs are dependent, in part, on the availability of reimbursement to the consumer from third-party payors, such as government and private insurance plans. Third-party payors decide which products and services they will cover and under what conditions they will do so. They also establish reimbursement rates for those products and services. Increasingly, third-party payors are challenging the prices charged for medical products and services. Some third-party payor benefit packages restrict reimbursement, charge copayments to patients, or do not provide coverage for specific drugs or drug classes.

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

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

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

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 "*Business - Current and Future Legislation"* and *"Business - United States Healthcare Reform and Legislation*".

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

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

We and any potential collaborators may be subject to federal, state, and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA. Although we are not directly subject to HIPAA – other than with respect to providing certain employee benefits – we could potentially be subject to criminal penalties if we, our affiliates, or our agents knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. In addition, state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

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

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

The REDUCE-IT cardiovascular outcomes trial was conducted in part through clinical sites in the EEA. As a result, we are subject to additional privacy restrictions. The collection and use of personal health data in the EU is governed by the provisions of the GDPR. The GDPR imposes several requirements relating to the legal basis for processing personal data which may include the consent of the individuals to whom the personal data relates, the information provided to the individuals and the security and confidentiality of the personal data. The GDPR also imposes strict rules on the transfer of personal data out of the EEA to the United States. A decision by the Court of Justice of the European Union, or CJEU, in 2020 invalidated the EU-U.S. Privacy Shield Framework, which was one of the primary mechanisms used by U.S. companies to import personal information from Europe in compliance with the GDPR's cross-border data transfer restrictions, and raised questions about whether the EC's Standard Contractual Clauses, or SCCs, one of the primary alternatives to the Privacy Shield, can lawfully be used for personal information transfers from Europe to the United States or most other countries. Furthermore, on June 4, 2021, the EC issued new forms of standard contractual clauses for data transfers from controllers or processors in the EEA, or otherwise subject to the GDPR, to controllers or processors established outside the EEA, and not subject to the GDPR. The new forms of standard contractual clauses have replaced the standard contractual clauses that were adopted previously under the Data Protection Directive. We will be required to transition to the new forms of standard contractual clauses and doing so will require significant effort and cost. The new standard contractual clauses may also impact our business as companies based in Europe may be reluctant to utilize the new clauses to legitimize transfers of personal information to third countries given the burdensome requirements of transfer impact assessments and the substantial obligations that the new standard contractual clauses impose upon exporters. Failure to comply with the requirements of the GDPR, and the related national data protection laws of the EEA Member States may result in restrictions against regulatory approval in the EEA or substantial fines for breaches of the data protection rules. The GDPR may impose additional responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with these and/or new data protection rules. This may be onerous and adversely affect our business, financial condition, prospects and results of operations.

The U.S. FDA, other regulatory agencies and industry organizations strictly regulate the promotional claims that may be made about prescription products and promotional efforts such as speaker programs. If we or our partners are found to have improperly promoted uses, efficacy or safety of VASCEPA or otherwise are found to have violated the law or applicable regulations, we may become subject to significant fines and other liability. The government may seek to find means to prevent our promotion of truthful and non-misleading information beyond the current court ruling and litigation settlement or seek to find violations of other laws or regulations in connection with the promotional efforts we undertake on our own or through third parties.

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

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

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

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

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

- the lack of efficacy during clinical trials;
- the inability to manufacture sufficient quantities of qualified materials under cGMPs for use in clinical trials;
- slower than expected rates of patient recruitment;

- the inability to observe patients adequately after treatment;
- changes in regulatory requirements for clinical trials or preclinical studies;
- the emergence of unforeseen safety issues in clinical trials or preclinical studies;
- delay, suspension, or termination of a trial by the institutional review board responsible for overseeing the study at a particular study site;
- unanticipated changes to the requirements imposed by regulatory authorities on the extent, nature or timing of studies to be conducted on quality, safety and efficacy;
- compliance with laws and regulations related to patient data privacy;
- government or regulatory delays or "clinical holds" requiring suspension or termination of a trial; and
- political instability or other social or government protocols affecting our clinical trial sites.

Even if we obtain positive results from our efforts to seek regulatory approvals, from early stage preclinical studies or clinical trials, we may not achieve the same success in future efforts. Clinical trials that we or potential partners conduct may not provide sufficient safety and efficacy data to obtain the requisite regulatory approvals for product candidates. The failure of clinical trials to demonstrate safety and efficacy for our desired indications could harm the development of that product candidate as well as other product candidates, and our business and results of operations would suffer.

For example, during the public advisory committee meeting held by U.S. FDA as part of its review of our ANCHOR data and sNDA in October 2013, a discussion regarding observed, nominally statistically significant changes from baseline in an adverse direction, while on background statin therapy, in certain lipid parameters, including LDL cholesterol and triglycerides, in the placebo group, raised questions about the possibility that the light liquid paraffin oil, or mineral oil, placebo used in the ANCHOR trial and then in use in the REDUCE-IT trial might not be biologically inert and might be viewed as artificially exaggerating the clinical effect of VASCEPA when measured against placebo. Ultimately, in 2012, before the U.S. FDA approval of VASCEPA after review of the MARINE and ANCHOR trials and consideration of other data regarding mineral oil, no strong evidence for biological activity of mineral oil was identified by the agency. It was ultimately concluded that the between-group differences likely provided the most appropriate descriptions of the treatment effect of VASCEPA and that whatever factor(s) led to the within-group changes over time in the placebo group were likely randomly distributed to all treatment groups. Thus, the U.S. FDA approved VASCEPA for use in the MARINE indication in July 2012, U.S. FDA did not dispute the veracity of the ANCHOR trial data and, in connection with the March 2016 agreement we reached with the U.S. FDA allowing us to promote the results of the ANCHOR study, the U.S. FDA did not seek to require that we include any qualification related to this earlier question regarding the mineral oil placebo.

In addition, in connection with U.S. FDA's review of REDUCE-IT data and sNDA in 2019, the agency determined that an interaction between mineral oil and statins leading to decreased absorption of statins cannot be excluded when the two are co-administered as could have been the case in some patients in REDUCE-IT and that, in the agency's view, indirect evidence suggested the presence of a potential inhibitory effect on statin absorption by mineral oil. However, U.S. FDA's exploratory analysis indicated that the effect of LDL cholesterol values on the time to the primary endpoint was numerically small and unlikely to change the overall conclusion of treatment benefit. U.S. FDA then relied on this assessment and all data available to it to approve a new indication statement and labeling based on REDUCE-IT results. This matter illustrates that concerns such as this may arise in the future that could affect our product development, regulatory reviews or the public perception of our products and our future prospects, including REDUCE-IT results.

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

As we continue to build our infrastructure for commercializing VASCEPA, we may encounter difficulties in managing the scale of our operations successfully.

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

In addition to sales force reductions and the shift to omnichannel in the United States, we continue to work on our own and with our international partners to support regulatory efforts outside the United States based on REDUCE-IT results. As our operations expand with the anticipated growth of our product sales, we expect that we will need to manage additional relationships with various collaborative partners, suppliers and other third parties. Future growth and streamlining efforts will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate the right number of employees. For example, in Europe we commenced 2021 with approximately 50 professionals involved in pre-approval and pre-launch planning and other commercial preparation activities, growing to approximately 250 professionals at the end of 2021, with plans to continue to expand our European staff as deemed appropriate on a country by country basis. The time required to secure reimbursement tends to vary from country to country and cannot be reliably predicted at this time. While we believe that we have strong arguments regarding the cost effectiveness of VAZKEPA, the success of such reimbursement negotiations could have a significant impact on our ability to hire and retain personnel and realize the commercial opportunity of VAZKEPA in Europe. Our future financial performance and our ability to commercialize VASCEPA and to compete effectively will depend, in part, on our ability to manage our future growth effectively, and such efforts may be disrupted by ongoing or reinstated COVID-19 protocols. To that end, we must be able to manage our development efforts effectively, and hire, train, integrate and retain an appropriate level of management, administrative and sales and marketing personnel and have limited experience managing a commercial organization. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

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

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

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

Risks Related to Our Reliance on Third Parties

Our supply of product for the commercial market and clinical trials is dependent upon relationships with third-party manufacturers and suppliers.

We have no in-house manufacturing capacity and rely on contract manufacturers for our clinical and commercial product supply. We cannot ensure that we will successfully manufacture any product we may develop, either independently or under manufacturing arrangements, if any, with our third-party manufacturers. Moreover, if our manufacturers should cease doing business with us or experience delays, shortages of supply or excessive demands on their capacity, we may not be able to obtain adequate quantities of product in a timely manner, or at all. If we are not able to continue to operate our business relationships in a manner that

is sufficiently profitable for us and our suppliers, certain members of our supply chain could compete with us through supply to competitors, such as generic drug companies, through breach of our agreements or otherwise.

Any manufacturing problem, natural or manmade disaster affecting manufacturing facilities, government action, or the loss of a contract manufacturer could be disruptive to our operations and result in lost sales. Any reliance on suppliers may involve several risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability and quality. Any unanticipated disruption to future contract manufacture caused by problems at suppliers could delay shipment of products, increase our cost of goods sold and/or result in lost sales. If our suppliers were unable to supply us with adequate volumes of active pharmaceutical ingredient, API, (drug substance) or encapsulated bulk product (drug product), it would have a material adverse effect on our ability to continue to commercialize VASCEPA.

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

Expanding manufacturing capacity and qualifying such capacity is complex and subject to numerous regulations and other operational challenges. We require supply capacity to support our direct commercialization of VASCEPA in the United States and VAZKEPA in Europe. We are also committed to providing supply to our commercial partners and distributors in Canada, China, the Middle East and North Africa, and we anticipate potential additional supply requirements as we pursue commercial opportunities in other countries. The resources of our suppliers vary and are limited; costs associated with projected expansion and qualification can be significant. And, lead-times for supply purchases and capacity expansion are long requiring certain supply related decisions and commitment to be made in advance, for example, prior to commercial launch in China and in various European countries. There can be no assurance that the expansion plans of any of our suppliers will be successful. Our aggregate capacity to produce API is dependent upon the continued qualification of our API suppliers and, depending on the ability of existing suppliers to meet our supply demands, potentially the qualifications of new suppliers. Each of our API suppliers has outlined plans for potential further capacity expansion, with certain of these expansion plans delayed due to COVID-19 and other market uncertainties. If no additional API supplier is approved by the U.S. FDA as part of an ANDA, our API supply will be limited to the API we purchase from previously approved suppliers. Similarly, the EMA has not initially approved use of each of our suppliers used for VASCEPA in the United States for VAZKEPA in the EU. While we believe that we have sufficient supply of VAZKEPA to support our initial launch plans in Europe, our supply in Europe will be limited until additional suppliers are qualified which qualifications may be delayed by COVID-19 and our exposure to manufacturing issues with our approved suppliers for the EU is less mitigated than is our objective by having more suppliers qualified. If our third-party manufacturing capacity is not expanded and/or compliant with applicable regulatory requirements, we may not be able to supply sufficient quantities of VASCEPA to meet anticipated demand. We cannot guarantee that we can contract with any future manufacturer on acceptable terms or that any such alternative supplier will not require capital investment from us in order for them to meet our requirements. Alternatively, our purchase of supply may exceed actual demand for VASCEPA.

There can be no guarantee that current suppliers and future suppliers with which we have contracted to encapsulate API will be continually qualified to manufacture the product to our specifications or that current and any future suppliers will have the manufacturing capacity to meet anticipated demand for VASCEPA.

We may purchase too much or not enough supply to satisfy actual demand, which could have a material adverse effect on our financial results and financial condition.

Certain of our agreements with our suppliers include minimum purchase obligations and limited exclusivity provisions. These purchases are generally made on the basis of rolling 12-month forecasts which in part are binding on us and the balance of which are subject to adjustment by us subject to certain limitations. Certain of our agreements also include contractual minimum purchase commitments regardless of the rolling 12-month forecasts. We may not purchase sufficient quantities of VASCEPA to meet actual demand or we may be required to purchase more supply than needed to meet actual demand. In either case, such event could have a material adverse effect on our financial results and financial condition.

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

We sell VASCEPA principally to a limited number of major wholesalers, as well as selected regional wholesalers and mail order pharmacy providers, or collectively, our distributors or our customers, that in turn resell VASCEPA to retail pharmacies for subsequent resale to patients and healthcare providers. These parties exercise a substantial amount of bargaining power over us given their control over large segments of the market for VASCEPA. This bargaining power has led us to bear increasingly higher discounts in the sale of VASCEPA. In addition, payors have broad latitude to change individual products' formulary position or to implement

other barriers that inhibit patients from receiving therapies prescribed by their healthcare professionals. These payor barriers include requirements that patients try another drug before VASCEPA, known as step edits, and the requirement that prior authorization be obtained by a healthcare provider after a prescription is written before a patient will be reimbursed by their health plan for the cost of a VASCEPA prescription. Further, pharmacy benefit managers implement plans that act as disincentives for VASCEPA use, such as increasingly higher deductibles. One practical impact of higher deductibles is that they may cause patients to delay filling prescriptions for asymptomatic, chronic care medications such as hypertriglyceridemia earlier in the year, until patients meet their deductible and the cost of VASCEPA is then borne more by their insurance carrier. Collectively, these dynamics negatively affect our profitability for the sale of VASCEPA and could increase over time further impacting our operating results. Consolidation among these industry participants could increase the pressure from these market dynamics.

The manufacture, packaging and distribution of pharmaceutical products such as VASCEPA are subject to U.S. FDA regulations and those of similar foreign regulatory bodies. If we or our third-party manufacturers fail to satisfy these requirements, our product development and commercialization efforts may be materially harmed.

The manufacture, packaging and distribution of pharmaceutical products, such as VASCEPA, are regulated by the U.S. FDA and similar foreign regulatory bodies and must be conducted in accordance with the U.S. FDA's cGMPs and comparable requirements of foreign regulatory bodies. There are a limited number of manufacturers that operate under these cGMPs as well as the International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, or ICH, regulations and guidelines, that are both capable of manufacturing VASCEPA and willing to do so. Failure by us or our third-party manufacturers to comply with applicable regulations, requirements, or guidelines could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our products, delays, suspension or withdrawal of approvals, license revocation, seizures or voluntary recalls of product, operating restrictions and criminal prosecutions and penalties, any of which could significantly and adversely affect our business. If we are not able to manufacture VASCEPA to required specifications through our current and potential API suppliers, we may be delayed in successfully supplying the product to meet anticipated demand and our anticipated future revenues and financial results may be materially adversely affected.

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

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

Furthermore, the U.S. FDA and foreign regulatory agencies require that we be able to consistently produce the API and the finished product in commercial quantities and of specified quality on a repeated basis, including demonstrated product stability, and document our ability to do so. This requirement is referred to as process validation. Process validation includes stability testing, measurement of impurities and testing of other product specifications by validated test methods. If the U.S. FDA does not consider the result of the process validation or required testing to be satisfactory, the commercial supply of VASCEPA may be delayed, or we may not be able to supply sufficient quantities of VASCEPA to meet anticipated demand. On March 27, 2020, former President Trump

signed into law the CARES Act in response to the COVID-19 pandemic. Throughout the COVID-19 pandemic, there has been public concern over the availability and accessibility of critical medical products, and the CARES Act enhances U.S. FDA's existing authority with respect to drug shortage measures. Under the CARES Act, we must have in place a risk management plan that identifies and evaluates the risks to the supply of approved drugs for certain serious diseases or conditions for each establishment where the drug or API is manufactured. The risk management plan will be subject to U.S. FDA review during an inspection. If we experience shortages in the supply of our marketed products, our results could be materially impacted.

The U.S. FDA and similar foreign regulatory bodies may also implement new requirements, or change their interpretation and enforcement of existing requirements, for manufacture, packaging or testing of products at any time. If we or our approved suppliers are unable to comply, we may be subject to regulatory, civil actions or penalties, or we may be prevented from manufacturing or selling VASCEPA, all of which could significantly and adversely affect our business. Furthermore, reductions in government operations due to pandemic mitigation efforts, or other factors, may delay timely regulatory review by U.S. FDA or similar foreign regulatory bodies. For example, since March 2020 when foreign and domestic inspections of facilities were largely placed on hold, the U.S. FDA has been working to resume routine surveillance, bioresearch monitoring and pre-approval inspections on a prioritized basis. Since April 2021, the U.S. FDA has conducted limited inspections and employed remote interactive evaluations, using risk management methods, to meet user fee commitments and goal dates. Ongoing travel restrictions and other uncertainties continue to impact oversight operations both domestic and abroad and it is unclear when standard operational levels will resume. The U.S. FDA is continuing to complete mission-critical work, prioritize other higher-tiered inspectional needs (e.g., for-cause inspections), and carry out surveillance inspections using risk-based approaches for evaluating public health. Should the U.S. FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, and the U.S. FDA does not determine a remote interactive evaluation to be adequate, the agency has stated that it generally intends to issue, depending on the circumstances, a complete response letter or defer action on the application until an inspection can be completed. During the COVID-19 public health emergency, a number of companies announced receipt of complete response letters due to the U.S. FDA's inability to complete required inspections for their applications. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the ongoing COVID-19 pandemic and may experience delays in their regulatory activities.

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

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

In February 2015, we entered into a Development, Commercialization and Supply Agreement, or the DCS Agreement, with Edding, related to the development and commercialization of VASCEPA in the China Territory. Under the DCS Agreement, Edding is responsible for development and commercialization activities in the China Territory and associated expenses. Additionally, Edding is required to conduct clinical trials in the China Territory to secure regulatory approval in certain territories. In December 2017, Edding commenced a pivotal Phase 3 clinical trial aimed to demonstrate that VASCEPA lowers triglyceride levels and otherwise has beneficial effects in Chinese patients with severe hypertriglyceridemia (TG >500 mg/dL), as we previously demonstrated with VASEPA in the more diverse population studied in the MARINE study. In November 2020, we announced statistically significant positive topline results from Edding's Phase 3 clinical trial of VASCEPA. On February 9, 2021, we announced that the regulatory review processes for approval of VASCEPA in Mainland China and Hong Kong have commenced. The Chinese National Medical Products Administration, or NMPA, has accepted for review the new drug application for VASCEPA, submitted by Edding, based on the results from the Phase 3 clinical trial and the results from our prior studies of VASCEPA. We expect to receive a decision from the NMPA in Mainland China in the second half of 2022. The Hong Kong Department of Health is evaluating VASCEPA based on current approvals in the United States and Canada. The review process in Hong Kong is expected to conclude in the second half of 2022. Even though such results are similar to the MARINE study, additional clinical development efforts may be necessary in this market to demonstrate the effectiveness of VASCEPA in reducing major adverse cardiovascular events in Chinese patients with persistent cardiovascular risk. Any development and regulatory efforts in the China Territory may be negatively impacted if the coronavirus pandemic continues or spreads, and if resources by regulators and industry professionals continue to be diverted to address the prolonged coronavirus outbreak. Any development and regulatory efforts in the China Territory may be negatively impacted by heightened political tension between China and the United States, including in connection with COVID-19 and other issues expressed between the countries regarding trade practices, tariffs and honoring intellectual property rights. If Edding is not able to effectively develop and commercialize VASCEPA in the China Territory, we may not be able to generate revenue from the DCS Agreement resulting from the sale of VASCEPA in the China Territory.

In March 2016, we entered into an agreement with Biologix FZCo, or Biologix, to register and commercialize VASCEPA in several Middle Eastern and North African countries. Under the terms of the distribution agreement, we granted to Biologix a non-exclusive license to use our trademarks in connection with the importation, distribution, promotion, marketing and sale of VASCEPA

in the Middle East and North Africa territory. Biologix was approved under the MARINE indication in the following countries: Lebanon in March 2018, United Arab Emirates in July 2018, Qatar in December 2019, Bahrain in April 2021 and Kuwait in January 2022. VASCEPA was approved under the REDUCE-IT indication in the following countries: Qatar in April 2021, Lebanon in August 2021 and United Arab Emirates in October 2021. VASCEPA was launched in Lebanon and the United Arab Emirates in June 2018 and February 2019, respectively. VASCEPA is under registration in additional countries in the Middle East and North Africa regions. Commercialization across the Middle East and North Africa is subject to similar risks as in the China Territory, and has been negatively impacted by COVID-19 and the destabilized local economies in the region.

In September 2017, we entered into an agreement with HLS Therapeutics Inc., or HLS, to register, commercialize and distribute VASCEPA in Canada. Under the agreement, HLS is responsible for regulatory and commercialization activities and associated costs. We are responsible for providing assistance towards local filings, supplying finished product under negotiated supply terms, maintaining intellectual property, and continuing the development and funding of REDUCE-IT related activities. In December 2019, VASCEPA was approved for use in Canada to reduce the risk of cardiovascular events in statin-treated patients with elevated triglycerides, who are at high risk of cardiovascular events due to established cardiovascular disease, or diabetes, and at least one other cardiovascular risk factor. In January 2020, HLS obtained an extended regulatory exclusivity designation. In February 2020, HLS launched VASCEPA in Canada, with strong initial uptake before the impact of COVID-19 pandemic. In July 2020, Patented Medicine Prices Review Board confirmed VASCEPA price is compliant with current guidelines, and CADTH recommended reimbursement for VASCEPA in Canada in secondary prevention population. However, if HLS is not able to effectively commercialize VASCEPA in Canada through effective pricing (initially and over time), reimbursement or otherwise we may not be able to generate revenue from the sale of VASCEPA in Canada.

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

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

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

Healthcare providers, physicians and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Arrangements with third-party payors and customers can expose pharmaceutical manufacturers to broadly applicable fraud and abuse and other healthcare laws and regulations, which may constrain the business or financial arrangements and relationships through which such companies sell, market and distribute pharmaceutical products. In particular, the promotion, sales and marketing of healthcare items and services, as well as a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. 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 "*Business - Government Regulation - Fraud and Abuse Laws and Data Regulation*" for further details.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products. In addition, manufacturers and other parties involved in the drug supply chain for prescription drug products must also comply with product tracking and tracing requirements and for notifying U.S. FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are otherwise unfit for distribution in the United States.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies continue to give regular and close scrutiny to interactions between healthcare companies and healthcare providers, and such scrutiny often leads to investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring business arrangements

comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from the business. For example, in June 2020, we received a CID from the DOJ informing us that the DOJ is investigating whether aspects of our promotional speaker programs and copayment waiver program during the period from January 1, 2015 to the present violated the U.S. Anti-Kickback Statute and the FCA in relation to the sale and marketing of VASCEPA by us and our previous co-marketing partner, Kowa America. Similarly, in March 2021, the FTC issued a CID to us in connection with the FTC's investigation of whether we have engaged in, or is engaging in, anticompetitive practices or unfair methods of competition relating to VASCEPA. The New York State attorney general similarly issued a subpoena to us regarding the same subject matter on which the FTC CID is focused. The investigations require us to produce documents and answer written questions, or interrogatories, relevant to specified time periods. We are cooperating with the government. We cannot predict when these investigations will be resolved, the outcome of the investigations or their potential impact on our business. Such investigations can be lengthy, costly and could materially affect and disrupt our business. If the government determines that we have violated the U.S. Anti-Kickback Statute, the FCA or antitrust regulations, we could be subject to significant civil and criminal fines and penalties. The failure to comply with any of these laws or regulatory requirements subjects entities to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in significant civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in federal and state funded healthcare programs (such as Medicare and Medicaid), contractual damages and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Any action for violation of these laws, even if successfully defended, could cause a pharmaceutical manufacturer to incur significant legal expenses and divert management's attention from the operation of the business. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, that person or entity may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way.

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

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

In addition, with the approval and commercialization of any of our products outside the United States, we will also likely be subject to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

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

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

Risks Related to Our Intellectual Property

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

Our success depends in part on our ability to obtain and maintain intellectual property protection for our drug candidates, technology and know-how, and to operate without infringing the proprietary rights of others. While certain key patents related to our product based on the MARINE clinical study were determined to be invalid as obvious by a district court in the United States, and we are pursuing an appeal process, it remains the case that our ability to successfully implement our business plan and to protect our products with our intellectual property will depend in large part on our ability to:

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

We have prosecuted, and are currently prosecuting, multiple patent applications to protect the intellectual property developed during the VASCEPA development program. As of the date of this Annual Report on Form 10-K, we had 123 patent applications in the United States that have been either issued or allowed and more than 30 additional patent applications are pending in the United States. Such 123 allowed and issued applications include the following:

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

- four additional patents covering a pharmaceutical composition comprised of EPA and a hydroxyl compound with a term that expires in 2034; and
- five additional patents covering a new combination therapy comprised of EPA and another drug.

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

We are the owner of the above-listed patents. We are also the exclusive licensee of certain patents owned by others covering products and products in development.

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

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

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

We may be dependent in some cases upon third-party licensors to pursue filing, prosecution and maintenance of patent rights or applications owned or controlled by those parties, including, for example, under our collaboration with Mochida. It is possible that third parties will obtain patents or other proprietary rights that might be necessary or useful to us. In cases where third parties are first to invent a particular product or technology, or first to file after various provisions of the America Invents Act of 2011 went into effect on March 16, 2013, it is possible that those parties will obtain patents that will be sufficiently broad so as to prevent us from utilizing such technology or commercializing our current and future products. Although we intend to make reasonable efforts to protect our current and future intellectual property rights and to ensure that any proprietary technology we acquire or develop does not infringe the rights of other parties, we may not be able to ascertain the existence of all potentially conflicting claims. Therefore, there is a risk that third parties may make claims of infringement against our current or future products or technologies. In addition, third parties may be able to obtain patents that prevent the sale of our current or future products or require us to obtain a license and pay significant fees or royalties in order to continue selling such products.

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

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

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

We plan to vigorously defend our rights under issued patents. For example, on November 30, 2020 we filed a patent infringement lawsuit against Hikma for making, selling, offering to sell and importing generic icosapent ethyl capsules in and into the United States in a manner that we allege has induced the infringement of patents covering the use of VASCEPA to reduce specified cardiovascular risk. On January 25, 2021, we expanded the scope of this patent infringement lawsuit to include a health care insurance provider, Health Net, LLC. On January 4, 2022, the district court hearing the case granted Hikma's motion to dismiss. We intend to appeal the decision of the district court. We also intend to continue to vigorously pursue our ongoing litigation with Health Net, LLC, but cannot predict the outcome or the impact on our business.

Patent litigation is a time-consuming and costly process. There can be no assurance that we will be successful in enforcing this patent or that it will not be successfully challenged and invalidated. Even if we are successful in enforcing this patent, the process could take years to reach conclusion. Other drug companies may challenge the validity, enforceability, or both of our patents and seek to design its products around our issued patent claims and gain marketing approval for generic versions of VASCEPA or branded competitive products based on new clinical studies. The pharmaceutical industry is highly competitive and many of our competitors have greater experience and resources than we have. Any such competition could undermine sales, marketing and collaboration efforts for VASCEPA, and thus reduce, perhaps materially, the revenue potential for VASCEPA.

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

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

We have filed and are prosecuting numerous families of patent applications in the United States and internationally with claims designed to protect the proprietary position of VASCEPA. For certain of these patent families, we have filed multiple patent applications. Collectively the patent applications include numerous independent claims and dependent claims. Several of our patent applications contain claims that are based upon what we believe are unexpected and favorable findings from our clinical trials. If granted, one or more of the resulting granted patents from REDUCE-IT, for example, would expire in 2039, beyond the 2030 and 2033 expiration dates of currently issued REDUCE-IT patents. However, no assurance can be given that any of our pending patent applications will be granted or, if they grant, that they will prevent competitors from competing with VASCEPA.

Securing patent protection for a product is a complex process involving many legal and factual questions. The patent applications we have filed in the United States and internationally are at varying stages of examination, the timing of which is outside our control. The process to getting a patent granted can be lengthy and claims initially submitted are often modified in order to satisfy the requirements of the patent office. This process includes written and public communication with the patent office. The process can also include direct discussions with the patent examiner. There can be no assurance that the patent office will accept our arguments with respect to any patent application or with respect to any claim therein. We cannot predict the timing or results of any patent application. In addition, we may elect to submit, or the patent office may require, additional evidence to support certain of the claims we are pursuing. Furthermore, third parties may attempt to submit publications for consideration by the patent office during examination of our patent applications. Providing such additional evidence and publications could prolong the patent office’s review of our applications and result in us incurring additional costs. We cannot be certain what commercial value any granted patent in our patent estate will provide to us.

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

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

Risks Related to Our Business

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

In January 2022, we disclosed our 2022 financial outlook. Such outlook is based on estimates, assumptions and the judgment of management. Because of the inherent nature of estimates, including during the uncertainty of COVID-19’s impact on our business, we have suspended providing net revenue guidance and there could be significant differences between our estimates and the actual amount of product demand. If we fail to realize or if we change or update any element of our publicly disclosed financial guidance as we have done in the past or other expectations about our business change, our stock price could decline in value.

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

We are highly dependent upon the efforts of our senior management. The loss of the services of one or more members of senior management could have a material adverse effect on us. Given our rapidly expanding enterprise coupled with a streamlined management structure and sales force, the departure of any key person could have a significant impact and would be potentially disruptive to our business until such time as a suitable replacement is hired. In the third quarter of 2021, John Thero and Joseph Kennedy, our President and Chief Executive Officer, and our Executive Vice President and General Counsel, respectively, retired and we welcomed Karim Mikhail, previously our Senior Vice President, Commercial Head Europe and Jason Marks as our new President and Chief Executive Officer and our new Senior Vice President and Chief Legal Officer, respectively. Although these transitions have been smooth, any such changes to senior management can be disruptive to operations, including by distracting management from our core business and effective employee productivity. Furthermore, because of the specialized nature of our business, as our business plan progresses, we will be highly dependent upon our ability to attract and retain qualified scientific, technical and key management personnel. As we continue to expand our commercialization efforts, particularly on a global scale, we may experience increased turnover among members of our senior management team. We may have difficulty identifying, attracting and integrating new executives to replace any such losses. As we prepare for commercialization in Europe, we need to rapidly hire employees and ensure that they are well trained and working cohesively with core values which are consistent with our existing operations and which, we believe, help improve our position for success. In the United States, employees are increasingly being recruited by other companies. While our business priorities emphasize continued promotion of VASCEPA in the United States, the current and potential threat of generic competition can create employee uncertainty which could lead to increased employee turnover. There is intense competition for qualified personnel in the areas of our activities. In this environment, we may not be able to attract and retain the personnel necessary for the development of our business, particularly if we do not achieve profitability. The failure to recruit key scientific, technical and management personnel would be detrimental to our ability to implement our business plan.

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

Despite the implementation of security measures, our internal computer systems and those of our third-party clinical research organizations and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war, and telecommunication and electrical failures. Any such incident could cause interruptions in our operations or a material disruption of our programs. To the extent that any disruption or security breach results in a loss of or damage to our data or applications or other data or applications relating to our technology or products candidates, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and our research and development program could be delayed.

We could be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of information maintained in the information systems and networks of our company and our vendors, including personal information of our employees and patients, and company and vendor confidential data. In addition, outside parties may attempt to penetrate our systems or those of our vendors or fraudulently induce our personnel or the personnel of our vendors to disclose sensitive information in order to gain access to our data and/or systems. We may experience threats to our data and systems, including malicious codes and viruses, phishing and other cyber-attacks. The number and complexity of these threats continue to increase over time. For example, in June 2019, a report published by security researchers claimed that a database belonging to one of our vendors containing information about individuals who use or have expressed interest in VASCEPA was accessible to unauthorized users. Although we were informed that such breach did not include social security numbers or credit card information, we cannot guarantee that a more material breach will not occur in the future. If a material breach of our information technology systems or those of our vendors occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks and to repair reputational costs. In addition, we could be subject to regulatory actions and/or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices. We may incur significant costs or divert significant internal resources as a result of any regulatory actions or private litigation. Any of the foregoing consequences may adversely affect our business and financial condition.

Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely. As we outsource more of our information systems to vendors, engage in more electronic transactions with payors and patients, and rely more on cloud-based information systems, the related security risks will increase and we will need to expend additional resources to protect our technology and information systems. In addition, there can be no assurance that our internal information technology systems or those of our third-party contractors, or our consultants' efforts to implement adequate security and control measures, will be sufficient to

protect us against breakdowns, service disruption, data deterioration or loss in the event of a system malfunction, or prevent data from being stolen or corrupted in the event of a cyberattack, security breach, industrial espionage attacks or insider threat attacks which could result in financial, legal, business or reputational harm.

We are subject to potential product liability.

We are subject to the potential risk of product liability claims relating to the manufacturing and marketing of VASCEPA. Any person who is injured as a result of using VASCEPA may have a product liability claim against us without having to prove that we were at fault.

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

A change in our tax residence and/or tax laws could have a negative effect on our future profitability.

We expect that our tax jurisdiction will remain in Ireland. Under current UK legislation, a company incorporated in England and Wales, or which is centrally managed and controlled in the UK, is regarded as resident in the UK for taxation purposes. Under current Irish legislation, a company is regarded as resident for tax purposes in Ireland if it is centrally managed and controlled in Ireland, or, in certain circumstances, if it is incorporated in Ireland. Up to December 31, 2019, where a company was treated as tax resident under the domestic laws of both the UK and Ireland, then the provisions of article 4(3) of the Double Tax Agreement, or DTA, between the UK and Ireland provided that such enterprise would be treated as resident only in the jurisdiction in which its place of effective management is situated. We had at all times sought to conduct our affairs in such a way so as to be solely resident in Ireland for tax purposes by virtue of having our place of effective management situated in Ireland.

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

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

Our and our subsidiaries' income tax returns are periodically examined by various tax authorities, including the Internal Revenue Service, or the IRS, and states. For example, the IRS began an examination of our 2018 US 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 37%, 28%, and 27%, respectively, of gross product sales for the year ended December 31, 2021 and represented 39%, 22%, and 35%, respectively, of the gross accounts receivable balance as of December 31, 2021. Customers A, B, and C accounted for 38%, 29%, and 25%, respectively, of gross product sales for the year ended December 31, 2020 and represented 31%, 18%, and 37%, respectively, of the gross accounts receivable balance as of December 31, 2020. 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, 2021, we reported net income of approximately $7.7 million. For the fiscal years ended December 31, 2020 and 2019, we reported net losses of approximately $18.0 million, and $22.6 million, respectively, and we had an accumulated deficit as of December 31, 2021 of $1.4 billion. Substantially all of our operating losses resulted from costs incurred in connection with our research and development programs, from general and administrative costs associated with our operations, and costs related to the commercialization of VASCEPA. Additionally, as a result of our significant expenses relating to research and development and to commercialization, we expect to continue to incur significant operating losses for an indefinite period. Because of the numerous risks and uncertainties associated with developing and commercializing pharmaceutical products, we are unable to predict the magnitude of these future losses. Our historic losses, combined with expected future losses, have had and will continue to have an adverse effect on our cash resources, shareholders' deficit and working capital.

Although we began generating revenue from VASCEPA in January 2013, we may never be consistently profitable for a full year.

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

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

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

Our operating results are difficult to predict and will likely fluctuate from quarter to quarter and year to year, and VASCEPA prescription figures will likely fluctuate from month to month. VASCEPA sales are difficult to predict from period to period and as a result, you should not rely on VASCEPA sales results in any period as being indicative of future performance, and sales of VASCEPA may be below the expectation of securities analysts or investors in the future. We believe that our quarterly and annual results of operations may be affected by a variety of factors, including those risks and uncertainties described in this Part II, Item 1A and the following:

- the recent and potential launches of additional generic versions of VASCEPA;
- continued and prolonged disruption to our business, or delays in resuming normal business activities, or reinstating restrictions after protocols have been lifted, from the COVID-19 pandemic;
- the continuing evolution of the medical community's and the public's perception of the REDUCE-IT study results;
- the level of demand for VASCEPA, due to changes in prescriber sentiment, quarterly changes in distributor purchases, and other factors;
- the extent to which coverage and reimbursement for VASCEPA is available from government and health administration authorities, private health insurers, managed care programs and other third-party payers and the timing and extent to which such coverage and reimbursement changes;
- the timing, cost and level of investment in our sales and marketing efforts to support VASCEPA sales, including our recently implemented Go-to-Market strategy, and the resulting effectiveness of those efforts;
- disruptions or delays in our or our partners' commercial or development activities, including as a result of political instability, civil unrest, terrorism, pandemics or other natural disasters, such as the coronavirus outbreak;
- the timing and ability of efforts outside the United States, to develop, register and commercialize VASCEPA in Europe, China Territory, several Middle Eastern and North African countries, and Canada, for example, including obtaining necessary regulatory approvals, favorable pricing and establishing marketing channels;

- additional developments regarding our intellectual property portfolio and regulatory exclusivity protections, if any;
- outcomes of litigation and other legal proceedings; and
- our ongoing regulatory dialogue.

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

We currently operate with limited resources. We believe that our cash and cash equivalents balance of $219.5 million and short-term investment balance of $234.7 million as of December 31, 2021, will be sufficient to fund our projected operations for at least 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could deplete our capital resources sooner than we expect or fail to achieve positive cash flow. Depending on the level of cash generated from operations, and depending in part on the rate of prescription growth for VASCEPA, additional capital may be required to support planned VASCEPA promotion and potential VASCEPA promotion beyond which we are currently executing and for commercialization of VAZKEPA in Europe. If additional capital is required and we are unable to obtain additional capital on satisfactory terms, or at all, we may be forced to delay, limit or eliminate certain promotional activities. We anticipate that quarterly net cash outflows in future periods will be variable as a result of the timing of certain items, including our purchases of API, VASCEPA promotional and educational activities, including launch activities in Europe and the impact from COVID-19 on our operations and those of our customers and any current or potential generic competition.

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

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

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

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

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

Tax law and policies in the United States and Ireland are unsettled and may be subject to significant change, including based on adjustments in political perspectives and administration shifts. In the United States and internationally, how to tax entities with international operations, like Amarin, has been subject to significant re-evaluation. We believe we developed VASCEPA in and from Ireland based on understanding of applicable requirements. In recent years, particularly since 2013 when commercial sale of VASCEPA commenced in the United States, the majority of our consolidated operations have been in the United States. Ownership of VASCEPA continues to reside with our wholly-owned Ireland-based subsidiary, Amarin Pharmaceuticals Ireland Ltd., and oversight and operations of that entity are structured to be maintained in Ireland. In order to effectively utilize our accumulated net operating loss carryforwards for tax purposes in Ireland, our operations, particularly for this subsidiary, need to be active in Ireland under applicable requirements. In addition, utilization of these accumulated net operating loss carryforwards assumes that tax treaties between Ireland and other countries, particularly the United States, do not change in a manner that limit our future ability to offset earnings with these operating loss carryforwards for tax purposes.

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

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

Risks Related to Ownership of our ADSs and Common Shares

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

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

As of February 25, 2022, we had 396,737,811 common shares outstanding including 396,540,984 shares held as ADSs and 196,827 held as ordinary shares (which are not held in the form of ADSs). There is a risk that there may not be sufficient liquidity in the market to accommodate significant increases in selling activity or the sale of a large block of our securities. Our ADSs have historically had limited trading volume, which may also result in volatility. If any of our large investors seek to sell substantial amounts of our ADSs, particularly if these sales are in a rapid or disorderly manner, or other investors perceive that these sales could occur, the market price of our ADSs could decrease significantly.

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

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

Further, the United Kingdom ceased to be a member of the European Union on January 31, 2020, commonly referred to as Brexit, the 11-month implementation period ended on December 31, 2020 and a new trade deal between the United Kingdom and the European Union was agreed to on December 24, 2020. The effects of Brexit are uncertain and may have a negative effect on global economic conditions, financial markets and our business, which could reduce the price of our ADSs and common shares. In particular, Brexit could lead to a period of considerable uncertainty in relation to the UK financial and banking markets, as well as on the regulatory process in Europe, which could cause the broader global financial markets to experience significant volatility. Asset valuations, currency exchange rates and credit ratings may also be subject to increased market volatility due to the ongoing uncertainty. Lack of clarity about future UK laws and regulations as the United Kingdom determines which EU rules and regulations to replace or replicate could decrease foreign direct investment in the UK, increase costs, disrupt our business, depress economic activity and restrict our access to capital, any of which could negatively impact the price of our ADSs and common shares.

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

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

ADSs to fall or prevent it from increasing. Also, actual or potential sales by such persons could be viewed negatively by other investors.

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

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

Based on certain estimates of our gross income and gross assets, the latter determined by reference to the expected value of our ADSs and shares, we believe that we will not be classified as a PFIC for the taxable year ended December 31, 2021 and we do not expect to be treated as a PFIC in any future taxable year for the foreseeable future. However, because PFIC status is based on our income, assets and activities for the entire taxable year, which we expect may vary substantially over time, it is not possible to determine whether we will be characterized as a PFIC for any taxable year until after the close of the taxable year. Moreover, we must determine our PFIC status annually based on tests that are factual in nature, and our status in future years will depend on our income, assets and activities in each of those years. There can be no assurance that we will not be considered a PFIC for any taxable year.

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

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

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

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

- Under English law and our Articles of Association, each shareholder present at a meeting has only one vote unless demand is made for a vote on a poll, in which case each holder gets one vote per share owned. Under U.S. law, each shareholder typically is entitled to one vote per share at all meetings.
- Under English law, it is only on a poll that the number of shares determines the number of votes a holder may cast. You should be aware, however, that the voting rights of ADSs are also governed by the provisions of a deposit agreement with our depositary bank.
- Under English law, subject to certain exceptions and disapplications, each shareholder generally has preemptive rights to subscribe on a proportionate basis to any issuance of ordinary shares or rights to subscribe for, or to convert securities into, ordinary shares for cash. Under U.S. law, shareholders generally do not have preemptive rights unless specifically granted in the certificate of incorporation or otherwise.
- Under English law and our Articles of Association, certain matters require the approval of 75% of the shareholders who vote (in person or by proxy) on the relevant resolution (or on a poll of shareholders representing 75% of the ordinary shares voting (in person or by proxy)), including amendments to the Articles of Association. This may make it more difficult for us to complete corporate transactions deemed advisable by our board of directors. Under U.S. law, generally only majority shareholder approval is required to amend the certificate of incorporation or to approve other significant transactions.
- In the United Kingdom, takeovers may be structured as takeover offers or as schemes of arrangement. Under English law, a bidder seeking to acquire us by means of a takeover offer would need to make an offer for all of our outstanding ordinary shares/ADSs. If acceptances are not received for 90% or more of the ordinary shares/ADSs under the offer, under English law, the bidder cannot complete a "squeeze out" to obtain 100% control of us. Accordingly, acceptances of 90% of our outstanding ordinary shares/ADSs will likely be a condition in any takeover offer to acquire us, not 50% as is more common in tender offers for corporations organized under Delaware law. By contrast, a scheme of arrangement, the

successful completion of which would result in a bidder obtaining 100% control of us, requires the approval of a majority of shareholders voting at the meeting and representing 75% of the ordinary shares voting for approval.

- Under English law and our Articles of Association, shareholders and other persons whom we know or have reasonable cause to believe are, or have been, interested in our shares may be required to disclose information regarding their interests in our shares upon our request, and the failure to provide the required information could result in the loss or restriction of rights attaching to the shares, including prohibitions on certain transfers of the shares, withholding of dividends and loss of voting rights. Comparable provisions generally do not exist under U.S. law.
- The quorum requirement for a shareholders' meeting is a minimum of two shareholders entitled to vote at the meeting and present in person or by proxy or, in the case of a shareholder which is a corporation, represented by a duly authorized officer (although the marketplace rules of the Nasdaq Stock Market require that shareholders holding at least one-third of our outstanding shares of voting stock are present at the meeting or by proxy). Under U.S. law, a majority of the shares eligible to vote must generally be present (in person or by proxy) at a shareholders' meeting in order to constitute a quorum. The minimum number of shares required for a quorum can be reduced pursuant to a provision in a company's certificate of incorporation or bylaws, but typically not below one-third of the shares entitled to vote at the meeting.

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

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

- In connection with a potential offer, if following an approach by or on behalf of a potential bidder, the company is "the subject of rumor or speculation" or there is an "untoward movement" in the company's share price, there is a requirement for the potential bidder to make a public announcement about a potential offer for the company, or for the company to make a public announcement about the potential offer.
- When a person or group of persons who are treated as "acting in concert" with each other (a) acquires interests in shares carrying 30% or more of the voting rights of a company (which percentage is treated by the Takeover Code as the level at which effective control is obtained) or (b) increases the aggregate percentage interest they have when they are already interested in not less than 30% and not more than 50%, they must make a cash offer to all other shareholders at the highest price paid by them in the 12 months before the offer was announced.
- When interests in shares of any class representing 10% of shares of that class have been acquired for cash by an offeror (i.e., a bidder) during the offer period (i.e., broadly speaking, the period after the potential offer has been made public) and within 12 months prior to commencement of the offer period, the offer must be in cash or be accompanied by a cash alternative for all shareholders of that class at the highest price paid by the offeror in that period. Further, if an offeror acquires any interest in shares for cash during the offer period, the offer for the shares must be in cash or accompanied by a cash alternative at a price at least equal to the price paid for such shares during the offer period.
- If after an announcement is made, the offeror acquires an interest in shares in an offeree company (i.e., a target) at a price higher than the value of the offer, the offer must be increased accordingly.
- The offeree company must appoint a competent independent adviser whose advice on the financial terms of the offer must be made known to all the shareholders, together with the opinion of the board of directors of the offeree company.
- Favorable deals for selected shareholders are not permitted, except in certain circumstances where independent shareholder approval is given and the arrangements are regarded as fair and reasonable in the opinion of the financial adviser to the offeree.
- All shareholders must be given the same information.
- The directors of those parties issuing takeover circulars must include statements taking responsibility for the contents thereof.
- Profit forecasts, quantified financial benefits statements and asset valuations must be made to specified standards and must be reported on by professional advisers.
- Misleading, inaccurate or unsubstantiated statements made in documents or to the media must be publicly corrected immediately.

- Actions during the course of an offer (or even before if the board of the offeree company is aware that an offer is imminent) by the offeree company, which might frustrate the offer are generally prohibited unless shareholders approve these plans (or the bidder consents to the proposed course of action). Frustrating actions would include, for example, issuing new shares, lengthening the notice period for directors under their service contract or agreeing to sell off material parts of the target group.
- Stringent requirements are laid down for the disclosure of dealings in relevant securities during an offer, including the prompt disclosure of positions and dealing in relevant securities by the parties to an offer and any person who is interested (directly or indirectly) in 1% or more of any class of relevant securities.
- Employees of both the offeror and the offeree company and the trustees of the offeree company's pension scheme must be informed about an offer. In addition, the offeree company's employee representatives and pension scheme trustees have the right to have a separate opinion on the effects of the offer on employment and pension schemes appended to the offeree board of directors' circular or published on a website.

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

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

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

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

General Risk Factors

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

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

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

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

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

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

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

We may also face new regulatory costs and challenges that could have an adverse effect on our operations. The impact of the terms of the recent trade deal between the UK and EU are uncertain. Since the regulatory framework in the UK covering quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from EU directives and regulations, Brexit could materially impact the future regulatory regime with respect to the commercialization of our products in the UK. Any delay in commercializing our products in the UK and/or the EU could restrict our ability to generate revenue and achieve and sustain profitability. The uncertainty around the UK's future relationship with the EU continues to cause economic uncertainty which could adversely impact customer confidence resulting in customers reducing their spending budgets on our solutions, which could adversely affect our business, revenue, financial condition, results of operations and could adversely affect the market price of our ADSs.

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

While we may seek additional funding through public or private financings, we may not be able to obtain financing on acceptable terms, or at all. There can be no assurance that we will be able to access equity or credit markets in order to finance our current operations or expand development programs for VASCEPA, or that there will not be deterioration in financial markets and confidence in economies, particularly in light of the continued volatility attributed to COVID-19. We may also have to scale back or further restructure our operations. If we are unable to obtain additional funding on a timely basis, we may be required to curtail or terminate some or all of our research or development programs or our commercialization strategies.

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

We may seek additional capital through a combination of private and public equity offerings, debt financings and collaboration, strategic and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a shareholder.

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

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

On a regular basis, we explore potential business combination transactions, including an acquisition of us by a third party, exclusive licenses of VASCEPA or other strategic transactions or collaborations with third parties. The consummation and performance of any such future transactions or collaborations will involve risks, such as:

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

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

Item 1B. ***Unresolved Staff Comments***

None.

Item 2. ***Properties***

The following table lists the location, use and ownership interest of our principal properties as of March 1, 2022:

Location	Use	Ownership	Size (sq. ft.)
Dublin, Ireland	Offices	Leased	1,408
Bridgewater, New Jersey, USA	Offices	Leased	67,747
Frankfurt, Germany	Offices	Leased	1,324
Solna, Sweden	Offices	Leased	463
Zug, Switzerland	Offices	Leased	4,511

On April 12, 2019, we entered into an Office Centre Sharing Agreement for office space in Dublin, Ireland effective May 1, 2019, which has been extended for two successive one year periods, currently through April 30, 2022, and can continue to be extended automatically for successive one year periods. On July 4, 2019, we entered into an Office Centre Sharing Agreement effective October 1, 2019 for office space in Dublin, Ireland, which also has been annually extended for successive one year periods, currently through April 30, 2022, and can be extended automatically for successive one year periods. On August 1, 2020 we entered into an Office Centre Sharing Agreement effective September 14, 2020 for office space in Dublin, Ireland which was extended for one additional year through April 30, 2022, and can be extended automatically for successive one year periods. On July 6, 2021, we entered into an Office Centre Sharing Agreement for office space in Dublin, Ireland effective September 1, 2021, with month-to-month terms set to automatically renew at the end of every month. On November 6, 2021, we entered into an Office Centre Sharing Agreement for office space in Dublin, Ireland effective November 15, 2021, with month-to-month terms set to automatically renew at the end of every month.

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 March 30, 2021, we entered into two Office Centre Share Agreements for office space in Frankfurt, Germany effective April 1, 2021 and July 1, 2021 which terminates on June 30, 2022 and can be extended automatically for successive one year periods. On October 4, 2021 we entered into two Office Centre Share Agreements for office space in Frankfurt, Germany effective October 15, 2021 which terminates on June 30, 2022 and can be extended automatically for successive one year periods.

On October 21, 2021, we entered into two Office Centre Share Agreements for office space in Solna, Sweden effective November 1, 2021 and December 1, 2021 which terminates on November 30, 2022 and can be extended automatically for successive one year periods.

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 5-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—8 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 2021		Fiscal 2020	
	High	Low	High	Low
First Quarter	$ 9.25	$ 4.80	$ 21.84	$ 3.95
Second Quarter	$ 6.58	$ 4.16	$ 8.46	$ 4.00
Third Quarter	$ 5.97	$ 3.84	$ 7.90	$ 3.36
Fourth Quarter	$ 5.24	$ 3.11	$ 5.57	$ 3.96

Shareholders

As of January 31, 2022, there were approximately 340 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 common shares and do not anticipate paying any cash dividends on the common 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.

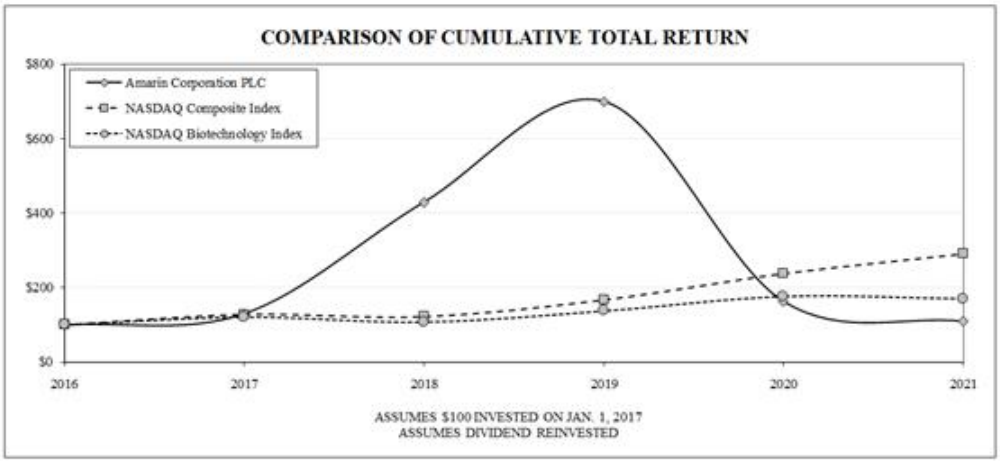
Performance Graph—5 Year

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 5-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 30, 2016 and its relative performance is tracked through December 31, 2021.

Included in this 5-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 5-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. During

the majority of this 5-year time period, cumulative total return for Amarin's ADSs approximated or exceeded both the NASDAQ Composite Index and NASDAQ Biotechnology Index.



Company/Market/Peer Company	12/31/2017	12/31/2018	12/31/2019	12/31/2020	12/31/2021
Amarin Corporation PLC	$ 130.19	$ 429.87	$ 699.68	$ 162.66	$ 109.42
NASDAQ Composite Index	$ 128.24	$ 122.32	$ 167.31	$ 237.87	$ 290.63
NASDAQ Biotechnology Index	$ 121.06	$ 107.67	$ 137.61	$ 176.79	$ 170.55

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 2021 are as follows:

Period	Total Number of Shares Purchased [1]	Average Price Paid per Share
October 1 – 31, 2021	4,446	$ 4.94
November 1 – 30, 2021	22,417	4.06
December 1 – 31, 2021	5,401	3.70
Total	32,264	$ 4.12

(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, 2021 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, 2021.

Overview

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

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

United States

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

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

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

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

We have continued to monitor the effect of COVID-19 and its impact on patient visits to doctors. Our level and type of promotion has varied during the pandemic based on the determination of whether the cost was justified in light of COVID-19's impact at a given time. We anticipate that at-risk patients will increasingly resume visiting their doctors for non-urgent medical care after they are vaccinated for COVID-19, however, we cannot accurately predict when this resumption in visits to doctors will occur and, because many patients have multiple medical issues, we cannot predict the degree to which healthcare professionals will be proactive in seeking to reduce cardiovascular risk in at-risk patients when these patients resume visiting their doctors. The timing is likely to vary by geography. We resumed on a very limited basis, a direct-to-patient campaign in January 2021, including television-based promotion, digital and social media promotion to continue to grow consumer awareness of VASCEPA. In June 2021, we launched an educational campaign, *It's Clear to Me Now*, to help physicians and patients learn more about the differentiation between VASCEPA and fenofibrates for CV risk reduction. The differentiation is important for physicians and patients as the U.S. FDA removed use with statins for CV risk reduction from the fenofibrates' label based on a failed CV risk outcomes trial. In September 2021, we announced our Go-to-Market strategy to optimize provider engagement and drive demand for VASCEPA and contains three key strategic priorities:

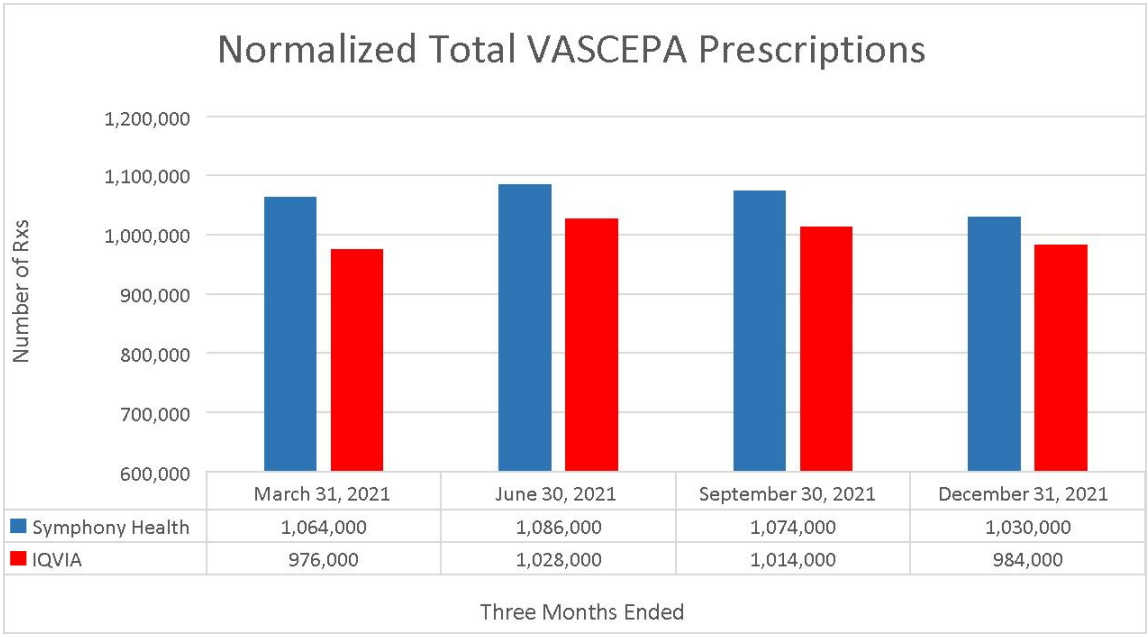
- *Expanding healthcare provider engagement:* Our omnichannel approach which is designed to enhance our reach to healthcare professionals, and aims to target a far greater number of the almost 700,000 statin prescribers through high frequency, and tailored messaging regarding the significant benefits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

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

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

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

when actual data is unavailable. Based on data from Symphony Health and IQVIA, the below chart represents the estimated number of normalized total VASCEPA prescriptions over the year ended December 31, 2021.



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

The resulting conclusions from Symphony Health and IQVIA are rarely identical and should be viewed with caution. The previous calculations of prescription levels by these vendors can change between periods and can be significantly affected by lags in data reporting from various sources or by changes in pharmacies and other distributors providing data. Such methods can from time to time result in significant inaccuracies in information when ultimately compared with actual results. These inaccuracies have historically been most prevalent and pronounced during periods of time of inflections upward or downward in rates of use. Further, data for a single and limited period may not be representative of a trend or otherwise predictive of future results. We are not responsible for the accuracy of these companies' information and we do not receive prescription data directly from retail pharmacies.

Europe

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

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

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

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

Rest of World

China

In February 2015, we announced an exclusive agreement with Eddingpharm (Asia) Macao Commercial Offshore Limited, or Edding, to develop and commercialize VASCEPA capsules in what we refer to as the China Territory, consisting of the territories of Mainland China, Hong Kong, Macau and Taiwan, for uses that are currently commercialized and under development by us in the United States. Edding, with our support, conducted a clinical trial of VASCEPA in China, which evaluated the effect of VASCEPA on patients with very high triglyceride levels (>500 mg/dL). In November 2020, we announced statistically significant topline positive results from this Phase 3 clinical trial of VASCEPA conducted by Edding. The study, which investigated VASCEPA as a treatment for patients with very high triglycerides (≥500 mg/dL), met its primary efficacy endpoint as defined in the clinical trial protocol and demonstrated a safety profile similar to placebo. Importantly, the VASCEPA 4 gram per day dose in this study appeared to be well-tolerated with a safety profile similar to placebo. There were no treatment-related serious adverse events in this study. On February 9, 2021, we announced that the regulatory review processes in Mainland China and Hong Kong have commenced. The National Medical Products Administration, or NMPA, has accepted for review the new drug application for VASCEPA, submitted by Edding, based on the results from the Phase 3 clinical trial and the results from our prior studies of VASCEPA. We expect to receive a decision from the NMPA in Mainland China in the second half of 2022. The Hong Kong Department of Health is evaluating VASCEPA based on current approvals in the United States and Canada. The review process in Hong Kong is expected to conclude in the second half of 2022.

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 2018	April 2021	—
Bahrain	April 2021	—	—
Kuwait	December 2021	—	—

Canada

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

plans for statin-treated patients with established cardiovascular diseases and elevated triglycerides. HLS also received notification by the Patented Medical Prices Review Board that, further to its review, VASCEPA's price did not trigger the investigation criteria for excessive pricing. Coverage of patients with established cardiovascular disease represents a substantial portion of VASCEPA's approved label in Canada. VASCEPA has the benefit of data protection afforded through Health Canada until the end of 2027, in addition to separate patent protection with expiration dates that could extend into 2039.

Other

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

Research and Development

Since its inception in 2011, conduct of the REDUCE-IT cardiovascular outcomes study of VASCEPA has been the centerpiece of our research and development. Most of our other research and development during this period also pertained to VASCEPA, including study of the mechanism of action of the single active ingredient in VASCEPA, icosapent ethyl. The REDUCE-IT study was conducted based on a special protocol assessment, or SPA, agreement with the U.S. FDA. 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. The REDUCE-IT study topline results were made public in September 2018, and the primary results of the REDUCE-IT study were presented at the 2018 Scientific Sessions of the AHA on November 10, 2018 with such results concurrently published in *The New England Journal of Medicine*. The total (first and subsequent) cardiovascular events results of the REDUCE-IT study were presented at the American College of Cardiology's 68th Annual Scientific Session in March 2019 and concurrently published in the *Journal of the American College of Cardiology.*

The U.S. FDA granted Priority Review designation to our March 2019 sNDA seeking an expanded indication for VASCEPA in the United States based on the positive results of the REDUCE-IT study. The U.S. FDA grants Priority Review designation to applications for drugs that, if approved, have the potential to offer significant improvements in the effectiveness and safety of the treatment of serious conditions when compared to standard applications. In November 2019, the U.S. FDA held an EMDAC meeting to review the REDUCE-IT sNDA. The EMDAC voted unanimously (16-0) to recommend approval of an indication and label expansion for VASCEPA to reduce cardiovascular events in high-risk patients based on the REDUCE-IT results. On December 13, 2019, the U.S. FDA approved an indication and related label expansion based on REDUCE-IT. 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. Reflecting the robust results of the clinical development program for VASCEPA, no additional post-approval clinical study or other special post-approval requirement (as often seen with other drug approvals) was requested by the U.S. FDA in conjunction with its approval of VASCEPA.

Based on REDUCE-IT results, as of the date of the filing of this Annual Report on Form 10-K, 26 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 2021 through the filing date of this Annual Report on Form 10-K as listed below:

- The Polish Cardiac Society Working Group on Cardiovascular Pharmacotherapy, or SFSN PTK, published a consensus statement on the management of dyslipidemia. The statement by SFSN PTK recommends 4g of EPA, icosapent ethyl, daily in combination with statins for patients with TG levels 135–499 mg/dL in the high- and very-high-risk categories. The statement mentions that based on the REDUCE-IT study, 2g of icosapent ethyl twice daily in combination with statins significantly reduced the risk of CV events and lowered TG levels. SFSN PTK acknowledges that icosapent ethyl is not approved for use in Poland and data from REDUCE-IT cannot be extrapolated to other doses and formulation of omega-3s.
- The Diabetes CardioRenal Metabolic Diseases, or DCRM, Task Force published practice recommendations for the management of DCRM. The practice recommendation recommends icosapent ethyl, VASCEPA, for the primary prevention of myocardial infarction, coronary artery disease, or stroke in patients with diabetes and for secondary prevention of these events in those with and without diabetes. DCRM further states that based on evidence from

REDUCE-IT, adding IPE to statin therapies further reduces the risk of ASCVD events in patients with TG levels 135–500 mg/dL (1.5–5.7 mmol/L) who have ASCVD or diabetes plus 2 major ASCVD risk factors.

- The AHA issued a scientific statement on the comprehensive management of CV risk factors for adults with type 2 diabetes. The AHA statement recommends patients with diabetes and ASCVD or patients with diabetes at high risk for ASCVD with serum TG levels of 135–500 mg/dL despite maximally tolerated statin therapy, and addressing contributory factors including lifestyle modification, prescription IPE at a dose of 4 grams/day should be considered given the 30% additional CV risk reduction in the REDUCE-IT trial. AHA further states that for primary prevention in type 2 diabetes, a moderate-intensity statin should be considered based on age, absolute ASCVD risk, or the presence of risk-enhancing factors. Non-statin therapies including ezetimibe, PCSK9 inhibitors, IPE, bile acid resins, and fibrates should be considered after thorough evaluation of risk, LDL-C level after optimal statin therapy, and presence of hypertriglyceridemia.

Based on our current understanding of the biological effects of a COVID-19 infection, including that patients at high risk of cardiovascular disease are at higher risk of mortality and severe effects from a COVID-19 infection, and based on data related to the mechanism of action and effects of VASCEPA in lowering cardiovascular risk in certain high-risk patients, we believe that VASCEPA could play a beneficial clinical role in helping patients infected by the virus. We have supported investigator initiated studies by providing study drug product and limited financial support to investigators in multiple pilot studies designed to better understand the potential of VASCEPA and its potentially beneficial role. On December 12, 2020, we announced at the National Lipid Association Scientific Sessions 2020 positive clinical results from the first study of VASCEPA in COVID-19 infected outpatients, CardioLink-9. On August 31, 2021 and November 16, 2021, we announced the results from the PREPARE-IT-1 and PREPARE-IT-2 studies on the effects of VASCEPA reducing COVID-19 infections and hospitalizations, respectively, neither of which met the primary and/or other endpoints studied. If the results of the other pilot study is positive, we will evaluate whether additional studies will be appropriate. The clinical effects of VASCEPA are multi-factorial. Multiple mechanisms of action associated with VASCEPA from clinical and mechanistic studies support the rationale to study its effects in patients with the COVID-19 infection. Additional postulated mechanisms that might play a role in the use of VASCEPA in the patients infected with COVID-19 include potential antiviral/antimicrobial effects, fibrosis and cardiac damage mitigation in animal models and anti-inflammatory effects (acute) in pulmonary/lung tissue.

In June 2018, we entered into a multi-faceted collaboration with Mochida Pharmaceutical Co. Ltd., or Mochida, related to the development and commercialization of drug products and indications based on the active pharmaceutical ingredient in VASCEPA, the omega-3 acid, EPA. 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.

During 2021, we added to our growing body of knowledge on VASCEPA as a result of our continued analysis of the REDUCE-IT trial results. The REDUCE-IT STROKE analyses examined stroke rates across the enrolled patient population, noting a relative risk reduction in strokes and ischemic stroke of 28% and 36%, respectively. The REDUCE-IT HEART FAILURE analyses examined the effects of icosapent ethyl on the incidence of the new heart failure by achieved on-treatment serum EPA levels, with further testing needed. We also analyzed the effect of VASCEPA on patients with prior myocardial infarction to determine if treatment reduced further ischemic events in those subjects, noting VASCEPA reduced first and total primary endpoints by 26% and 35%, respectively. Finally, we analyzed the effects of VASCEPA on patients with prior peripheral artery diseases to determine if it reduced further ischemic events, noting VASCEPA reduced first and total primary endpoints by 32%.

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

Commercial and Clinical Supply

We manage the manufacturing and supply of VASCEPA internally and have done so since we began clinical development of VASCEPA prior to the drug's marketing approval by U.S. FDA in 2012. We rely on contract manufacturers in each step of our commercial and clinical product supply chain. These steps include active pharmaceutical ingredient, or API, manufacturing, encapsulation of the API, product packaging and supply-related logistics. Our approach to product supply procurement is designed to mitigate risk of supply interruption and maintain an environment of cost competition through diversification of contract manufacturers at each stage of the supply chain and lack of reliance on any single supplier. We have multiple U.S. FDA-approved international API suppliers, encapsulators and packagers to support the VASCEPA commercial franchise. We also have multiple international API suppliers, encapsulators and packagers to support the commercialization of VASCEPA in geographies where the drug is approved

outside the United States. Not all of our suppliers approved by the U.S. FDA are approved in every other geography. The regulatory process generally requires extensive details as part of the submission provided to a country or region in connection with a company's request for regulatory approval. Suppliers must be specifically identified as part of the submission for qualification and approval for commercialization in a country or region. As a result, only supply, as approved, may be used in finished goods available for sale in a specific country or region. The amount of supply we seek to purchase in future periods will depend on the level of growth of VASCEPA revenues and minimum purchase commitments with certain suppliers. While our current supply chain is scalable, we continue efforts to expand, diversify and further enhance it.

Impact of COVID-19

As of December 31, 2021, according to CDC data, approximately 60% of the U.S. population has been fully vaccinated, which does not include a booster shot, and approximately 75% of the U.S. population has received at least one dose of a vaccine. While according to CDC data, the population's vaccination rate has increased, the number of new cases increased at the end of 2021 and into early 2022, driven by the Omicron variant.

Our ability to directly promote VASCEPA to healthcare professionals has been limited due to appropriate social distancing practices associated with COVID-19 and by patients electing to forego visiting their doctors for non-urgent medical examinations and/or choosing to not get blood tests which the results of these tests provide useful information to the treatment of cardiovascular risk. These limitations have had a significant impact on slowing VASCEPA prescription and revenue growth. Although some of these restrictions were lifted throughout parts of 2021, in light of the increase in cases in the fourth quarter of 2021 due to the Omicron variant and despite the prevalence of the vaccines, many restrictions have been put back in place and access remains variable and challenging due to COVID-19. While COVID-19 continues to impact our promotion of VASCEPA, we have seen signs of improvement in access to face-to-face interactions with healthcare providers.

In the United States, prior to the recent surge at the end of 2021, at-risk patients increasingly resumed visiting their doctors for non-urgent medical care after they are vaccinated for COVID-19 and we anticipate that to continue when the current surge in cases decreases. We continued to adjust our promotional initiatives throughout 2021 and plan to adjust throughout 2022, including pursuing increased face-to-face interactions with health care professionals and expanding various forms of direct-to-patient promotion based on COVID-19 protocols that are in place.

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

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

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

Management Succession Plans

As announced in April 2021, effective August 1, 2021, John Thero retired from his positions as President and Chief Executive Officer and member of our board of directors and is now providing phased transitional and consulting services to us. Effective August 1, 2021, our board of directors appointed Karim Mikhail, previously our Senior Vice President, Commercial Head Europe, to succeed Mr. Thero as our President and Chief Executive Officer, as well as, a member of our board of directors. In addition, we have announced the appointment of Laurent Abuaf as our new Senior Vice President, and President of Europe to fill the opening left by Mr. Mikhail's promotion. Effective August 1, 2021, Joseph Kennedy retired from his position of Executive Vice President and General Counsel. Our search to hire a new General Counsel was completed with Jason Marks joining the Company in August 2021, in the role of Senior Vice President and Chief Legal Officer with Mr. Kennedy supporting this transition and providing consulting support on certain legal matters.

In addition, we announced that Per Wold-Olsen joined our board of directors on January 10, 2022.

Financial Operations Overview

Product revenue, net. All of our product revenue is derived from product sales of 1-gram and 0.5-gram size capsules of VASCEPA, net of allowances, discounts, incentives, rebates, chargebacks and returns. In the United States, we sell product to a limited number of major wholesalers, as well as selected regional wholesalers and mail order pharmacy providers, or collectively, our distributors or our customers, most of whom resell the product to retail pharmacies for purposes of their reselling the product to fill patient prescriptions. Revenues from product sales are recognized when the customer obtains control of our product, which occurs at a point in time, typically upon delivery to the customer. Timing of shipments to wholesalers, as used for revenue recognition, and timing of prescriptions as estimated by third-party sources such as Symphony Health and IQVIA may differ from period to period. During the years ended December 31, 2021 and 2020, our Product revenue, net included adjustment for co-pay mitigation rebates provided by us to commercially insured patients. Such support is intended to offset a portion of the out-of-pocket expense that patients are required to pay for VASCEPA based upon the benefit design of their prescription drug coverage. Our cost for these co-payment support payments in both of the years ended December 31, 2021 and 2020 was up to $150 per 30-day prescription filled and up to $450 per 90-day prescription filled.

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

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

Cost of goods sold. Cost of goods sold includes the cost of API for VASCEPA on which revenue was recognized during the period, as well as the associated costs for encapsulation, packaging, shipment, supply management, quality assurance, insurance, and other indirect manufacturing, logistics and product support costs. The cost of the API included in Cost of goods sold reflects the average cost method of inventory valuation and relief. This average cost reflects the actual purchase price of VASCEPA API. Our cost of goods sold is not materially impacted by whether we sell VASCEPA directly in a country or we sell VASCEPA to a commercial partner for resale in a country.

Selling, general and administrative expense. Selling, general and administrative expense consists primarily of salaries and other related costs, including stock-based compensation expense, for personnel in our sales, marketing, executive, business development, finance and information technology functions. Other costs primarily include facility costs and professional fees for accounting, consulting and legal services.

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

Restructuring expense. Restructuring expense consists of restructuring costs incurred under our September 2021 Go-to-Market strategy implementation, which consists of severance pay, incentive compensation, insurance benefits and stock-based compensation expense.

Interest and other (expense) income, net. Interest expense primarily consists of interest incurred under our December 2012 royalty-bearing instrument financing arrangement, which was calculated based on an estimated repayment schedule and was paid in full in 2020. Interest income consists of interest earned on our cash and cash equivalents, as well as our short term and long-term investments. Other (expense) income, net, consists primarily of foreign exchange losses and gains.

Income tax (provision) benefit. Income tax (provision) benefit, 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, 2021 and 2020 are not more likely than not to be realized. On March 27, 2020, the CARES Act was enacted in the United States. Among other provisions, the CARES Act allows businesses to carry back net operating losses arising in years 2018 to 2020 to the five prior tax years.

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, we evaluate our estimates and judgments. We base our estimates on historical experience and on various market-specific and other relevant assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. Estimates are assessed each period and updated to reflect current information. A summary of our critical accounting policies, significant judgments and estimates is presented in 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, we recognize revenue when our distributors obtain control of promised goods or services, 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 $583.2 million and $614.1 million during the years ended December 31, 2021 and 2020, respectively. For a complete discussion of our accounting for net product revenue and licensing and royalty revenues, which make up Total revenue, net, see Note 2—Significant Accounting Policies.

We sell VASCEPA principally to a limited number of distributors that in turn resell VASCEPA to retail pharmacies that subsequently resell it to patients and healthcare providers.

We began recognizing revenue from the sale of VASCEPA following our commercial launch in the United States in January 2013. Prior to 2013, we recognized no revenue from VASCEPA sales. In accordance with GAAP, we recognize revenue when the Distributor obtains control of our product, which occurs at a point in time, typically upon delivery to the Distributor. We recognized Product revenue, net of $580.3 million and $607.0 million based on sales to distributors during the years ended December 31, 2021 and 2020, respectively.

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 that we charge 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 discounts, such as Medicaid reimbursements, (c) reserves for expected product returns and (d) estimated costs of incentives offered to certain indirect customers, including patients. The gross to net deductions are estimated based on available actual information, historical data, known trends, and levels of inventory in the distribution channel. We rely on resale data provided by our distributors as well as prescription data provided by Symphony Health 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 each of the three and twelve months ended December 31, 2021 and 2020.

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. Up-front payments and fees are recorded as deferred revenue upon receipt or when due and may require deferral of revenue recognition to a future period until 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, 2021, 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, 2021 and 2020. 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 2021 and 2020. For a comparison of our results of operations and financial condition for fiscal years 2020 and 2019, see "Item 7—Management's Discussion and Analysis of Financial Condition and Results of Operations" of our 2020 Annual Report on Form 10-K, filed with the SEC on February 25, 2021.

Comparison of Fiscal Years Ended December 31, 2021 and December 31, 2020

Total revenue, net. We recorded total revenue, net, of $583.2 million and $614.1 million during the years ended December 31, 2021 and 2020, respectively, a decrease of $30.9 million, or 5%. Total revenue, net consists primarily of revenue from the sale of VASCEPA in the United States. In addition to the United States, we also sell VASCEPA by prescription in Germany and is available by prescription in Canada, Lebanon and the United Arab Emirates through collaborations with third-party companies. As further discussed below, this decrease consists of a $20.2 million decrease in U.S. product revenue, a decrease of $6.5 million in net product revenue from sales of VASCEPA outside of the United States and a $4.2 million decrease licensing and royalty revenue.

Product revenue, net. We recorded product revenue, net, of $580.3 million and $607.0 million during the years ended December 31, 2021 and 2020, respectively, a decrease of $26.7 million, or 4%. This decrease was driven primarily by volume of VASCEPA sales to our customers in the United States, which was adversely impacted by generic availability in the U.S., as well as timing of sales outside the U.S., as further described below.

- Generics in the U.S. - Inclusive of generic icosapent ethyl, based on prescription levels reported by Symphony Health, the icosapent ethyl market increased for the year ended December 31, 2021 by 11% as compared to the year ended December 31, 2020. Based on the available data from Symphony Health, generic prescriptions of icosapent ethyl for the year ended December 31, 2021 were approximately 15% of the total icosapent ethyl prescriptions, which includes the second generic entrant into the market, Dr. Reddy's, late in the second quarter of 2021 providing additional generic supply, further impacting the volume of branded sales during the year ended December 31, 2021. Product revenue, net in the fourth quarter of 2021 was flat as compared to the third quarter of 2021, following the launch of our Go-to-Market strategy which was announced on September 22, 2021.

  We will continue to monitor the generic prescription market in the U.S. and will vigorously protect our cardiovascular risk reduction patents, as deemed appropriate. In addition, based on available information, we believe that a significant number of icosapent ethyl prescriptions in the U.S. have gone unfilled during 2021, due to general market disruption of order fulfillment processes. These processes at the pharmacy level have favored generic products in that in anticipation of receiving generic supply, in certain circumstances pharmacists have opted to wait to fill prescriptions with generic product by ordering product for later fulfillment. In the case of icosapent ethyl, in many U.S. markets, generic product has been delayed or unavailable. In addition, we have heard multiple reports of patients finding that the generic product is more expensive than they have historically paid for the branded product resulting in their refusal to fill their prescriptions.

- In addition, we recognized net product revenue of approximately $2.4 million and $8.9 million as of December 31, 2021 and 2020, respectively for VASCEPA sales outside of the United States, primarily as a result of an initial order to ensure availability of adequate product supply for the launch of VASCEPA in Canada in 2020. We also recognized product revenue of $0.7 million related to VAZKEPA sales in Europe, where the launch of VAZKEPA occurred at the end of the third quarter of 2021.

Despite the generic competition in the U.S., including a third generic entrant in January 2022, we remain confident that the patient need for VASCEPA is high. We believe that our U.S. Go-to-Market strategy began showing early signs of positive results in the fourth quarter of 2021. We will continue to work closely with payers to ensure that VASCEPA maintains a net cost advantage compared to generic icosapent ethyl products. We have partnered with BlinkRx, a unique patient solution, to provide an enhanced, digital first prescription fulfillment channel. As a result of the continued uncertainty of the global impact of COVID-19, the impact of generic competition in the U.S. and challenges for most drugs seeking market access in Europe, we are not providing revenue guidance at this time. We will consider resuming revenue guidance when there is greater clarity on the impact of these items.

Licensing and royalty revenue. Licensing and royalty revenue during the years ended December 31, 2021 and 2020 was $2.9 million and $7.0 million, respectively, a decrease of $4.2 million, or 59%. Licensing and royalty revenue relates to the recognition of amounts received in connection with the following VASCEPA licensing agreements:

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

The up-front and milestone payments are being recognized over the estimated period in which we are required to provide regulatory and development support pursuant to the agreements. The amount of licensing and royalty revenue is expected to vary from period to period based on timing of milestones achieved and changes in estimates of the timing and level of support required.

As part of our licensing agreements 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, 2021 and 2020 was $121.3 million and $131.4 million, respectively, a decrease of $10.1 million, or 8%. Cost of goods sold includes the cost of API for VASCEPA on which revenue was recognized during the period, as well as the associated costs for encapsulation, packaging, shipment, supply management, insurance and quality assurance. The cost of the API included in cost of goods sold reflects the average cost of API included in inventory. This average cost reflects the actual purchase price of VASCEPA API.

The API included in the calculation of the average cost of goods sold during the years ended December 31, 2021 and 2020 was sourced from multiple API suppliers. These suppliers compete with each other based on cost, consistent quality, capacity, timely delivery and other factors. In the future, we may see the average cost of supply change based on numerous potential factors including increased volume purchases, continued improvement in manufacturing efficiency, the mix of purchases made among suppliers, currency exchange rates and other factors. We currently anticipate API average cost in 2022 to be similar to or modestly lower than 2021. The average cost may be variable from period to period depending upon the timing and quantity of API purchased from each supplier.

Our gross margin on product sales for the years ended December 31, 2021 and 2020 was 79% and 78%, respectively.

Selling, General and Administrative Expense. Selling, general and administrative expense for the years ended December 31, 2021 and 2020 was $408.3 million and $463.3 million, respectively, a decrease of $55.0 million, or 12%. Selling, general and administrative expenses for the years ended December 31, 2021 and 2020 are summarized in the table below:

	Year Ended December 31,	
In thousands	**2021**	**2020**
Selling expense (1)	$ 266,474	$ 350,648
General and administrative expenses (2)	109,555	73,419
Non-cash stock-based compensation expense (3)	32,305	39,245
Total selling, general and administrative expense	$ 408,334	$ 463,312

(1) Selling expense for the years ended December 31, 2021 and 2020 was $266.5 million and $350.6 million, respectively, a decrease of $84.2 million, or 24%. This decrease is primarily due to a decrease in marketing and direct-to-consumer promotions in 2021, as a result of the impact of COVID-19 and our focus on improving the profitability of our operations in the United States. The decrease also includes a reduction in costs associated with our Go-to-Market strategy resulting in decreased promotional initiatives, reduced travel and a decrease in our sales force.

(2) General and administrative expense for the years ended December 31, 2021 and 2020 was $109.6 million and $73.4 million, respectively, an increase of $36.1 million, or 49%. This increase is primarily due to increased personnel costs related to preparing for and commencing expansion into Europe.

(3) Non-cash stock-based compensation expense for the years ended December 31, 2021 and 2020 was $32.3 million and $39.2 million, respectively, a decrease of $6.9 million, or 18%. 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 certain performance-based awards as it was no longer deemed probable that the performance criteria for vesting would be achieved within the required timeframe and the reversal of expense associated with the reduction in U.S. field force.

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

Research and Development Expense. Research and development expense for the years ended December 31, 2021 and 2020 was $29.3 million and $39.0 million, respectively, a decrease of $9.7 million, or 25%. Research and development expenses for the years ended December 31, 2021 and 2020 are summarized in the table below:

	Year Ended December 31,	
In thousands	**2021**	**2020**
REDUCE-IT study (1)	$ 3,607	$ 10,777
Regulatory filing fees and expenses (2)	1,441	2,651
Internal staffing, overhead and other (3)	19,932	18,963
Research and development expense, excluding non-cash expense	24,980	32,391
Non-cash stock-based compensation expense (4)	4,327	6,568
Total research and development expense	$ 29,307	$ 38,959

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

(2) The regulatory filing fees in each of the years ended December 31, 2021 and 2020 included annual U.S. FDA fees for maintaining manufacturing sites. Such fees primarily represent fees for qualification of new suppliers, including increasing capacity capabilities, and fees to support international regulatory review of VASCEPA, particularly in Europe, sites used for the manufacture of product used in the REDUCE-IT clinical outcomes study.

(3) Internal staffing, overhead and other research and development expenses primarily relate to the costs of our personnel employed to manage research, development and regulatory affairs activities and related overhead costs including consulting and other professional fees that are not allocated to specific projects, including costs associated with securing regulatory approvals for VAZKEPA in Europe as achieved in 2021. Also included are costs related to qualifying suppliers. Also included are costs associated with various other investigations, including other costs in collaboration with Mochida and pilot studies regarding VASCEPA.

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

We anticipate our research and development expenses to significantly increase in 2022 primarily due to our initiative to reduce residual cardiovascular risk by developing a fixed dose combination of VASCEPA and a statin.

Restructuring expense. Restructuring expense for the years ended December 31, 2021 and 2020 was $13.7 million and nil, respectively. The charge is due to the launch of the Go-to-Market strategy announced on September 22, 2021, which primarily related to the reduction of our U.S. field force to approximately 300 sales professionals. Refer to *Note 2 Significant Accounting Policies* for additional information.

Interest Income, net. Net interest income for the years ended December 31, 2021 and 2020 was $1.1 million and $2.3 million, respectively, a decrease of $1.2 million, or 52%. Net interest income for the years ended December 31, 2021 and 2020 is summarized in the table below:

	Year ended December 31,	
In thousands	**2021**	**2020**
Debt from royalty-bearing instrument (1):		
Cash interest	$ —	$ (1,614)
Non-cash interest	—	(635)
Total debt from royalty-bearing instrument interest expense	—	(2,249)
Other interest expense	(129)	(356)
Total interest expense	(129)	(2,605)
Interest income (2)	1,220	4,901
Total interest income, net	$ 1,091	$ 2,296

(1) Cash and non-cash interest expense related to the December 2012 royalty-bearing instrument for the years ended December 31, 2021 and 2020 was nil and $2.2 million, respectively. In November 2020, we made the final payment on our royalty-bearing instrument and, as a result, no interest from this instrument was incurred in 2021.

(2) Interest income for the years ended December 31, 2021 and 2020 was $1.2 million and $4.9 million, respectively. Interest income represents income earned on cash and investment balances. The decrease is a result of COVID-19 and the related economic conditions, including a reduction in interest rates in 2021 as compared to the prior year, resulting in a decrease in interest income, as well as, an overall decrease in our short-term and long-term investment balance during 2021.

Other (expense) income, net. Other (expense) income, net, for the year ended December 31, 2021 and 2020 was expense of $0.3 million and income of $0.1 million, respectively. Other (expense) income, net, in the years ended December 31, 2021 and 2020 primarily consists of gains and losses on foreign exchange transactions.

Provision for income taxes. Provision for income taxes for the year ended December 31, 2021 and 2020 was $3.6 million and $0.7 million, respectively. The increase in the provision for income taxes is due to a change in geographic mix of pre-tax income as well as an increase in our uncertain tax positions.

Liquidity and Capital Resources

Our aggregate sources of liquidity as of December 31, 2021 are approximately $490.0 million, with no debt. Our aggregate sources of liquidity include cash and cash equivalents and restricted cash of $223.4 million, short-term investments of $234.7 million and long-term investments of $35.0 million. Our cash and cash equivalents primarily include checking accounts and money market funds with original maturities less than 90 days. Our short-term investments consist of held-to-maturity securities that will be due in one year or less. Our long-term investments consist of held-to-maturity securities that will be due in more than one year. We invest cash in excess of our immediate requirements, in accordance with our investment policy, which limits the amounts we may invest in any one type of investment and requires all investments held by us to maintain minimum ratings from Nationally Recognized Statistical Rating Organizations so as to primarily achieve our goals of liquidity and capital preservation. Our cash flows from operating, investing and financing activities, as reflected in the consolidated statements of cash flows, are summarized in the following table:

	Year Ended December 31,		
In millions	**2021**	**2020**	**2019**
Cash (used in) provided by:			
Operating activities	$ (66.5)	$ (21.7)	$ (9.4)
Investing activities	104.1	(377.0)	(2.5)
Financing activities	(5.1)	(58.9)	409.6
Increase (decrease) in cash and cash equivalents and restricted cash	$ 32.5	$ (457.6)	$ 397.7

Net cash used in operating activities during 2021 compared to 2020 increased primarily as a result of a decrease in product sales as well as due to costs associated with our expansion into Europe.

Net cash provided by investing activities during the year ended December 31, 2021 is due to the proceeds from the maturity of our investment-grade interest bearing instruments of $394.3 million, partially offset by our purchase of approximately $290.2 million of securities during 2021. Net cash used in investing activities during the year ended December 31, 2020 is as a result of our purchasing approximately $678.7 million investment-grade interest bearing instruments during 2020, partially offset by $302.0 million in proceeds from the maturity and sale of securities.

Net cash used in financing activities during the year ended December 31, 2021 is primarily as a result of costs associated with our stock compensation plan. Net cash used in financing activities during the year ended December 31, 2020 primarily reflects the payments made on our royalty-bearing instrument with CPPIB, with the final payment made in the fourth quarter of 2020.

Net cash provided by financing activities during the year ended December 31, 2019 is primarily due to completing a public offering of 22,222,223 ADS with each ADS representing one ordinary share at a price of $18.00 per ADS, $17.235 per ADS after commission, on July 18, 2019. In addition, we granted the underwriters a 30-day option to purchase up to an additional 3,333,333 ADS at the same price per ADS. On July 29, 2019, the underwriters exercised the full option. This public offering, including the exercised option, resulted in net proceeds of $440.1 million, after deducting customary commissions and offering expenses.

As of December 31, 2021, we had net accounts receivable of $163.7 million and inventory of $355.9 million. We have incurred annual operating losses since our inception until this year and, as a result, we had an accumulated deficit of $1.4 billion as of December 31, 2021. 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, promotional activities under our Go-to-Market strategy and the impact from COVID-19 on our operations and those of our customers, the generic competition in the United States as a result of our ANDA litigation and commercialization of VAZKEPA in Europe.

We believe that our cash and cash equivalents of $219.5 million as of December 31, 2021 together with our short-term investments of $234.7 million as of December 31, 2021, will be sufficient to fund our projected operations for at least twelve months and is adequate to achieve positive cash flow from VASCEPA 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. From time to time, we maintain a small amount of our cash and cash equivalents in Euro and Pound Sterling. We purchase a portion of our supply from Novasep 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., re-financing or re-investment risk). Interest rate risk mainly arises through interest bearing liabilities and assets. Our portfolio of held-to-maturity investments as of December 31, 2021 was composed of U.S. Treasury securities, commercial paper, corporate, CD and asset-backed securities and other government-related securities. At December 31, 2021 and 2020, we had short-term investments and long-term investments of $269.7 million and $376.4 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 held-to-maturity securities that will be due in one year or less. Our long-term investments consist of held-to-maturity securities that will be due in more than one year. We invest cash in excess of our immediate requirements, in accordance with our investment policy, which limits the amounts we may invest in any one type of investment and requires all investments held by us to maintain minimum ratings from Nationally Recognized Statistical Rating Organizations so as to primarily achieve our goals of liquidity and capital preservation. 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, 2021, 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, 2021, 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, 2021. 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, 2021, 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, 2021. 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 2021 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, 2021, 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, 2021, 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, 2021 and 2020, the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2021, and the related notes and our report dated March 1, 2022 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
March 1, 2022

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

Entry into Rule 10b5-1 Trading Plans

Our policy governing transactions in our securities by our directors, officers and employees permits our officers, directors and certain other persons to enter into trading plans complying with Rule 10b5-1 under the Exchange Act. Consistent with such regulation, our policy permits such plans to be entered into only when that person confirms they are not in possession of material non-public information. Our policy also requires a waiting period after a trading plan is created before shares can be traded under the plan. Our open trading windows are established in consultation with legal counsel. We have been from time to time advised that a number of our directors and employees, including members of our senior management team, and investment funds associated with such persons, have entered into trading plans in accordance with Rule 10b5-1 and our policy governing transactions in our securities. It is not our policy to publicly disclose the terms of these private trading plans. We undertake no obligation to update or revise the information provided herein, including for revision or termination of an established trading plan.

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 2022 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 2022 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 2022 Annual General Meeting of Shareholders. 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 2022 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 2022 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 2002 Stock Option Plan*	Annual Report on Form 20-F for the year ended December 31, 2006, as Exhibit 4.17	March 5, 2007
10.2	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
10.3	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
10.4	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
10.5	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
10.6	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
10.7	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
10.8	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
10.9	Amarin Corporation plc Management Incentive Compensation Plan*	Annual Report on Form 10-K for the year ended December 31, 2010, as Exhibit 10.44	March 16, 2011
10.10	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
10.11	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
10.12	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
10.13	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

10.14	2020 Stock Incentive Plan*	Current Report on Form 8-K dated July 13, 2020, as Exhibit 10.1	July 14, 2020
10.15	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
10.16	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
10.17	Form of Restricted Stock Unit Award Agreement*	Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2020, as Exhibit 10.4	November 5, 2020
10.18	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
10.19	Form of Deferred Restricted Stock Unit for Non-Employee Director Award Agreement*	Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2020, as Exhibit 10.6	November 5, 2020
10.20	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
10.21	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
10.22	Employment Agreement between Jason Marks and Amarin Corporation plc, dated July 19, 2021*	Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2021, as Exhibit 10.1	November 3, 2021
10.23	Letter Agreement with Steve Ketchum, dated February 8, 2012*	Registration Statement on Form F-1, as Exhibit 10.1	February 28, 2012
10.24	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
10.25	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
10.26	Letter Agreement, dated May 9, 2016, by and between Amarin Corporation plc and Michael Kalb*	Current Report on Form 8-K dated June 30, 2016, as Exhibit 10.1	June 30, 2016
10.27	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
10.28	Letter Agreement with John Thero, dated January 10, 2014*	Current Report on Form 8-K dated January 8, 2014, as Exhibit 10.1	January 10, 2014
10.29	Amendment, dated July 6, 2015, to Letter Agreement with John Thero, dated January 10, 2014*	Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2015, as Exhibit 10.3	August 6, 2015
10.30	Transitional Services and Separation Agreement between John Thero and Amarin Corporation plc, dated April 12, 2021*	Current Report on Form 8-K dated April 12, 2021, File No. 0-21392, as Exhibit 10.1	April 12, 2021
10.31	Letter Agreement with Joseph Kennedy, dated December 13, 2011*	Current Report on Form 8-K dated December 23, 2011, as Exhibit 10.5	December 23, 2011

10.32	Amendment, dated July 6, 2015, to Letter Agreement with Joseph Kennedy, dated December 13, 2011*	Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2015, as Exhibit 10.1	August 6, 2015
10.33	2011 Long Term Incentive Award with Joseph Kennedy dated December 16, 2011*	Registration Statement on Form S-8, as Exhibit 4.1	March 16, 2012
10.34	Transitional Services and Separation Agreement between Joseph Kennedy and Amarin Corporation plc, dated April 28, 2021*	Current Report on Form 8-K dated April 28, 2021, as Exhibit 10.1	April 29, 2021
10.35	API Commercial Supply Agreement, dated May 25, 2011, between Amarin Pharmaceuticals Ireland Ltd. and Chemport Inc. **	Filed herewith	
10.36	Amendment to API Commercial Supply Agreement by and between Amarin Pharmaceuticals Ireland Ltd and Chemport Inc., dated April 4, 2012 **	Filed herewith	
10.37	Second Amendment to API Commercial Supply Agreement by and between Amarin Pharmaceuticals Ireland Ltd. and Chemport Inc., dated July 19, 2012 **	Filed herewith	
10.38	Purchase and Sale Agreement, dated December 6, 2012, by and between Amarin Corporation plc, Amarin Pharmaceuticals Ireland Limited and BioPharma Secured Debt Fund II Holdings Cayman LP **	Filed herewith	
10.39	Consent and Waiver, dated December 20, 2017, by and among Amarin Pharmaceuticals Ireland Limited, Amarin Corporation PLC, BioPharma Secured Debt Fund II Holdings Cayman LP and Pharmakon Advisors LP	Annual Report on Form 10-K for the year ended December 31, 2017, as Exhibit 10.66	February 27, 2018
10.40	Co-Promotion Agreement dated March 31, 2014, by and among the Company and Kowa Pharmaceuticals America, Inc. ††	Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2014, as Exhibit 10.1	May 9, 2014
10.41	First Amendment to the Co-Promotion Agreement of March 31, 2014 dated July 25, 2017, by and among Amarin Pharmaceuticals Ireland Limited, Amarin Pharma, Inc., and Kowa Pharmaceuticals America, Inc. ††	Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2017, as Exhibit 10.1	August 2, 2017
10.42	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
10.43	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
10.44	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

10.45	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
10.46	Online Office Agreement, dated as of April 12, 2019, by and between Amarin Pharmaceuticals Ireland Limited and Regus CME Ireland Limited	Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2019, as Exhibit 10.2	July 31, 2019
10.47	Office Service Agreement, dated as of April 12, 2019, by and between Amarin Pharmaceuticals Ireland Limited and Regus CME Ireland Ltd.	Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2019, as Exhibit 10.3	July 31, 2019
10.48	Online Office Agreement, dated as of July 3, 2019, by and between Amarin Pharmaceuticals Ireland Limited and Regus CME Ireland Ltd.	Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2019, as Exhibit 10.4	July 31, 2019
10.49	Online Office Renewal Agreement dated as of June 26, 2020, by and between Amarin Pharamecueticals Ireland Limited and Regus CME Irelnad Limited	Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2020, as Exhibit 10.7	November 5, 2020
10.50	Online Office Renewal Agreement dated as of August 30, 2020, by and between Amarin Pharmaceuticals Ireland Limited and Regus CME Ireland Limited	Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2020, as Exhibit 10.8	November 5, 2020
10.51	Online Office Renewal Agreement dated as of February 1, 2020, by and between Amarin Pharmaceuticals Ireland Limited and Regus CME Ireland Limited	Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2020, as Exhibit 10.1	April 30, 2020
10.52	Online Office Agreement dated as of March 30, 2021, by and between Amarin Germany GmbH and Regus	Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2021, as Exhibit 10.1	April 29, 2021
10.53	Online Office Agreement dated as of March 30, 2021, by and between Amarin Germany GmbH and Regus	Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2021, as Exhibit 10.2	April 29, 2021
10.54	English Summary of German Language Commercial Lease Agreement dated October 10, 2021, by and between Amarin Switzerland GmbH and Zug Estates AG	Filed herewith	
10.55	Online Office Agreement dated October 21, 2021, by and between Amarin Switzerland GmbH and Regus	Filed herewith	
10.56	Online Office Agreement dated October 21, 2021, by and between Amarin Switzerland GmbH and Regus	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 Senior Vice President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer) pursuant to Section 302 of Sarbanes-Oxley Act of 2002	Filed herewith
32.1	Certification of President and Chief Executive Officer (Principal Executive Officer) and Senior Vice President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer) pursuant to Section 906 of Sarbanes-Oxley Act of 2002	Furnished herewith
101.INS	Inline XBRL Instance Document	Filed herewith
101.SCH	Inline XBRL Taxonomy Extension Schema Document	Filed herewith
101. CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	Filed herewith
101. DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	Filed herewith
101. LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	Filed herewith
101. PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	Filed herewith
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibit 101.)	Filed herewith

†† 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/ Karim Mikhail
Karim Mikhail
President and *Chief Executive Officer*
(Principal Executive Officer)

Date: March 1, 2022

We, the undersigned officers and directors of the Registrant hereby severally constitute and appoint Karim Mikhail, Michael W. Kalb and Jason Marks, 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/ Karim Mikhail Karim Mikhail	Director, President and Chief Executive Officer (Principal Executive Officer)	March 1, 2022
/s/ Michael W. Kalb Michael W. Kalb	Senior Vice President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 1, 2022
/s/ Lars Ekman, M.D., Ph.D. Lars Ekman, M.D., Ph.D.	Director	March 1, 2022
/s/ Patrick O'Sullivan Patrick O'Sullivan	Director	March 1, 2022
/s/ Kristine Peterson Kristine Peterson	Director	March 1, 2022
/s/ David Stack David Stack	Director	March 1, 2022
/s/ Jan van Heek Jan van Heek	Director	March 1, 2022
/s/ Per Wold-Olsen Per Wold-Olsen	Director	March 1, 2022
/s/ Joseph Zakrzewski Joseph Zakrzewski	Director	March 1, 2022

AMARIN CORPORATION PLC

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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, 2021 and 2020, the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, 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, 2021, 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 March 1, 2022 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, 2021, the Company recorded a liability for product returns totaling $8.1 million. As discussed in Note 14 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

March 1, 2022

AMARIN CORPORATION PLC

CONSOLIDATED BALANCE SHEETS
(in thousands, except share amounts)

	December 31,	
	2021	**2020**
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 219,454	$ 186,964
Restricted cash	3,918	3,915
Short-term investments	234,674	313,969
Accounts receivable, net	163,653	154,574
Inventory	234,676	188,864
Prepaid and other current assets	22,352	30,947
Total current assets	878,727	879,233
Property, plant and equipment, net	1,425	2,016
Long-term investments	34,996	62,469
Long-term inventory	121,254	—
Operating lease right-of-use asset	7,660	8,054
Other long-term assets	456	432
Intangible asset, net	23,547	13,817
TOTAL ASSETS	$ 1,068,065	$ 966,021
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 114,922	$ 105,876
Accrued expenses and other current liabilities	253,111	198,641
Current deferred revenue	2,649	2,926
Total current liabilities	370,682	307,443
Long-Term Liabilities:		
Long-term deferred revenue	14,060	15,706
Long-term operating lease liability	8,576	9,153
Other long-term liabilities	7,648	6,214
Total liabilities	400,966	338,516
Commitments and contingencies (Note 8)		
Stockholders' Equity:		
Common stock, £0.50 par, unlimited authorized; 404,084,775 shares issued, 396,598,008 shares outstanding at December 31, 2021; 398,425,000 shares issued, 392,538,081 shares outstanding at December 31, 2020	294,027	290,115
Additional paid-in capital	1,855,246	1,817,649
Treasury stock; 7,486,767 shares at December 31, 2021; 5,886,919 shares at December 31, 2020	(60,726)	(51,082)
Accumulated deficit	(1,421,448)	(1,429,177)
Total stockholders' equity	667,099	627,505
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 1,068,065	$ 966,021

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,		
	2021	2020	2019
Product revenue, net	$ 580,320	$ 607,025	$ 427,391
Licensing and royalty revenue	2,867	7,035	2,364
Total revenue, net	583,187	614,060	429,755
Less: Cost of goods sold	121,327	131,444	96,019
Gross margin	461,860	482,616	333,736
Operating expenses:			
Selling, general and administrative	408,334	463,312	323,623
Research and development	29,307	38,959	34,392
Restructuring	13,717	—	—
Total operating expenses	451,358	502,271	358,015
Operating income (loss)	10,502	(19,655)	(24,279)
Interest income	1,220	4,901	8,499
Interest expense	(129)	(2,605)	(6,626)
Other (expense) income, net	(302)	104	(75)
Income (Loss) from operations before taxes	11,291	(17,255)	(22,481)
Provision for income taxes	(3,562)	(745)	(164)
Net income (loss)	7,729	(18,000)	(22,645)
Earnings (loss) per share:			
Basic	$ 0.02	$ (0.05)	$ (0.07)
Diluted	$ 0.02	$ (0.05)	$ (0.07)
Weighted average shares outstanding:			
Basic	395,992	381,759	342,538
Diluted	402,480	381,759	342,538

See the notes to the consolidated financial statements.

AMARIN CORPORATION PLC

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

	Preferred Shares	Common Shares	Treasury Shares	Preferred Stock	Common Stock	Additional Paid-in Capital	Treasury Stock	Accumulated Deficit	Total
December 31, 2018	**289,317,460**	**329,110,863**	**(3,260,850)**	**$ 21,850**	**$ 246,663**	**$ 1,282,762**	**$ (10,413)**	**$ (1,388,532)**	**$ 152,330**
Issuance of common stock, net of transaction costs	—	25,555,556	—	—	15,879	424,229	—	—	440,108
Issuance of common stock under employee stock purchase plan	—	123,031	—	—	79	2,086	—	—	2,165
Issuance of common stock for milestone payment	—	257,713	—	—	173	6,043	—	—	6,216
Exercise of stock options	—	5,997,919	—	—	3,876	20,602	—	—	24,478
Vesting of restricted stock units	—	3,969,811	(1,650,142)	—	2,503	(2,503)	(25,487)	—	(25,487)
Stock-based compensation	—	—	—	—	—	31,098	—	—	31,098
Loss for the period	—	—	—	—	—	—	—	(22,645)	(22,645)
December 31, 2019	**289,317,460**	**365,014,893**	**(4,910,992)**	**$ 21,850**	**$ 269,173**	**$ 1,764,317**	**$ (35,900)**	**$ (1,411,177)**	**$ 608,263**
Conversion of Series A Convertible Preferred Stock, net	(289,317,460)	28,931,746	—	(21,850)	18,020	3,326	—	—	(504)
Issuance of common stock under employee stock purchase plan	—	347,153	—	—	225	1,732	—	—	1,957
Exercise of stock options	—	1,623,460	—	—	1,062	4,096	—	—	5,158
Vesting of restricted stock units	—	2,507,748	(975,927)	—	1,635	(1,635)	(15,182)	—	(15,182)
Stock-based compensation	—	—	—	—	—	45,813	—	—	45,813
Loss for the period	—	—	—	—	—	—	—	(18,000)	(18,000)
December 31, 2020	**—**	**398,425,000**	**(5,886,919)**	**$ —**	**$ 290,115**	**$ 1,817,649**	**$ (51,082)**	**$ (1,429,177)**	**$ 627,505**
Issuance of common stock under employee stock purchase plan	—	399,286	—	—	275	1,375	—	—	1,650
Exercise of stock options	—	1,203,845	—	—	827	2,094	—	—	2,921
Vesting of restricted stock units	—	4,056,644	(1,599,848)	—	2,810	(2,810)	(9,644)	—	(9,644)
Stock-based compensation	—	—	—	—	—	36,938	—	—	36,938
Income for the period	—	—	—	—	—	—	—	7,729	7,729
December 31, 2021	**—**	**404,084,775**	**(7,486,767)**	**$ —**	**$ 294,027**	**$ 1,855,246**	**$ (60,726)**	**$ (1,421,448)**	**$ 667,099**

See the notes to the consolidated financial statements.

AMARIN CORPORATION PLC

CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,		
	2021	**2020**	**2019**
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net income (loss)	$ 7,729	$ (18,000)	$ (22,645)
Adjustments to reconcile net income (loss) to net cash used in operating activities:			
Depreciation and amortization	587	597	180
Amortization of investments	1,929	1,602	—
Stock-based compensation	36,938	45,813	30,917
Amortization of debt discount and debt issuance costs	-	635	1,644
Amortization of intangible asset	2,270	1,441	679
Changes in assets and liabilities:			
Accounts receivable, net	(9,079)	(38,144)	(49,907)
Inventory	(167,066)	(112,095)	(18,967)
Prepaid and other current assets	8,595	(17,636)	(10,366)
Other long-term assets	(24)	642	(900)
Interest receivable	738	(1,329)	—
Accrued interest payable	-	(428)	(210)
Deferred revenue	(1,923)	(2,214)	136
Accounts payable, accrued expenses and other current liabilities	51,516	114,741	65,913
Other long-term liabilities	1,253	2,629	(5,840)
Net cash used in operating activities	(66,537)	(21,746)	(9,366)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Sale and maturities of securities	394,294	301,989	—
Purchases of securities	(290,195)	(678,700)	—
Disposal (purchases) of furniture, fixtures and equipment	4	(252)	(2,478)
Net cash provided by (used in) investing activities	104,103	(376,963)	(2,478)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of common stock, net of transaction costs	—	—	440,108
Proceeds from issuance of common stock under employee stock purchase plan	1,650	1,957	2,165
Proceeds from exercise of stock options, net of transaction costs	2,921	5,158	24,478
Payment of transaction costs for conversion of preferred stock	—	(504)	—
Payment on debt from royalty-bearing instrument	—	(50,336)	(31,652)
Taxes related to stock-based awards	(9,644)	(15,182)	(25,487)
Net cash (used in) provided by financing activities	(5,073)	(58,907)	409,612
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS AND RESTRICTED CASH	32,493	(457,616)	397,768
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH, BEGINNING OF PERIOD	190,879	648,495	250,727
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH, END OF PERIOD	$ 223,372	$ 190,879	$ 648,495
Supplemental disclosure of cash flow information:			
Cash received (paid) during the year for:			
Interest	$ -	$ (2,043)	$ (4,591)
Income taxes	$ 3,656	$ (207)	$ (67)
Supplemental disclosure of non-cash transactions:			
Laxdale milestone	$ 12,000	$ —	$ 8,457
Initial recognition of operating lease right-of-use asset	$ —	$ —	$ 8,995
Conversion of Series A Convertible Preferred Stock into common stock	$ —	$ 18,020	$ —

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. Most of the Company's historical revenue and sales, marketing and administrative activities and costs have been associated with commercial operations in the United States, or U.S. In 2021 the Company began to increase pre-launch commercial activities throughout Europe. As of September 1, 2021, product was made available in Germany and as of October 1, 2021 was included in the country's electronic prescribing system. The Company's operations outside of the U.S. and Europe are in early stages of development with reliance on third-party commercial partners in select geographies, including China where regulatory approval for the Company's lead product is being actively sought.

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

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

On May 22, 2020, Hikma received U.S. FDA approval to market its generic version of VASCEPA for the MARINE indication of VASCEPA. In November 2020, Hikma launched their generic version of VASCEPA on a limited scale. On November 30, 2020 the Company filed a patent infringement lawsuit against Hikma for making, selling, offering to sell and importing generic icosapent ethyl capsules in and into the United States in a manner that the Company alleges has induced the infringement of patents covering the use of VASCEPA to reduce specified cardiovascular risk. On January 4, 2022, the district court hearing the case granted Hikma's motion to dismiss. Amarin intends to appeal the decision of the district court. Amarin also intends to continue to vigorously pursue the ongoing litigation with Health Net, LLC, but cannot predict the outcome or impact on its business. On August 10, 2020, Dr. Reddy's received U.S. FDA approval to market its generic version for the MARINE indication of VASCEPA. In June 2021, Dr. Reddy's launched its generic version of VASCEPA with labeling that is substantially similar to labeling of the Hikma generic product. On September 11, 2020, Teva Pharmaceuticals USA, Inc.'s, or Teva's, abbreviated new drug application, or ANDA, was approved by the U.S. FDA and on June 30, 2021, Apotex, Inc.'s, or Apotex's, ANDA was approved by the U.S. FDA. In January 2022, Apotex launched its generic version of VASCEPA with labeling that is substantially consistent with the labeling of the Hikma and Dr. Reddy's generic product, not the cardiovascular risk reduction indication.

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

In November 2020, the Company announced topline results from the Phase 3 clinical trial of VASCEPA conducted by the Company's partner in China. On February 9, 2021, the Company announced that regulatory review processes for approval of VASCEPA in Mainland China and Hong Kong have commenced. The Chinese National Medical Products Administration, or NMPA, has accepted for review the new drug application for VASCEPA based on the results from the Phase 3 clinical trial and the results from the Company's prior studies of VASCEPA. The Hong Kong Department of Health is evaluating VASCEPA based on current approvals in the United States and Canada.

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

Basis of Presentation

The 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, 2021, 2020 and 2019 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, as well as the ongoing global pandemic, COVID-19.

At December 31, 2021, the Company had Total assets of $1,068.1 million, of which $489.1 million consisted of cash and liquid short-term and long-term investments. More specifically, the Company had Current assets of $878.7 million, including Cash and cash equivalents of $219.5 million, Short-term investments of $234.7 million, Accounts receivable, net, of $163.7 million and Inventory of $234.7 million. In addition, at December 31, 2021, the Company had Long-term investments of $35.0 million and Long-term inventory of $121.3 million. At December 31, 2021, 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 are used in determining such items as provisions for sales returns, rebates and incentives, chargebacks, and other sales allowances; depreciable/amortizable lives; asset impairments; valuation allowance on deferred taxes; probabilities of achievement of performance conditions for certain equity awards; amounts recorded for licensing revenue; contingencies and accruals. 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 14—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 remaining maturities at the date of purchase of 90 days or less. Restricted cash represents cash and cash equivalents pledged to guarantee repayment of certain expenses which may be incurred for business travel under corporate credit cards held by employees.

Accounts Receivable, net

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

The following table summarizes the impact of accounts receivable reserves on the gross trade accounts receivable balances at December 31, 2021 and 2020:

In thousands	December 31, 2021	December 31, 2020
Gross trade accounts receivable	$ 262,948	$ 203,875
Trade allowances	(86,636)	(36,242)
Chargebacks	$ (11,714)	(12,114)
Allowance for doubtful accounts	(945)	(945)
Accounts receivable, net	$ 163,653	$ 154,574

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. We classify inventory as long-term inventory when consumption of the inventory is expected beyond our normal operating cycle. An allowance is established when management determines that certain inventories may not be saleable. If inventory cost exceeds expected net realizable value due to obsolescence, damage or quantities in excess of expected demand, changes in price levels or other causes, the Company will reduce the carrying value of such inventory to net realizable value and recognize the difference as a component of cost of goods sold in the period in which it occurs. The Company capitalizes inventory purchases of saleable product from approved suppliers while inventory purchases from suppliers prior to regulatory approval are included as a component of research and development expense. The Company expenses inventory identified for use as marketing samples when they are packaged. The average cost reflects the actual purchase price of VASCEPA active pharmaceutical ingredient, or API.

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 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 and is amortized over its estimated useful life on a straight-line basis. See Note 8—Commitments and Contingencies for further information regarding other obligations related to the acquisition of Laxdale Limited.

Costs for Patent Litigation and Legal Proceedings

Costs for patent litigation or other legal proceedings are expensed as incurred and included in Selling, general and administrative 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 costs of programs and infrastructure necessary for the general conduct of the Company's business, including those incurred as a result of the commercialization of VASCEPA in the United States.

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 share-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 states. The Company is currently under audit by the IRS for the Company's 2018 U.S. income tax return

and by the New Jersey Department of Treasury for the years 2012 to 2015 and the New York State Department of Taxation and Finance for the years 2017 and 2018. 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.

Earnings (Loss) per Share

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

The Company's preferred stock, of which none is outstanding as of December 31, 2021 and December 31, 2020, was entitled to receive dividends on an as-if-converted basis in the same form as dividends actually paid on common shares. Accordingly, the preferred stock was considered a participating security and the Company was required to apply the two-class method to consider the impact of the preferred stock on the calculation of basic and diluted earnings per share. The Company is in a net loss position for the years ended December 31, 2020 and 2019 and is therefore not required to present the two-class method. For the year ended December 31, 2021, while the Company is in a net income position, the two-class method does not need to be applied as only one class of stock was outstanding during the year.

The calculation of net income (loss) and the number of shares used to compute basic and diluted net earnings (loss) per share for the years ended December 31, 2021, 2020, and 2019 are as follows:

In thousands	2021	2020	2019
Net income (loss)—basic and diluted	$ 7,729	$ (18,000)	$ (22,645)
Weighted average shares outstanding—basic	395,992	381,759	342,538
Effect of dilutive securities:			
Stock options	4,420	—	—
Restricted stock and restricted stock units	2,068	—	—
Weighted average shares outstanding—diluted	402,480	381,759	342,538
Net earnings (loss) per share—basic	$ 0.02	$ (0.05)	$ (0.07)
Net earnings (loss) per share—diluted	$ 0.02	$ (0.05)	$ (0.07)

For the years ended December 31, 2021, 2020 and 2019, the following potentially dilutive securities were not included in the computation of net earnings (loss) 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	2021	2020	2019
Stock options	9,926	16,664	15,619
Restricted stock and restricted stock units	3,764	7,710	6,921
Laxdale milestone shares	1,984	—	—
Preferred stock (if converted)	—	—	28,932

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

Stock-based compensation cost is generally measured at the grant date, based on the fair value of the award, and is recognized as compensation expense over the requisite service period. For awards with performance conditions, if the achievement of the performance conditions is deemed probable, the Company recognizes compensation expense based on the fair value of the award over the estimated service period. The Company reassesses the probability of achievement of the performance conditions for such awards each reporting period. 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 11—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 37%, 28%, and 27%, respectively, of gross product sales for the year ended December 31, 2021 and represented 39%, 22%, and 35%, respectively, of the gross accounts receivable balance as of December 31, 2021. Customers A, B, and C accounted for 38%, 29% and 25%, respectively, of gross product sales for the year ended December 31, 2020 and represented 31%, 18%, and 37%, respectively, of the gross accounts receivable balance as of December 31, 2020. The Company has not experienced any significant write-offs of its accounts receivable. All customer accounts are actively managed and no losses in excess of amounts reserved are currently expected; however, the Company is monitoring the potential negative impact of COVID-19 on the Company's customers' ability to meet their financial obligations.

Concentration of Suppliers

The Company has contractual freedom to source the API for VASCEPA and to procure other services supporting its supply chain and has entered into supply agreements with multiple suppliers. The Company's supply of product for commercial sale and clinical trials is dependent upon relationships with third-party manufacturers and suppliers.

The Company cannot provide assurance that its efforts to procure uninterrupted supply of VASCEPA to meet market demand will continue to be successful or that it will be able to renew current supply agreements on favorable terms or at all. Significant alteration to or disruption or termination of the Company's current supply chain, including as a result of COVID-19, or the Company's failure to enter into new and similar agreements in a timely fashion, if needed, could have a material adverse effect on its business, condition (financial and other), prospects or results of operations.

The Company currently has manufacturing agreements with multiple independent API manufacturers and several independent API encapsulators and packagers for VASCEPA manufacturing. Each of these API manufacturers, encapsulators and packagers is U.S. FDA-approved and certain of these API manufacturers, encapsulators and packagers are also approved by the European Regulatory Authorities for manufacturing VAZKEPA in Europe. These suppliers are also used by the Company to source supply to meet the clinical trial and commercial demands of its partners in other countries. Each of these suppliers has qualified and validated its manufacturing processes. There can be no guarantee that these or other suppliers with which the Company may contract in the future to manufacture VASCEPA or VASCEPA API will remain qualified to do so to its specifications or that these and any future suppliers will have the manufacturing capacity to meet potential global demand for VASCEPA.

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 (expense) income, net in the consolidated statements of operations. For transactions settled during the applicable period, gains and losses are included in Other (expense) income, net in the consolidated statements of operations. Certain amounts payable pursuant to supply contracts are denominated in currencies other than the U.S. dollar. The Company recorded a foreign currency loss within the Other (expense) income, net on the consolidated statement of operations of $0.6 million for the year ended December 31, 2021 and less than $0.1 million for each of the years ended December 31, 2020 and 2019.

Fair Value of Financial Instruments

The Company provides disclosure of financial assets and financial liabilities that are carried at fair value based on the price that would be received upon sale of an asset or paid to transfer a liability in an orderly transaction between market participants at the

measurement date. Fair value measurements may be classified based on the amount of subjectivity associated with the inputs to fair valuation of these assets and liabilities using the following three levels:

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

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

Level 3—Unobservable inputs that reflect the Company's estimates of the assumptions that market participants would use in pricing the asset or liability. The Company develops these inputs based on the best information available, including its own data.

The following tables present information about the estimated fair value of the Company's assets and liabilities as of December 31, 2021 and 2020 and indicate the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value:

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

	December 31, 2020			
In thousands	Total	Level 1	Level 2	Level 3
Asset:				
Money Market Fund	$ 88,266	$ 88,266	$ —	$ —
U.S. Treasury Shares	48,356	48,356	—	—
Corporate Bonds	179,864	—	179,864	—
Commercial Paper	106,650	—	106,650	—
Agency Securities	20,782	—	20,782	—
Repo Securities	10,000	—	10,000	—
Asset Backed Securities	8,599	—	8,599	—
Certificate of Deposit	6,125	—	6,125	—
Non-US Government	5,240	—	5,240	—
Total	$ 473,882	$ 136,622	$ 337,260	$ —

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

The Company's held-to-maturity investments are stated at amortized cost, which approximates fair value. The Company does not intend to sell these investment securities and the contractual maturities are not greater than 24 months. Those with maturities greater than 90 days and 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 on held-to-maturity securities are not recognized until maturity, except other-than-temporary unrealized losses which are recognized in earnings in the period incurred. The Company evaluates securities with unrealized losses to determine whether such losses are other than temporary. The unrealized gain or loss for the year ended December 31, 2021 and December 31, 2020 was a loss of $0.2 million and a gain of $0.5 million, respectively. Interest on investments is reported in interest income.

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

Segment and Geographical Information

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

Restructuring

On September 22, 2021, the Company announced a Go-to-Market strategy for VASCEPA, or the Plan, which aims to expand healthcare professional engagement through a new omnichannel platform, enhance managed care access and optimize VASCEPA prescriptions for cardiovascular risk reduction. As part of the process, the Company completed a reduction of its field force to approximately 300 sales representatives. 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 are cash expenditures for one-time termination benefits and associated costs, within Restructuring expense in the consolidated statements of operations.

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

In thousands	Restructuring Liability
Balance at December 31, 2020	$ —
Costs incurred	14,115
Payments	(12,225)
Adjustments	(398)
Other [1]	(306)
Balance at December 31, 2021	$ 1,186

(1) - Represents the acceleration of expense associated with the vesting of certain equity awards.

Recent Accounting Pronouncements

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

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740), Simplifying the Accounting for Income Taxes*, which simplifies the accounting for income taxes by eliminating certain exceptions to the guidance in ASC 740 related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period, the recognition of deferred tax liabilities for outside basis differences, among other simplifications. The Company adopted this standard effective January 1, 2021, which did not have an impact on the Company's consolidated financial statements.

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

(3) Intangible Asset

Intangible asset consists of milestone payments to the former shareholders of Laxdale related to the 2004 acquisition of the rights to VASCEPA, which is the result of VASCEPA receiving marketing approval in the U.S. for the first indication in 2012, the expanded label in 2019 and marketing approval in Europe in 2021. Upon approval of the marketing authorization application for VAZKEPA in March 2021, a milestone for £7.5 million was achieved, which resulted in the Intangible asset increasing by $12.0 million. Refer to Note 8 – Commitments and Contingencies for further details. In accordance with ASC 350, the Company evaluates the remaining useful life of the intangible asset at each reporting period to determine if any events or circumstances warrant a revision to the remaining period of amortization. As of December 31, 2021, the intangible asset has an estimated weighted-average remaining useful life of 9.3 years. The carrying value as of December 31, 2021 and 2020 is as follows:

In thousands	December 31, 2021	December 31, 2020
Technology rights	$ 32,081	$ 20,081
Accumulated amortization	(8,534)	(6,264)
Intangible asset, net	$ 23,547	$ 13,817

Amortization expense for the years ended December 31, 2021 and 2020 was $2.3 million and $1.4 million, respectively. Estimated future amortization expense, based upon the Company's intangible asset, as of December 31, 2021 is as follows:

In thousands Year Ending December 31,	Amount
2022	$ 2,546
2023	2,546
2024	2,546
2025	2,546
2026	2,546
Thereafter	10,817
Total	$ 23,547

(4) Inventory

The Company capitalizes its purchases of saleable inventory of VASCEPA from suppliers that have been qualified by the U.S. FDA and other global regulatory agencies. Inventories as of December 31, 2021 and 2020 consist of the following:

In thousands	December 31, 2021	December 31, 2020
Raw materials	$ 107,695	$ 50,657
Work in process	41,965	30,388
Finished goods	206,270	107,819
Inventory	$ 355,930	$ 188,864

As of December 31, 2021 and 2020, we had $121.3 million and nil of Long-term inventory, respectively, as consumption is expected beyond our normal operating cycle.

(5) Property, Plant and Equipment

Property, plant and equipment as of December 31, 2021 and 2020 consist of the following:

In thousands	Useful Life (in years)	December 31, 2021	December 31, 2020
Furniture and fixtures	5	$ 1,633	$ 1,699
Leasehold improvements	lesser of useful life or lease term	869	1,026
Software	3 - 5	617	617
Computer equipment	3 - 5	227	290
Property, plant and equipment		3,346	3,632
Accumulated depreciation and amortization		(1,921)	(1,616)
Property, plant and equipment, net		$ 1,425	$ 2,016

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 years ended December 31, 2021, 2020, and 2019 were $0.6 million, $0.6 million, and $0.2 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, 2021 and 2020:

In thousands	December 31, 2021	December 31, 2020
Payroll and payroll-related expenses	$ 19,730	$ 22,772
Sales and marketing accruals	3,563	6,220
Accrued revenue allowances	184,216	140,863
All other	45,602	28,786
Accrued expenses and other current liabilities	$ 253,111	$ 198,641

(7) Debt

Debt from Royalty-Bearing Instrument—December 2012 Financing

On December 6, 2012, the Company entered into a Purchase and Sale Agreement with BioPharma Secured Debt Fund II Holdings Cayman LP, or BioPharma. Under this agreement, the Company granted to BioPharma a security interest in future receivables associated with the VASCEPA patent rights, in exchange for $100.0 million received at the closing of the agreement which occurred in December 2012. In the agreement, the Company agreed to repay BioPharma up to $150.0 million with such repayment based on a portion of net revenues and receivables generated from VASCEPA. On December 20, 2017, BioPharma assigned all rights under this agreement to CPPIB Credit Europe S.à r.l., or CPPIB.

As of December 31, 2021, the Company has no outstanding debt as the $150.0 million was previously repaid in full to CPPIB with the final payment being made in November 2020. During the year ended December 31, 2020, the Company recorded $1.6 million and $0.6 million of cash and non-cash interest expense, respectively, in connection with the royalty-bearing instrument (none during 2021).

(8) Commitments and Contingencies

Litigation – U.S. ANDAs

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

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

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

In November 2020, the Company filed a patent infringement lawsuit against Hikma in the United States District Court in Delaware. The complaint alleges that Hikma induced the infringement of VASCEPA-related cardiovascular 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 alleges that Health Net has actively induced pharmacies to dispense, and patients to use, Hikma

generic icosapent ethyl capsules in infringement of the related patents. In the complaint, the Company is seeking remedies including a permanent injunction against the unlawful inducement by Hikma and Health Net of infringing uses of the Hikma generic product, i.e., uses to reduce cardiovascular risk as detailed in the patents, and monetary damages in an amount sufficient to compensate the Company for such infringement. On January 4, 2022, the district court hearing the case granted Hikma's motion to dismiss. The Company intends to appeal the decision of the district court and also intends to continue to vigorously pursue its ongoing litigation with Health Net, but cannot predict the outcome or the impact on its business. The Company will continue to consider its legal options against parties similarly situated to Health Net and Hikma and acting in concert with either by making or selling any drug product or component thereof covered by the subject patents, or inducing others to do the same. The Company intends to vigorously enforce its intellectual property rights relating to VASCEPA, but cannot predict the outcome of these lawsuits or any subsequently filed lawsuits

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

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

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

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

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

Litigation – Other

On February 22, 2019, a purported investor in the Company’s publicly traded securities filed a putative class action lawsuit against Amarin Corporation plc, the chief executive officer and chief scientific officer in the U.S. District Court for the District of New Jersey, Debendra Sharma v. Amarin Corporation plc, John F. Thero and Steven Ketchum, No. 2:19-cv-06601 (D.N.J. Feb. 22, 2019). On March 12, 2019, another purported investor filed a substantially similar lawsuit captioned Richard Borghesi v. Amarin Corporation

plc, John F. Thero and Steven Ketchum, No. 3:19-cv-08423 (D.N.J. March 12, 2019). On May 14, 2019 the court consolidated the cases under the caption In re Amarin Corporation PLC Securities Litigation, No. 3:19-cv-06601 and appointed two other purported shareholders, Dan Kotecki and the Gaetano Cecchini Living Trust, as Co-Lead Plaintiffs. Co-Lead Plaintiffs filed a consolidated amended complaint, or Amended Complaint, on July 22, 2019 that added as defendants the Company's former chief medical officer and the Company's former chief executive officer. The Amended Complaint alleged that from September 24, 2018 to November 9, 2018 the Company misled investors by releasing topline results for the REDUCE-IT study without disclosing data on biomarker increases in the placebo group as compared with baseline measurement. The Amended Complaint alleged that these data suggest that the mineral oil placebo used in the REDUCE-IT study may have interfered with statin absorption in the placebo group, which they alleged may have increased adverse outcomes in the placebo group. The Amended Complaint further alleged that these purported misrepresentations and omissions inflated the share price. Based on these allegations, the suit asserted claims under the Securities Exchange Act of 1934 and sought unspecified monetary damages and attorneys' fees and costs.

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

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

In addition to the above, in the ordinary course of business, the Company is from time to time involved in lawsuits, claims, investigations, proceedings, and threats of litigation relating to intellectual property, commercial arrangements and other matters.

Milestone and Supply Purchase Obligations

The Company entered into long-term supply agreements with multiple API suppliers and encapsulators. The Company is relying on these suppliers to meet current and potential future global demand for its lead product. Certain supply agreements require annual minimum volume commitments by the Company and certain volume shortfalls may require payments for such shortfalls.

These agreements include requirements for the suppliers to meet certain product specifications and qualify their materials and facilities with applicable regulatory authorities including the U.S. FDA. The Company has incurred certain costs associated with the qualification of product produced by these suppliers.

Pursuant to the supply agreements, there is a total of approximately $196.1 million that is potentially payable over the term of such agreements based on minimum purchase obligations. The Company continues to meet its contractual purchase obligations.

On March 26, 2021, the EC approved the marketing authorization application for VAZKEPA. Under the 2004 share repurchase agreement with Laxdale upon receipt of pricing approval in Europe for the first indication for VASCEPA (or first indication of any product containing intellectual property acquired from Laxdale in 2004), the Company must make an aggregate stock or cash payment to the former shareholders of Laxdale (at the sole option of each of the sellers) of £7.5 million. The Company recorded a liability of $12.0 million in Accrued expenses and other current liabilities on the consolidated balance sheet as of December 31, 2021.

Also under the Laxdale agreement, upon receipt of a marketing approval in Europe for a further indication of VASCEPA (or further indication of any other product acquired from Laxdale in 2004), the Company must make an aggregate stock or cash payment (at the sole option of each of the sellers) of £5.0 million (approximately $6.8 million as of December 31, 2021) for the potential market approval.

The Company has no provision for any of these obligations, except as noted above, since the amounts are either not paid or payable as of December 31, 2021.

Marketing Obligations

As of December 31, 2021, the Company had certain marketing commitments, consisting of communication costs related to the direct-to-consumer activities, totaling approximately $0.3 million.

(9) Equity

Preferred Stock

In March 2015, the Company entered into subscription agreements with both existing and new investors, or the Purchasers, for the private placement of a total of 391,017,970 restricted American Depositary Shares, or ADSs, each representing one share of Amarin's Series A Convertible Preference Shares, par value £0.05 per share, in the capital of the Company, or Series A Preference Shares. For each restricted ADS, the Purchasers paid a negotiated price of $0.15 (equating to $1.50 on an as-if-converted-to-ordinary-shares basis), resulting in gross proceeds to the Company of approximately $58.6 million before deducting estimated offering expenses of approximately $0.7 million. At the request of the holders and provided certain conditions were met, each ten Series A Preference Shares were able to be consolidated and redesignated as one ordinary share, par value £0.50 per share, in the capital of the Company, each ordinary share to be represented by ADSs. During the years ended December 31, 2020, 2018, and 2015, the Company issued 28,931,746, 3,886,718, and 6,283,333 ADSs, respectively, upon consolidation and redesignation of Series A Preference Shares at the request of the holders, such that no Series A Preference Shares remained outstanding as of December 31, 2021 and December 31, 2020. Refer to the Company's Annual Report on Form 10-K for the year ended December 31, 2020 for a more complete background.

Common Stock

During the years ended December 31, 2021 and 2020, 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 *Preferred Stock* above for discussion of the consolidation and redesignation of Series A Preference Shares which resulted in the issuance of ordinary shares. Refer to *Incentive Equity Awards below* for discussion of ordinary shares issued as a result of stock option exercises and restricted stock unit vestings. Refer to Note 11—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 11—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, 2021:

	December 31, 2021
Outstanding stock options	18,493,303
% of outstanding shares on a fully diluted basis	4%
Outstanding RSUs	9,277,176
% of outstanding shares on a fully diluted basis	2%

The following table represents equity awards activity during the years ended December 31, 2021 and 2020:

	For the Year Ended December 31,	
	2021	2020
Common shares issued for stock option exercises	1,203,845	1,623,460
Gross and net proceeds from stock option exercises	$ 2,921,000	$ 5,158,000
Common shares issued in settlement of vested RSUs	2,133,328	1,267,164
Shares retained for settlement of employee tax obligations — RSUs	782,917	461,143
Common shares issued in settlement of vested Performance-Based RSUs [(1)]	1,923,316	1,240,584
Shares retained for settlement of employee tax obligations — Performance-Based RSUs	816,931	514,784

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

During the years ended December 31, 2021 and 2020, the Company granted a total of 4,535,117 and 2,890,450 stock options, respectively, and 5,497,700 and 1,811,470 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 2021 and 2020, the Company granted a total of 2,008,800 and 1,483,400 RSUs, respectively, to employees under the Plans that vest upon the achievement of specified performance conditions.

In addition, during the years ended December 31, 2021 and 2020, the Company granted a total of 278,271 and 210,764 stock options, respectively, and 218,000 and 164,657 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.

(10) Income Taxes

The Company recognizes interest and penalties related to uncertain tax positions within the provision for income taxes. Interest and penalties related to any uncertain tax positions have historically been insignificant. The total amount of unrecognized tax benefits that would affect the Company's effective tax rate if recognized is $7.9 million and $5.6 million as of December 31, 2021 and 2020, respectively. The Company recognized interest related to uncertain tax positions of $0.9 million and nil for the years ended December 31, 2021 and 2020, 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, 2021, 2020 and 2019:

In thousands	2021	2020	2019
Beginning uncertain tax benefits	$ 24,034	$ 26,743	$ 6,815
Prior year—increases	16	2,428	295
Prior year—decreases	(2,248)	(5,391)	—
Current year—increases	238	254	19,633
Ending uncertain tax benefits	$ 22,040	$ 24,034	$ 26,743

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, 2021:

Jurisdiction	Tax Years
United States—Federal	2018-2021
United States—State	2012-2021
Ireland	2017-2021
United Kingdom	2020-2021

The Company does not expect any gross liabilities to expire in 2022 based on statutory lapses or audits.

The components of income (loss) from operations before taxes were as follows for the years ended December 31, 2021, 2020 and 2019:

In thousands	2021	2020	2019
United States	$ 10,222	$ 14,915	$ 10,269
Ireland and United Kingdom	(4,368)	(32,170)	(32,750)
Other	5,437	—	—
Total Income / (Loss) Before Taxes	$ 11,291	$ (17,255)	$ (22,481)

The provision for income taxes shown in the accompanying consolidated statements of operations consists of the following for fiscal 2021, 2020 and 2019:

In thousands	2021	2020	2019
Current:			
United States—Federal	$ 2,690	$ 45	$ —
United States—State	716	700	164
Foreign	156	—	—
Total current	$ 3,562	$ 745	$ 164
Deferred:			
United States—Federal	5,222	1,972	1,777
United States—State	(3,057)	1,956	(914)
Ireland and United Kingdom	(1,619)	(26,793)	1,278
Change in valuation allowance	(546)	22,865	(2,141)
Total deferred	$ —	$ —	$ —
Provision for income taxes	$ 3,562	$ 745	$ 164

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 fiscal 2021, 2020 and 2019:

In thousands	2021	2020	2019
Benefits from taxes at statutory rate	$ 2,823	$ (4,314)	$ (5,620)
Rate differential	(4,416)	128	3,009
Change in valuation reserves	(546)	22,865	(2,141)
Nondeductible employee compensation	5,249	6,122	5,472
Stock option/RSU windfall (shortfall)	81	(3,262)	(14,342)
ISO disqualifying disposition windfall	(219)	(253)	(2,849)
Research and development credits	(1,170)	(6,225)	(1,607)
Tax return to provision adjustments	(8,372)	(138)	(3,222)
Net Operating Loss Carryback	—	(2,465)	—
Cumulative translation adjustment	4,109	(10,852)	2,025
Permanent and other	863	(4,283)	(443)
Tax reserves	5,160	3,422	18,799
Corscianto liquidation	—	—	1,727
Long-term debt from royalty-bearing instrument	—	—	(644)
Provision for income taxes	$ 3,562	$ 745	$ 164

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, 2021, 2020, and 2019, 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.

On March 27, 2020, the Coronavirus Aid, Relief and Economic Security Act, or CARES Act, was enacted in the United States. Among other provisions, the CARES Act allows businesses to carry back net operating losses arising in years 2018 to 2020 to the five prior tax years. We recorded an income tax benefit of $2.5 million for the year ended December 31, 2020 as a result of these loss carrybacks and an income tax benefit of nil for the years ended December 31, 2021 and 2019, respectively.

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, 2021, 2020 and 2019 includes $0.1 million, $3.7 million and $21.9 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, 2021 and 2020 is as follows:

In thousands	December 31, 2021	December 31, 2020
Deferred tax assets:		
Net operating losses	$ 127,378	$ 125,859
Stock-based compensation	8,563	7,565
Tax credits	15,803	14,690
Lease Liability	2,348	2,219
Other reserves and accrued liabilities	11,257	14,702
Gross deferred tax assets	165,349	165,035
Less: valuation allowance	(160,295)	(160,841)
Total deferred tax assets	5,054	4,194
Deferred tax liabilities:		
Depreciation and amortization	(3,404)	(2,399)
Lease Asset	(1,639)	(1,784)
Other liabilities	(11)	(11)
Total deferred tax liabilities	(5,054)	(4,194)
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., UK, 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, 2021 and 2020:

In thousands	2021	2020
Beginning valuation allowance	$ 160,841	$ 137,976
Increase as reflected in income tax expense	2,899	12,453
Cumulative translation adjustment	(3,445)	10,412
Ending valuation allowance	$ 160,295	$ 160,841

During 2021, 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., Irish, UK, and Israeli net operating loss carryforwards of $849.9 million, which do not expire. The total net operating loss carryforwards decreased by approximately $50.6 million from the prior year primarily as a result of current year income generated by the Company’s U.S. and Irish subsidiaries, the impact of foreign exchange rate changes, and adjustments to reconcile the financial statement accounts to the amounts reported on the filed 2020 foreign tax returns. In addition, the Company has U.S. Federal tax credit carryforwards of $13.7 million and state tax credit carryforwards of $4.5 million. These amounts exclude the impact of any unrecognized tax benefits and valuation allowances. These carryforwards, which will expire between 2024 and 2040, may be used to offset future taxable income, if any.

As of December 31, 2021, 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, by the New Jersey Department of Treasury for the years 2012 to 2015 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) 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 Stock Incentive Plan, or 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 Stock Option Plan, as amended, or the 2011 Plan, which was set to expire on July 12, 2021, and the Company's 2002 Stock Option Plan, as amended, or the 2002 Plan, and together with the 2020 Plan and 2011 Plan, the Plans.

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 over shares 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 Plan. The award of stock options (both incentive and non-qualified options) and restricted stock units, and awards of unrestricted shares to Directors are permitted. 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, expire after a ten-year term and 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, 2021:

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, 2021	16,664	$ 8.00		
Granted	4,813	5.12		
Forfeited	(1,481)	10.88		
Expired	(299)	12.04		
Exercised	(1,204)	2.43		
Outstanding as of December 31, 2021	18,493	7.32	6.4 years	$ 7,762
Exercisable as of December 31, 2021	12,487	6.81	5.2 years	$ 7,744
Vested and expected to vest as of December 31, 2021	18,193	$ 7.30	6.3 years	$ 7,761
Available for future grant as of December 31, 2021	13,229			

The weighted average grant date fair value of stock options granted during the years ended December 31, 2021, 2020, and 2019 was $5.12, $14.43, and $17.07, respectively. The total grant date fair value of options vested during the years ended December 31, 2021, 2020, and 2019 was $21.1 million, $22.5 million, and $14.5 million, respectively.

During the years ended December 31, 2021, 2020 and 2019, the Company received proceeds from the exercise of options of $2.9 million, $5.2 million, and $24.5 million, respectively. The total intrinsic value of options exercised during the years ended December 31, 2021, 2020, and 2019 was $4.9 million, $9.0 million, and $90.5 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, 2021, there was $30.7 million of unrecognized stock-based compensation expense related to unvested stock option share-based compensation arrangements granted under the Company's stock award plans. This expense is expected to be recognized over a weighted-average period of approximately 2.2 years. The Company recognizes compensation expense for the fair values of those awards which have graded vesting on a straight-line basis.

The fair value of stock options on the date of grant was estimated using the Black-Scholes option pricing model. Use of a valuation model requires management to make certain assumptions with respect to selected model inputs. Expected stock price volatility was calculated based on the historical volatility of the Company's common stock over the expected life of the option. The expected life was determined using the simplified method based on the term and vesting period. 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. 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. Estimated forfeitures are based on the Company's historical forfeiture activity.

Employee stock options generally vest over a four-year service period and all stock options are settled by the issuance of new shares. Compensation expense recognized for all option grants is net of estimated forfeitures and is recognized over the awards' respective requisite service periods. The vesting of certain stock options is contingent upon the attainment of performance criteria. The probability that such 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 Company recorded compensation expense in relation to stock options of $23.0 million, $22.4 million, and $16.3 million for the years ended December 31, 2021, 2020, and 2019, respectively.

For 2021, 2020, and 2019, the Company used the following assumptions to estimate the fair value of share-based payment awards:

	2021	2020	2019
Risk-free interest rate	0.53% - 1.36%	0.33% - 1.74%	1.55% - 2.95%
Expected dividend yield	0.00%	0.00%	0.00%
Expected option life (years)	6.25	6.25	6.25
Expected volatility	96% - 99%	84% - 99%	92% - 94%

Restricted Stock Units

The Plans also allow for granting of restricted stock unit awards under the terms of the Plans. The restricted stock units vest based upon a time-based service condition, a performance condition, or both. 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. Restricted stock units are recorded as compensation expense based on fair value, representing the market value of the Company's common stock on the date of grant. The fair value of restricted stock units is amortized on a straight-line basis through the statement of operations over the service period until the shares have vested. The following table presents the restricted stock unit activity for the years ended December 31, 2021 and 2020:

In thousands (except per share amounts)	Shares	Weighted Average Grant Date Fair Value
Outstanding as of January 1, 2021	7,710	9.67
Granted	7,725	5.07
Vested	(4,057)	5.98
Forfeited	(2,101)	8.57
Outstanding as of December 31, 2021	9,277	$ 7.70

The Company recorded compensation expense in relation to restricted stock units of $13.9 million, $23.4 million, and $14.6 million for the years ended December 31, 2021, 2020, and 2019 respectively.

The following table presents the stock-based compensation expense related to stock-based awards for the years ended December 31, 2021, 2020, and 2019:

In thousands	2021	2020	2019
Research and development	$ 4,327	$ 6,568	$ 4,615
Selling, general and administrative	32,305	39,245	26,302
Restructuring	306	—	—
Stock-based compensation expense	$ 36,938	$ 45,813	$ 30,917

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, 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. For the offering periods ended on the last business day on or before each of May 31, 2020 and November 30, 2020, the Company issued 123,608 shares and 223,545 shares, respectively, at a purchase price of $5.83 per share and $4.22 per share, respectively. For the

offering periods ended on the last business day on or before each of May 31, 2019 and November 30, 2019, the Company issued 47,358 shares and 75,673 shares, respectively, at a purchase price of $15.02 per share and $14.92 per share, respectively. As of December 31, 2021, 1,818,273 shares were reserved for future issuance under the ESPP.

(12) 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 $1.9 million, $1.7 million and $1.1 million of related compensation expense for the year ended December 31, 2021, 2020 and 2019, respectively.

(13) Co-Promotion Agreement

On March 31, 2014, the Company entered into a Co-Promotion Agreement, or the Agreement, with Kowa Pharmaceuticals America, Inc. related to the commercialization of VASCEPA capsules in the United States. The Company and Kowa Pharmaceuticals America, Inc. intentionally designed the Agreement to naturally end as of December 31, 2018 and mutually agreed not to renew the Agreement.

During 2018, which was the last year of the co-promotion of VASCEPA by Kowa Pharmaceuticals America, Inc., the Company incurred expense for co-promotion tail payments which are calculated as a percentage of the 2018 co-promotion fee, which was eighteen and a half percent (18.5%) of VASCEPA gross margin in 2018. The accrued tail payments are paid over three years with declining amounts each year. Kowa Pharmaceuticals America, Inc. was eligible to receive $17.8 million in co-promotion tail payments, the present value of which $16.6 million, was fully accrued as of December 31, 2018.

As of December 31, 2021 a net payable to Kowa Pharmaceuticals America, Inc. of $0.6 million was classified as current on the consolidated balance sheets, representing the remaining accrued co-promotion tail payments. As of December 31, 2020, the Company recognized a net payable to Kowa Pharmaceuticals America, Inc. of $3.8 million, of which $3.2 million was classified as current on the consolidated balance sheets.

(14) 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, that in turn resell VASCEPA to retail pharmacies for subsequent resale to patients and healthcare providers. Patients are required to have a prescription in order to purchase VASCEPA. In addition to distribution agreements with distributors, the Company enters into arrangements with health care providers and payors that provide for government-mandated and/or privately-negotiated rebates, chargebacks and discounts with respect to the purchase of the Company's product.

Revenues from product sales are recognized when the distributor obtains control of the Company's product, which occurs at a point in time, typically upon delivery to the distributor or customer. Payments from distributors are generally received 30-60 days from the date of sale. The Company evaluates the creditworthiness of each of its distributors to determine whether revenues can be recognized upon delivery, subject to satisfaction of the other requirements, or whether recognition is required to be delayed until receipt of payment. The Company calculates gross product revenues generally based on the wholesale acquisition cost or list price that the Company charges its distributors for VASCEPA.

Reserves for Variable Consideration

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

estimates, the Company adjusts these estimates, which would affect net product revenue and earnings in the period such variances become known.

Trade Allowances: The Company generally provides invoice discounts on VASCEPA sales to its distributors for prompt payment and fees for distribution services, such as fees for certain data that distributors provide to the Company. The payment terms for sales to distributors in the U.S. and Germany generally include a 2-3% discount for prompt payment while the fees for distribution services are based on contractual rates agreed with the respective distributors. Based on historical data, the Company expects its distributors to earn these discounts and fees, and deducts the full amount of these discounts and fees from its gross product revenues and accounts receivable at the time such revenues are recognized.

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

Product Returns: The Company's distributors have the right to return unopened unprescribed VASCEPA during the 18-month period beginning six months prior to the labeled expiration date and ending 12 months after the labeled expiration date. The expiration date for VASCEPA 1-gram and 0.5-gram size capsules is currently four years and three years, respectively, after being converted into capsule form, which is the last step in the manufacturing process for VASCEPA and generally occurs within a few months before VASCEPA is delivered to distributors. The Company estimates future product returns on sales of VASCEPA based on: (i) data provided to the Company by its distributors (including weekly reporting of distributors' sales and inventory held by distributors that provided the Company with visibility into the distribution channel in order to determine what quantities were sold to retail pharmacies and other providers), (ii) information provided to the Company from retail pharmacies, (iii) data provided to the Company by a third-party data provider which collects and publishes prescription data, and other third parties, (iv) historical industry information regarding return rates for similar pharmaceutical products, (v) the estimated remaining shelf life of VASCEPA previously shipped and currently being shipped to distributors and (vi) contractual agreements intended to limit the amount of inventory maintained by the Company's distributors. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in Accrued expenses and other current liabilities on the 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, 2021 and 2020:

In thousands	Trade Allowances	Rebates, Chargebacks and Discounts	Product Returns	Other Incentives	Total
Balance as of January 1, 2020	**$ 29,261**	**$ 90,997**	**$ 4,579**	**$ 3,720**	**$ 128,557**
Provision related to current period sales	132,881	621,937	3,543	64,452	822,813
Provision related to prior period sales	—	(3,872)	—	—	(3,872)
Credits/payments made for current period sales	(96,834)	(482,254)	—	(58,911)	(637,999)
Credits/payments made for prior period sales	(29,066)	(85,608)	(324)	(3,677)	(118,675)
Balance as of December 31, 2020	**36,242**	**141,200**	**7,798**	**5,584**	**190,824**
Provision related to current period sales	121,378	684,010	1,531	45,501	852,420
Provision related to prior period sales	—	(2,034)	—	—	(2,034)
Credits/payments made for current period sales	(36,473)	(504,210)	—	(42,754)	(583,437)
Credits/payments made for prior period sales	(34,511)	(134,210)	(1,240)	(5,586)	(175,547)
Balance as of December 31, 2021	**$ 86,636**	**$ 184,756**	**$ 8,089**	**$ 2,745**	**$ 282,226**

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.

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

adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect licensing revenues and earnings in the period of adjustment.

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

(15) Development, Commercialization and Supply Agreements

In-licenses

Mochida Pharmaceutical Co., Ltd.

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

Upon closing of the collaboration agreement, the Company made a non-refundable, non-creditable upfront payment of approximately $2.7 million. In addition, the agreement provides for the Company to pay milestone payments upon the achievement of certain product development milestones and royalties on net sales of future products arising from the collaboration, if any.

In January 2021, the Company exercised certain rights under the agreement, resulting in a payment of $1.0 million to Mochida, which was recorded as Research and development expense in the consolidated statement of operations. In January 2020 and December 2020, the Company exercised certain rights under the agreement, resulting in payments of $1.0 million, respectively, to Mochida, which were 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 Eddingpharm (Asia) Macao Commercial Offshore Limited, or Edding, related to the development and commercialization of VASCEPA in Mainland China, Hong Kong, Macau and Taiwan, or the China Territory. Under the terms of the DCS Agreement, the Company granted to Edding an exclusive (including as to the Company) license with right to sublicense to develop and commercialize VASCEPA in the China Territory for uses that are currently commercialized and under development by the Company based on the Company's MARINE, ANCHOR and REDUCE-IT clinical trials of VASCEPA.

Under the DCS Agreement, Edding is solely responsible for development and commercialization activities in the China Territory and associated expenses. The Company provides development assistance and is responsible for supplying finished and later bulk drug product at defined prices under negotiated terms. The Company retains all VASCEPA manufacturing rights. Edding agreed to certain restrictions regarding the commercialization of competitive products globally and the Company agreed to certain restrictions regarding the commercialization of competitive products in the China Territory.

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

The term of the DCS Agreement expires, on a product-by-product basis, upon the later of (i) the date on which such product is no longer covered by a valid claim under a licensed patent in the China Territory, or (ii) the 12th anniversary of the first commercial sale of such product in Mainland China. The DCS Agreement may be terminated by either party in the event of a bankruptcy of the other party and for material breach, subject to customary cure periods. In addition, at any time following the third anniversary of the first

commercial sale of a product in Mainland China, Edding has the right to terminate the DCS Agreement for convenience with 12 months' prior notice. Neither party may assign or transfer the DCS Agreement without the prior consent of the other party, provided that the Company may assign the DCS Agreement in the event of a change of control transaction.

Upon closing of the DCS Agreement, the Company received a non-refundable $15.0 million up-front payment. In March 2016, Edding submitted its clinical trial application, or CTA, with respect to the MARINE indication for VASCEPA to the Chinese regulatory authority. Following the CTA submission, the Company received a non-refundable $1.0 million milestone payment. In March 2017, the CTA was approved by the Chinese regulatory authority, and, in December 2017, Edding commenced a pivotal clinical trial aimed to support the regulatory approval of the first indication of VASCEPA in a patient population with severe hypertriglyceridemia in Mainland China. In November 2020, the Company announced statistically significant topline results from the Phase 3 clinical trial of VASCEPA conducted by Edding, which is being used to seek regulatory approval in Mainland China. Edding is also seeking regulatory approval of VASCEPA in Hong Kong.

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

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

The transaction price includes the $15.0 million up-front consideration received and the $1.0 million milestone payment received related to the successful submission of the CTA for the MARINE indication. None of the other clinical or regulatory milestones have been included in the transaction price, as all milestone amounts are fully constrained. As part of its evaluation of the constraint, the Company considered numerous factors, including that receipt of the milestones is outside the control of the Company and contingent upon success in future clinical trials and the licensee's efforts. Any consideration related to sales-based milestones including royalties, will be recognized when the related sales occur and therefore have also been excluded from the transaction price. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

During the years ended December 31, 2021 and 2020, the Company recognized $1.1 million and $3.0 million, respectively, as licensing revenue related to the up-front and milestone payments received in connection with the Edding agreement. From contract inception through December 31, 2021 and 2020, the Company recognized $7.1 million and $6.1 million, respectively, as licensing revenue under the DCS Agreement concurrent with the input measure of support hours provided by Amarin to Edding in achieving the combined development and regulatory performance obligation, which in the Company's judgment is the best measure of progress towards satisfying this performance obligation. The remaining transaction price of $9.8 million and $10.8 million is recorded in deferred revenue as of December 31, 2021 and 2020, respectively, on the consolidated balance sheets and will be recognized as revenue over the remaining period of 13 years.

Biologix FZCo

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

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

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

The Company recognized net product revenue of approximately $1.4 million and $0.5 million as of December 31, 2021 and 2020, respectively, related to sales to Biologix.

HLS Therapeutics, Inc.

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

Upon closing of the agreement, the Company received one-half of a non-refundable $5.0 million up-front payment, and received the remaining half on the six-month anniversary of the closing. Following achievement of the REDUCE-IT trial primary endpoint, which was announced in September 2018, the Company received a non-refundable $2.5 million milestone payment. Following approval from Health Canada in December 2019, the Company received a non-refundable milestone payment of $2.5 million in February 2020. In addition, in January 2020 HLS obtained regulatory exclusivity from the Office of Patented Medicines and Liaison, or OPML, as a result the Company received a non-refundable $3.8 million milestone payment. In addition to the non-refundable, up-front and regulatory milestone payments just described, the Company is entitled to receive certain sales-based milestone payments of up to an additional $50.0 million, as well as tiered double-digit royalties on net sales of VASCEPA in Canada.

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

The transaction price includes the $5.0 million up-front consideration, the $2.5 million milestone related to the achievement of the REDUCE-IT trial primary endpoint, the $2.5 million milestone related to obtaining approval from Health Canada and $3.8 million milestone related to obtaining regulatory exclusivity from the OPML. Any consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur and therefore have also been excluded from the transaction price. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

During the years ended December 31, 2021 and 2020, the Company recognized $0.9 million and $3.9 million, respectively, as licensing revenue related to up-front and milestone payments received in connection with the HLS agreement. From the contract's inception through December 31, 2021 and 2020, the Company has recognized $7.5 million and $6.6 million, respectively, as licensing revenue is recognized under the agreement concurrent with the input measure of support hours provided by Amarin to HLS in achieving this performance obligation, which in the Company's judgment is the best measure of progress towards satisfying the combined development and regulatory performance obligation. The remaining transaction price of $6.2 million and $7.1 million is recorded in deferred revenue as of December 31, 2021 and 2020, respectively, on the consolidated balance sheets and will be recognized as revenue over the remaining period of 9 years.

The Company recognized net product revenue of nil and $8.5 million for the years ended December 31, 2021 and 2020, respectively, related to sales to HLS.

The following table presents changes in the balances of the Company's contract assets and liabilities for years ended December 31, 2021 and 2020:

In thousands	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
Year ended December 31, 2021:				
Contract assets	$ —	$ —	$ —	$ —
Contract liabilities:				
Deferred revenue	$ 18,632	$ 128	$ (2,051)	$ 16,709
Year ended December 31, 2020:				
Contract assets	$ —	$ —	$ —	$ —
Contract liabilities:				
Deferred revenue	$ 20,846	$ 4,608	$ (6,822)	$ 18,632

During the years ended December 31, 2021 and 2020, 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:	2021	2020
Amounts included in contract liability at the beginning of the period	$ 1,997	$ 4,705
Performance obligations satisfied in previous periods	$ 46	$ 1,262

(16) Leases

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

The Company has determined that the rate implicit in the lease is not determinable and the Company does not have borrowings with similar terms and collateral. Therefore, the Company considered a variety of factors, including the Company's credit rating, observable debt yields from comparable companies with a similar credit profile and the volatility in the debt market for securities with similar terms, in determining that 11.5% was reasonable to use as the incremental borrowing rate for purposes of the calculation of lease liabilities and a change of 1% would not result in a material change to the Company's 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. The operating lease liability is $10.3 million and $10.6 million and the operating lease right-of-use asset is $7.7 million and $8.1 million, as of December 31, 2021 and December 31, 2020, respectively.

The lease expense for the years ended December 31, 2021, December 31, 2020 and December 31, 2019 is approximately $2.2 million, $1.6 million and $1.5 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, 2021:

		Undiscounted lease payments ($000s)
2022		1,774
2023		1,808
2024		1,842
2025		1,876
2026		1,910
2027 and thereafter		7,202
Total undiscounted payments	$	16,412
Discount Adjustments	$	(6,062)
Current operating lease liability		1,774
Long-term operating lease liability	$	8,576

The Company entered into a lease agreement for new office space in Zug, Switzerland. The lease commenced on February 1, 2022 for a five year period. Under the lease, the Company will pay rent of approximately $0.2 million per year.

Exhibit 10.35

CONFIDENTIAL

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED AND REPLACED WITH "[***]". SUCH IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

API COMMERCIAL SUPPLY AGREEMENT

by and between

AMARIN PHARMACEUTICALS IRELAND LTD.

and

CHEMPORT INC.

Dated as of May 25, 2011

API COMMERCIAL SUPPLY AGREEMENT

THIS API COMMERCIAL SUPPLY AGREEMENT (this "Agreement") is entered into and dated as of the 25th day of May, 2011 (the "Effective Date") by and between Amarin Pharmaceuticals Ireland Ltd., a corporation organized under the laws of Ireland and having its principal office at First Floor, Block 3, The Oval, Shelbourne Road, Ballsbridge, Dublin 4, Ireland ("Amarin"), and Chemport Inc., a corporation organized under the laws of South Korea and having its principal offices at 15-1, Dongsu-dong, Naju-si, Jeollanam-do 520-330 Korea ("Chemport"). Amarin and Chemport are sometimes referred to herein individually as a "Party" and collectively as the "Parties."

RECITALS

WHEREAS, Amarin is engaged in the research, development and commercialization of proprietary pharmaceutical products;

WHEREAS, Chemport is a company that has developed substantial expertise in manufacturing polyunsaturated fatty acids, including the Compound (as defined herein), for use in nutritional supplement and pharmaceutical products; and

WHEREAS, the Parties desire to enter into a supply agreement pursuant to which Chemport will manufacture a certain active pharmaceutical ingredient for Amarin.

NOW, THEREFORE, in consideration of the foregoing recitals, mutual covenants, agreements, representations and warranties contained herein, the Parties hereby agree as follows:

Article I
Definitions

"Additional Expansions" has the meaning in Section 3.1(a) of this Agreement.

"Adverse Event" has the meaning in Section 6.7(a) of this Agreement.

"Affiliate" means a corporation or non-corporate business entity that, directly or indirectly, controls, is controlled by, or is under common control with the Person specified, for so long as such control continues. An entity will be regarded as in control of another entity if: (a) it owns, directly or indirectly, at least fifty percent (50%) of the voting securities or capital stock of such entity, or has other comparable ownership interest with respect to any entity other than a corporation; or (b) it possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of the corporation or non-corporate business entity, as applicable, whether through the ownership or control of voting securities, by contract or otherwise.

"Agreement" means this API Commercial Supply Agreement, including all Schedules hereto.

"Amarin" has the meaning in the preamble of this Agreement.

"Amarin Confidential Information" has the meaning provided in Section 13.1 of this Agreement.

"Amarin Intellectual Property" means any and all Intellectual Property relating to the Product (as defined below) or the development or manufacture thereof that was (a) owned, licensed or controlled by Amarin or Amarin Affiliates as of the Effective Date, or (b) developed or acquired by Amarin or Amarin Affiliates after the Effective Date.

"Amarin License" has the meaning provided in Section 8.3 of this Agreement.

"API" means [***].

"API Price" has the meaning provided in Section 3.1(a) of this Agreement.

"API Product Developments" has the meaning provided in Section 8.2(a) of this Agreement.

"API Specifications" mean all specifications set forth on Schedule 5.1 to this Agreement.

"Approved Representatives" has the meaning provided in Section 5.4(a) of this Agreement.

"Calendar Quarter" means each three (3) month period beginning each January 1, April 1, July 1 and October 1 during the Term. The initial Calendar Quarter shall begin on the Effective Date and end on June 30, 2011, and the last Calendar Quarter shall end on the expiration or earlier termination date of the Term.

"Calendar Year" means each twelve (12) month period beginning each January 1 during the Term. The initial Calendar Year shall begin on the Effective Date and end on the first December 31 during the Term, and the last Calendar Year shall begin on January 1 of the last year of the Term and end on the expiration or earlier termination date of the Term.

"Certificate of Analysis" means a document identified as such and provided by Chemport to Amarin in the form set forth in Schedule 6.2 that (a) sets forth the analytical test results for a specified lot of API shipped to Amarin or its designee hereunder and includes a certified quality control protocol, (b) states that such API is in conformance with the Drug Application and API Specifications, and (c) states that such API is manufactured in accordance with the API Specifications, Legal Requirements and cGMPs.

"Certificates" has the meaning provided in Section 6.2 of this Agreement.

"Change of Control" means any proposed transaction or series of transactions which shall result in (a) any Person other than a Party having direct or indirect ownership of more than fifty percent (50%) of the voting stock or assets of such Party or an Affiliate that controls such Party by Persons who are not shareholders of such Party or the Affiliate that controls such Party as of the Effective Date, or (b) the merger of a Party with or into a Third Party in a transaction in which such Party is not the surviving or acquiring Person.

"Chemport" has the meaning in the preamble of this Agreement.

"Chemport Approval(s)" means the approval of the Facility as a cGMP facility for the manufacture of the API by the FDA and, as applicable, by any other applicable Governmental Body having jurisdiction to approve the Facility.

"Chemport Confidential Information" has the meaning provided in Section 13.2 of this Agreement.

"Chemport Intellectual Property" means (a) all Intellectual Property owned, licensed or controlled by Chemport as of the Effective Date, and (b) all Intellectual Property developed or acquired by Chemport after the Effective Date that does not relate to the Product or the development or manufacture of the Product, except that Intellectual Property developed by Chemport related to the API shall be included in Chemport Intellectual Property.

"Chemport's Initial Minimum Capacity" has the meaning provided in Section 4.1 of this Agreement.

"Chemport's Minimum Capacity" has the meaning provided in Section 4.1 of this Agreement.

"CMC" means the chemistry, manufacturing and controls section(s) and data in a Drug Application.

"Commercial Launch Forecast" has the meaning provided in Section 2.4(a) of this Agreement.

"Compound" means ethyl ester of eicosapentaenoic acid.

"Confidential Information" has the meaning provided in Section 13.3 of this Agreement.

"Consent" means any consent, authorization, permit, certificate, license or approval of, exemption by, or filing or registration with, any Governmental Body or other Person.

"Current Good Manufacturing Practices" or "cGMPs" means all applicable standards relating to manufacturing practices for intermediates, active pharmaceutical ingredients or finished pharmaceutical products, including without limitation (a) the principles detailed in the U.S. Current Good Manufacturing Practices, 21 C.F.R. Parts 210 and 211, The Rules Governing Medicinal Products in the European Community, Volume IV Good Manufacturing Practice for Medicinal Products, and Q7A Good Manufacturing Practice Guidance For Active Pharmaceutical Ingredients (ICH Q7A), and (b) the principles promulgated by any applicable Governmental Body having jurisdiction over the

manufacture of the API, in the form of laws, rules or regulations, in each case as in effect at the Effective Date and as amended, promulgated or accepted by any applicable Governmental Body from time to time during the Term.

“Days” (whether or not the word is capitalized) means, except where specified otherwise, calendar days.

“Development and Process Validation Plan” means the development and validation plan to be agreed to by the Parties within [***] days of the Effective Date.

“DMFs” has the meaning provided in Section 7.5 of this Agreement.

“Drug Application” means a ‘new drug application’ (as such term is used under the United States Federal Food, Drug and Cosmetic Act) filed with the FDA for the Product, including, without limitation, any supplements thereto, any product license or any equivalent drug application or similar pharmaceutical product approval for the Product administered by any foreign Governmental Body, or supplement, extension or renewal of any of the foregoing.

“Effective Date” has the meaning in the preamble of this Agreement.

“Effective Supply Date” means the date of completion of the Expansion in accordance with Sections 4.1 and 4.2 of this Agreement.

“Expansion” has the meaning set forth in Section 4.1 of this Agreement.

“Facility” means Chemport’s manufacturing facility located at [***] (as the same may be expanded as provided herein), or such other FDA approved facility as agreed in writing by the Parties.

“FDA” means the United States Food and Drug Administration, or any successor agency thereof.

“Force Majeure Event” has the meaning provided in Section 14.1 of this Agreement.

“Governmental Body” means any nation or government, any state, province or other political subdivision thereof, any entity with legal authority to exercise executive, legislative, judicial, regulatory or administrative functions, or any division of the FDA (as applicable) and any other applicable counterpart agency or foreign equivalent that administers the Legal Requirements.

“Indemnified Party” has the meaning provided in Section 11.3 of this Agreement.

“Indemnifying Party” has the meaning provided in Section 11.3 of this Agreement.

“Initial Manufacturing Process” has the meaning provided in Section 5.4(a) of this Agreement.

“Initial Term” has the meaning provided in Section 15.1 of this Agreement.

“Intermediate” means a material produced during steps in the synthesis of API that must undergo further molecular change or processing before it becomes API.

“Intellectual Property” means (a) patents, patent rights, provisional patent applications, patent applications, designs, registered designs, registered design applications, industrial designs, industrial design applications and industrial design registrations, including any and all divisions, continuations, continuations-in-part, extensions, restorations, substitutions, renewals, registrations, revalidations, reexaminations, reissues or additions, including supplementary certificates of protection, of or to any of the foregoing items; (b) copyrights, copyright registrations, copyright applications, original works of authorship fixed in any tangible medium of expression, including literary works (including all forms and types of computer software, including all source code, object code, firmware, development tools, files, records and data, and all documentation related to any of the foregoing), musical, dramatic, pictorial, graphic and sculptured works; (c) trade secrets, technology, developments, discoveries and improvements, know-how, proprietary rights, formulae, confidential and proprietary information, technical information, techniques, inventions, designs, drawings, procedures, processes, models, formulations, manuals and systems, whether or not patentable or copyrightable, including all biological, chemical, biochemical, toxicological, pharmacological and metabolic material and information and data relating thereto and formulation, clinical, analytical and stability information and data which have actual or potential commercial value and are not available in the public domain; (d)

trademarks, trademark registrations, trademark applications, service marks, service mark registrations, service mark applications, business marks, brand names, trade names, trade dress, names, logos and slogans, Internet domain names, and all goodwill associated therewith; and (e) all other intellectual property or proprietary rights worldwide, in each case whether or not subject to statutory registration or protection.

“Legal Requirements” means any and all local, municipal, state, provincial, federal and international laws, statutes, ordinances, rules or regulations now or hereafter enacted or promulgated by any Governmental Body applicable to the development, approval, manufacture, sale, shipment or licensing of any pharmaceutical products, ingredients for inclusion therein, or any aspect thereof, and the obligations of Chemport or Amarin, as the context requires, under this Agreement, including, without limitation, applicable laws, statutes, ordinances, rules and regulations of South Korea, as well as the United States Federal Food, Drug and Cosmetic Act, as amended, and the rules and regulations promulgated thereunder.

“Losses” means, collectively, any and all claims, liabilities, damages, losses, costs, expenses, including reasonable fees and disbursements of counsel and any consultants or experts and expenses of investigation, obligations, liens, assessments, judgments, fines and penalties imposed upon or incurred by an Indemnified Party.

“Material Third Party Supplier” means a Third Party Supplier that provides materials used in the cGMP manufacture, testing or processing of cGMP Intermediate or API.

“[***] Forecast” has the meaning provided in Section 2.4(b) of this Agreement.

“Nonconformity” has the meaning provided in Section 6.4(a) of this Agreement.

“Nonconforming API” means API that is subject to a Nonconformity.

“Party” and “Parties” have the meanings given such terms, respectively, in the preamble of this Agreement.

“Person” means any individual, corporation, company, partnership, trust, incorporated or unincorporated association, joint venture or other entity of any kind.

“Pre-Approval Inspection” means an inspection of manufacturing operations, records and facilities conducted prior to approval of a new product by the FDA or by any other applicable Governmental Body having jurisdiction to approve the Facility as a cGMP facility for the manufacture of the API.

“Product” means (a) Amarin’s AMR101 product, and (b) any finished pharmaceutical product of Amarin that incorporates the API supplied by Chemport pursuant to this Agreement.

“Purchase Orders” has the meaning provided in Section 2.5 of this Agreement.

“Quality Agreement” means the agreement identified in Section 5.6 of this Agreement.

“Secondary Supplier” has the meaning set forth in Section 2.5 of this Agreement.

“Second Expansion” has the meaning provided in Section 4.3 of this Agreement.

“Shipment Date” means the date specified by Amarin in a Purchase Order that Chemport shall ship the API in accordance with this Agreement.

“Subcontractor” means any Third Party that performs any of the activities with respect to the manufacture and supply of API under this Agreement on Chemport’s behalf.

“Term” has the meaning provided in Section 15.1 of this Agreement.

“Third Party” means any Person other than the Parties or their respective Affiliates.

“Third Party Materials” means (a) all raw materials, components, work-in-process and other ingredients required to manufacture the API, and (b) all packaging materials used in the manufacture, storage and shipment of the API.

"Third Party Supplier" means any Third Party that provides to Chemport any Third Party Materials for any API produced under this Agreement.

"Validation" means a procedure for establishing documentation evidence that a specific system or facility is constructed and operates according to a predetermined set of specifications, protocols and guidelines.

"Validation Batch" has the meaning provided in Section 4.2 of this Agreement.

Article II
Sale and Purchase of API

2.1 General.

(a) Development and Process Validation Plan. Subject to the terms and conditions of this Agreement, Chemport agrees to conduct the Development and Process Validation Plan.

(b) Manufacture of API. Subject to the terms and conditions of this Agreement, Chemport agrees to manufacture API at the Facility for sale to Amarin. Chemport may not manufacture API at locations other than the Facility without the prior written Consent of Amarin, such Consent not to be unreasonably withheld or delayed and as provided in the Quality Agreement. For the avoidance of doubt, the Parties agree that this Agreement does not obligate Amarin to purchase all of its requirements of the API from Chemport, nor does it obligate Amarin to purchase any particular volumes of API from Chemport except as expressly set forth herein, nor does it obligate Chemport to sell the API exclusively to Amarin except as set forth in Section 2.3. Amarin retains the right to engage or appoint additional suppliers and contract manufacturers of the API from time to time in its sole discretion and Chemport retains the right to supply API to Third Party customers and to appoint Third Party distributors of the API from time to time in its sole discretion.

2.2 Minimum Purchase Requirement and Supply of Development Quantities. Amarin agrees to purchase from Chemport, and Chemport agrees to supply to Amarin, (a) no more than [***] batches (each batch shall be in a quantity of [***], which shall include the quantity of the Validation Batches) of API upon the Validation of the Initial Manufacturing Process pursuant to the Development and Process Validation Plan, (b) [***] of API annually (or such prorated amount in the case of a partial year) following [***], and (c) [***] of API annually (or such prorated amount in the case of a partial year) following [***]. From time to time during Chemport's expansion activities, as may be reasonably necessary, and upon no less than ten (10) days' advance written notice, Chemport shall deliver to Amarin (at no cost) quantities of API not to exceed two (2) kilograms for Amarin to evaluate and test.

2.3 Limited Exclusivity; Capacity Allocation.

(a) During the Term (i) Chemport shall not export, sell or distribute a [***] product incorporating Compound having a purity level greater than [***] that [***] for use in [***], (ii) Chemport shall not export, sell or distribute Compound having a purity level greater than [***] to any Third Party that exports, sells or distributes a [***] product incorporating the Compound that [***] for use in [***], (iii) Chemport shall not export, sell or distribute a [***] product incorporating Compound having a purity level greater than [***] for use in the [***], and (iv) Chemport shall not export, sell or distribute Compound having a purity level greater than [***] to any Third Party for use in a [***] product in the [***]; provided, however, for the avoidance of doubt, the prohibitions in this Section 2.3 shall not apply to (A) sales of a generic form of [***], (B) [***] in Chemport's export, sale or distribution of Compound having a purity level greater than [***] to any Third Party that exports, sells or distributes a [***] product incorporating the Compound that [***] for use in the [***]; and (C) [***] in Chemport's export, sale or distribution of Compound having a purity level greater [***] to any Third Party for use in a [***] product in the [***].

(b) Except as set forth in Section 2.3(a), above, Chemport shall be entitled to maximize its capacity utilization of the Facility by manufacturing products for Third Parties or itself in addition to the API; provided, however, that if Chemport is expected to be unable to supply all of the API forecast by Amarin and all of the needs of such other Persons, Chemport shall allocate such Facility capacity on a first priority basis to Amarin.

(c) This Section 2.3 shall expire in the event Amarin does not order the minimum annual quantities set forth in Section 2.2(b) or (c), as applicable, in any Calendar Year. For purposes of determining the quantities ordered by

Amarin in a Calendar Year, (i) all quantities subject to Purchase Orders placed in such Calendar Year, (ii) all quantities of Validation Batches of API purchased pursuant to Section 5.4(a) in such Calendar Year, (iii) all quantities ordered from a Secondary Supplier due to Chemport's failure to supply API hereunder in such Calendar Year, and (iv) all quantities ordered from a Secondary Supplier due to a Force Majeure Event in such Calendar Year shall be included in such determination.

2.4 Forecasts.

(a) Not later than [***] following the Effective Date, Amarin shall provide Chemport with a [***], nonbinding forecast of the quantity of API Amarin projects it may purchase from Chemport beginning [***] prior to the anticipated commercial launch of the Product (the "Commercial Launch Forecast"). Amarin shall submit an updated Commercial Launch Forecast (which shall also be nonbinding) within [***] after [***].

(b) Not later than [***] after the [***], Amarin shall, on a [***] basis, provide Chemport with a [***] rolling forecast of the quantity Amarin intends to order during each [***] (each such forecast referred to herein as a "[***] Forecast"). The forecast amount for the first [***] of the [***] Forecast shall be binding on both Parties. The forecast amounts for the remaining [***] of each [***] Forecast, i.e., [***], shall be non-binding forecast amounts. Chemport shall not be obligated to supply API in excess of the binding forecast amounts contained in the [***] Forecasts. Notwithstanding anything in this Agreement to the contrary, (i) in no event shall Chemport be obligated to manufacture during a [***] prior to the Expansion more than its then-existing [***] capacity divided by [***] and (ii) in no event shall Chemport be obligated to manufacture in [***] following the Expansion more than Chemport's [***] divided by [***].

2.5 Purchase Orders. From time to time, Amarin shall deliver to Chemport one (1) or more purchase orders ("Purchase Orders") for the aggregate API volumes in each binding portion of a [***] Forecast. Each Purchase Order shall specify the volumes of API ordered, the Shipment Date and the destination for delivery of the API. The Purchase Orders may be delivered electronically or by other means to such location as Chemport shall designate. Chemport shall deliver such API to Amarin's carrier on the Shipment Date specified by Amarin; provided, however, that the Shipment Date is no less than [***] after the date of the submission of the Purchase Order. In the event that Chemport shall not be able to deliver API to Amarin's carrier by the Shipment Date specified in a Purchase Order, Chemport shall notify Amarin promptly in writing upon discovery of its inability to comply with the terms of this Section 2.5; provided, however, that such notification shall not relieve Chemport of any liability for failure to deliver API to Amarin's carrier on such Shipment Date.

If Chemport fails to meet the Purchase Order or any portion thereof on or before the applicable Shipment Date, in addition to other remedies that may be available to Amarin under the Legal Requirements, Amarin may purchase the shortage of such API from Third Parties and Chemport shall pay to Amarin the difference in price of such API purchased from a Third Party (a "Secondary Supplier") and the API Price for the API shortage; *provided*, however, that in no event shall such payment exceed an amount equal to the volume of shortage times [***] of the then applicable API Price that Chemport is charging to Amarin for API.

If Amarin fails to order API in the amount specified in the binding portion of the [***] Forecast, in addition to other remedies that may be available to Chemport under the Legal Requirements, Amarin shall pay to Chemport [***] of the then current API Price that Chemport is charging to Amarin for API for the volume of API under the binding portion of the [***] Forecast less the actual amount ordered by Amarin.

If Amarin fails to purchase the relevant minimum yearly purchase requirement as set forth above, in addition to other remedies that may be available to Chemport under the Legal Requirements, Amarin shall pay to Chemport [***] of the then current API Price that Chemport is charging to Amarin for API for the relevant minimum yearly purchase requirement as set forth above less the actual amount purchased by Amarin in the relevant year.

2.6 Accommodations. From time to time, Amarin may deliver to Chemport a Purchase Order for API volumes in excess of those specified in any binding portion of a [***] Forecast. Chemport shall notify Amarin in writing as to whether Chemport is able to supply the excess volume of API, but shall not otherwise be obligated to supply the excess volume of API.

2.7 Meetings. Unless otherwise mutually agreed, the Parties shall meet or otherwise communicate no less than [***] to discuss the progression of the Development and Process Validation Plan, the Expansion, the Second Expansion,

the forecasts delivered by Amarin pursuant to this Agreement and other matters relevant to the supply of API hereunder. The Parties shall use commercially reasonable efforts to accommodate technical meetings requested by both Parties.

Article III
Financial Matters

3.1 API Price.

(a) API Price. Schedule 3.1 to this Agreement sets forth the price for API (the "API Price") based on (i) the aggregate [***] represented by Purchase Orders in a Calendar Year (such aggregate quantities and associated pricing are delineated in Tier 1 of Matrix I and Tier 1, 2, 3, 4, 5 and 6 of Matrix II of Schedule 3.1) and (ii) timely completion of the Expansion and/or the Second Expansion (the associated pricing are delineated in Matrices I and II of Schedule 3.1). In the event Chemport expands the Facility beyond the Second Expansion ("Additional Expansions"), the Parties will negotiate in good faith the price of the API supplied in excess of [***] per year based on a tiered pricing scheme that recognizes relevant investments, the efficiencies in the manufacturing processes of the expanded Facility and any change in Chemport's cost of manufacturing API.

(b) Calculation. Following Amarin's first delivery of a [***] Forecast in each [***] during the Term of this Agreement, Amarin shall estimate:

(i) The aggregate forecast orders for such [***] to estimate whether pricing Tier 1 of Matrix I or Tier 1, 2, 3, 4, 5 or 6 of Matrix II (as set forth in Schedule 3.1) is applicable.

(ii) The aggregate [***] subject to the pricing set forth in Schedule 3.1. Up to [***] shall be subject to Matrix I pricing (as set forth in Schedule 3.1) once the Expansion is completed. In the event Amarin invests in the Second Expansion, up to [***] shall be subject to Column A of Matrix II pricing (as set forth in Schedule 3.1) once the Second Expansion is completed. In the event Amarin does not invest in the Second Expansion, up to [***] shall be subject to Column B of Matrix II pricing (as set forth in Schedule 3.1) once the Second Expansion is completed. All other amounts shall be subject to subsequent negotiation between the Parties. For the avoidance of doubt, the API Prices listed in Schedule 3.1 for quantities in excess of [***] are target prices and are subject to good faith negotiations. Furthermore, in the event the price for Column B of Tier 1 or Tier 2 of Matrix II (currently marked as "TBD") becomes necessary, Chemport and Amarin shall negotiate in good faith to reach an agreement on such prices.

Based on such estimates in (i) and (ii) above, Amarin shall advise Chemport in writing, and provide Chemport supporting documentation and calculations, of the weighted average API Price under Schedule 3.1. Chemport shall thereafter have the right to review Amarin's calculation of the weighted average API Price and consult with Amarin with respect thereto. In the event Chemport does not agree with Amarin's calculation of the weighted average API Price, the Parties shall use their respective commercially reasonable efforts to agree to the proper calculation of the weighted average API Price. In the event the Parties are unable to agree within [***], the dispute shall be resolved as provided in Section 16.5. The API Price determined by this subsection (b) shall be the API Price invoiced and paid for Purchase Orders submitted during such [***] (and retroactively applied to any Purchase Orders delivered in such [***] prior to the determination of such API Price). Such API Price, however, shall be subject to a year-end retroactive adjustment pursuant to subsection (c) below.

(c) Annual Adjustment. Within [***] after each December 31 during the Term of this Agreement and within [***] following the termination of this Agreement, Chemport will determine:

(i) The aggregate [***] represented by Purchase Orders in the prior Calendar Year to determine whether pricing Tier 1 of Matrix I or Tier 1, 2, 3, 4, 5 or 6 of Matrix II (as set forth in Schedule 3.1) is applicable. Chemport shall include in such determination the aggregate amount of API, if any, for which Amarin submits a purchase order to a Secondary Supplier in such Calendar Year due to (A) Chemport's failure to supply API hereunder and/or (B) a Force Majeure Event. Any Validation Batches of API purchased pursuant to Section 5.4 in such Calendar Year shall also be included. In the case of a partial year, the aggregate [***] represented by Purchase Orders in such prior partial year shall be annualized in such determination.

(ii) The aggregate [***] for the pricing is set forth in Schedule 3.1 based on (A) timely completion of the Expansion and Amarin's investment in the Second Expansion and (B) the limits set forth in Section 3.1(b).

(iii) The aggregate amounts paid to Chemport under Purchase Orders issued in the prior Calendar Year.

Based on such determinations set forth in (i), (ii) and (iii) above, Chemport shall advise Amarin in writing, and provide supporting documentation and calculations, of (A) the weighted average API Price for such prior Calendar Year, (B) the aggregate purchase price for all API subject to all Purchase Orders issued in the prior Calendar Year, and (C) the difference between (1) the aggregate amounts paid to Chemport under Purchase Orders issued in the prior Calendar Year and (2) the aggregate purchase price for all API subject to all Purchase Orders issued in the prior Calendar Year. Amarin shall thereafter have the right to review Chemport's calculations and consult with Chemport with respect thereto. In the event Amarin does not agree with Chemport's calculations, the Parties shall use their respective commercially reasonable efforts to agree to the proper calculations. In the event the Parties are unable to agree within thirty (30) days, the dispute shall be resolved as provided in Section 16.5. The API Price for such prior Calendar Year, the aggregate purchase price for all API subject to all Purchase Orders issued in the prior Calendar Year, and the difference between (x) the aggregate amounts paid to Chemport under Purchase Orders issued in the prior Calendar Year and (y) the aggregate purchase price for all API subject to all Purchase Orders issued in the prior Calendar Year determined by this Subsection (c) shall be the final determinations thereof. In the event that (x) the aggregate amounts paid to Chemport under Purchase Orders issued in the prior Calendar Year are greater than (y) the aggregate purchase price for all API subject to all Purchase Orders issued in the prior Calendar Year, Chemport shall pay Amarin the difference within [***] of the final determination thereof. In the event that (x) the aggregate amounts paid to Chemport under Purchase Orders issued in the prior Calendar Year are less than (y) the aggregate purchase price for all API subject to all Purchase Orders issued in the prior Calendar Year, Amarin shall pay Chemport the difference within [***] of the final determination thereof. In addition, the final API Price for the prior Calendar Year determined by this Subsection (c) shall be the price for API subject to Purchase Orders placed in the prior Calendar Year but not invoiced prior to final determination of the API Price, and Chemport shall invoice such amounts accordingly.

(d) Packaging. The Parties hereby agree that Chemport shall be responsible for up to [***] of the cost of each packaging container used for transportation of the API to Amarin. The rest of the cost of each such packaging container shall be borne by Amarin.

(e) Price Adjustment. Effective from the [***] anniversary date of the Effective Supply Date, Chemport shall be entitled to make an adjustment to the API Prices listed in Schedule 3.1 in accordance with the methodology described in Schedule 3.1(e) by giving Amarin written notice of such new API Prices at least [***] prior to the relevant anniversary of the Effective Supply Date. Amarin may request in writing that Chemport make such an API Price adjustment, if applicable, by providing such written notice at least [***] prior to the relevant anniversary of the Effective Supply Date. If so requested by Amarin, Chemport shall provide Amarin written notice of such new API Prices, if applicable, at least [***] prior to the relevant anniversary of the Effective Supply Date. Within [***] from the date of receipt of written notice of any API Price change, Amarin may request Chemport to provide its API Price adjustment records to an independent, mutually agreed upon, reputable certified public accounting firm, which will audit such records and certify whether the price adjustments notified by Chemport are correct and in accordance with the methodology described in Schedule 3.1(e). Such certification shall be made in writing on the auditing firm's letterhead and delivered to Amarin at least [***] prior to the relevant anniversary of the Effective Supply Date. No increase in the API Prices may occur until the audit has been completed and the price adjustment has been certified as described above. In the event the audit reveals that the increase is appropriate, Amarin shall bear the cost of the audit, and shall pay the increased API Prices for API in purchase orders from the relevant anniversary of the Effective Supply Date. In the event the audit reveals that the increase is not appropriate, then Chemport shall bear the cost of the audit and the API Prices of API may not increase. The increase of the API Prices of API shall be deemed accepted by Amarin if Amarin fails to make a timely request for an audit as described above or the requested audit is not completed at least [***] prior to the relevant anniversary of the Effective Supply Date.

3.2 Commercial Invoices. Chemport may invoice Amarin for API on or before the Shipment Date of such API to Amarin or its designee pursuant to Section 3.5(a). All invoices shall be commercial invoices and shall include the following: (a) 'Commercial Invoice' written on the top of the document, (b) the date of the invoice, (c) the number of the Purchase Order, (d) an invoice number, (e) the quantity of API, (f) the total amount being invoiced, and (g) a reference to this Agreement, and shall be submitted to:

Amarin Pharmaceuticals Ireland Ltd.
c/o Amarin Pharma, Inc.
12 Roosevelt Avenue, 3rd Floor
Mystic, CT, USA 06355
Facsimile: 860 572-4940

Attention: Accounts Payable
Email: [***]

3.3 Payment. Payments for API invoiced consistent with Section 3.2 above shall be due [***] from the date of shipment, subject in each case to Amarin's right to dispute invoice amounts and/or delay the payment of invoiced amounts disputed by Amarin in good faith, including, without limitation, the rights set forth in Article VI.

3.4 Payment Denominations. The API Price, all invoiced amounts and all payments to be made under this Agreement shall be in [***].

3.5 Shipment; Title; Transport.

(a) General. All API shall be shipped [***] (as defined in INCOTERMS® 2010) [***]. Subject to Section 3.1(d), Chemport shall package the API for shipment (including but not limited to containers, packaging, container closure systems and labeling) in accordance with the API Specifications, Amarin's reasonable instructions and its customary practices therefor. In the event of any conflict between Amarin's packaging instructions and Chemport's customary practices, the Parties shall endeavor in good faith to resolve such conflict as quickly as practicable. Chemport shall include the following with each shipment of the API: (i) the Purchase Order number; (ii) the lot and batch numbers; (iii) the quantity of the API; (iv) the Certificates, as applicable; and (v) such customs and other documentation as is necessary or appropriate. Chemport shall ship API to the destination designated by Amarin within [***] of the manufacture date for Purchase Orders of quantities up to [***] and [***] of the manufacture date for Purchase Orders of quantities exceeding [***].

(b) Title/Risk of Loss. Title to and risk of loss for any API shall pass from Chemport to Amarin when such API is [***]; provided, however, that nothing in this Article III shall in any manner limit Amarin's rights under Article VI. If API is rejected by Amarin after delivery under this Agreement, and such API is to be returned to Chemport, then title to and risk of loss for such rejected API shall pass from Amarin to Chemport when such API is [***]. All returned API shall be shipped [***] (as defined in INCOTERMS® 2010) [***].

(c) Single Order. To the extent reasonably possible, API which is purchased in a single order shall be delivered by Chemport in a single shipment, unless Amarin directs that such API should be delivered to more than one location.

(d) Shelf Life. The API shall have a minimum shelf life of [***] as of the applicable date of manufacture. The minimum shelf life set forth in the immediately preceding sentence is based on existing stability data. In the event future stability data justifies a longer shelf life, the Parties agree to discuss in good faith an extended minimum shelf life as of the applicable date of manufacture.

3.6 Taxes.

(a) Amarin shall pay and otherwise be responsible for all applicable sales, VAT, goods, services, transfer and similar taxes in connection with the supply of API pursuant to this Agreement, excluding any income tax or taxes levied with respect to gross receipts, payable by Chemport under the Legal Requirements with respect to amounts payable under this Agreement.

(b) Any tax that one Party is required to withhold and pay on behalf of the other Party with respect to amounts payable under this Agreement shall be deducted from said amounts prior to payment to the other Party; provided, however, that, in regard to any tax so deducted, the Party making the withholding shall give or cause to be given to the other Party such assistance as may reasonably be necessary to enable that other Party to claim exemption therefrom or credit therefor and in each case shall furnish the Party on whose behalf amounts were withheld proper evidence of the taxes paid on its behalf. Each Party shall comply with reasonable requests of the other Party to take any proper actions that may minimize any withholding obligation.

Article IV
Capacity, Expansion

4.1 Capacity. Within [***] after the Effective Date, Chemport shall expand the Facility's capacity to supply annually [***] of API (with design capacity of [***] annually) as further detailed in Schedule 4.1 (the "Expansion"). In the event that the Expansion is not complete (as described in Section 4.2) within such [***] period, Chemport shall provide Amarin a written request to extend such period accompanied with a summary of the progression of the Expansion and steps needed to complete the Expansion. Upon submission of such request, Chemport shall have an

additional [***] period to complete the Expansion. Following completion of the Expansion, Chemport shall maintain at all times during the Term the capacity to supply Amarin no less than [***] of API each Calendar Year ("Chemport's Initial Minimum Capacity"). Chemport's capacity as further expanded in accordance with this Agreement, together with Chemport's Initial Minimum Capacity, shall be referred to herein as "Chemport's Minimum Capacity."

4.2 Completion. The Expansion will be deemed to be completed for purposes of this Agreement if all of the requirements set forth in Schedule 4.1 have been satisfied and Chemport has manufactured [***] successful, consecutive batches (each batch shall be in a quantity of [***]) of API (each a "Validation Batch") in the expanded Facility that satisfy the requirements of this Agreement.

4.3 Second Expansion. Upon [***], Chemport will initiate a second expansion of the Facility to expand the capacity to [***] of API (with a design capacity of [***]) each Calendar Year (the "Second Expansion"), provided, however, the Parties shall mutually agree on the timing and schedule of such expansion activity. The summary plan for the Second Expansion is set forth in Schedule 4.5, and Chemport shall submit a detailed development and validation plan for the Second Expansion within thirty (30) days of the later to occur of [***] and [***]. The Second Expansion will be deemed completed for purposes of this Agreement if all the requirements set forth in Schedule 4.5 have been satisfied and Chemport has manufactured [***] successful, consecutive Validation Batches in the expanded Facility that satisfy the requirements of this Agreement.

Article V
Manufacture of API

5.1 General. Chemport shall manufacture, test, package, store, handle, label, release and ship all API in accordance with the applicable Drug Applications, API Specifications, cGMPs, Legal Requirements, this Agreement and the Quality Agreement.

5.2 API Specification Changes.

(a) Amarin Requested Changes. During the Term, except as set forth in Section 5.2(c), Amarin shall not be entitled to change the API Specifications related to Chemport's performance of its obligations hereunder related to API unless it receives the Consent of Chemport, which Consent shall not be unreasonably withheld or delayed. If Amarin requests, and Chemport approves, a discretionary change to the API Specifications, Chemport shall make all revisions to the API Specifications requested by Amarin. Amarin retains the right and responsibility for final approval of the API Specifications. Amarin shall pay Chemport all documented reasonable amounts incurred in implementing a change to the API Specifications requested by Amarin under this Section 5.2(a). For all changes to the API Specifications requested by Amarin pursuant to this Section 5.2, Amarin shall, in its discretion, following consultation with Chemport, if reasonably practicable, either (i) perform, or arrange for the performance of, all development work in connection therewith or (ii) have Chemport perform such development work at the Facility at Amarin's expense. For the avoidance of doubt, Section 5.2(a)(i) does not give Amarin any right to use or disclose (A) any Chemport Intellectual Property (except as may be permitted by any express license from Chemport), or (B) any Chemport Confidential Information (except as may be permitted under Article XIII hereof). Chemport agrees to use commercially reasonable efforts to minimize its costs associated with any API Specification change. At the request of Amarin, Chemport shall evaluate the estimated costs and timing of potential revisions to the API Specifications.

(b) Chemport Changes. Chemport shall not make any revisions to the API Specifications, the manufacturing process or Material Third Party Suppliers, without prior written Consent of Amarin, which Consent shall not be unreasonably withheld or delayed. If the Parties implement a change in the API Specifications or the manufacturing process under this Section 5.2, they shall negotiate any changes in any affected Purchase Order to provide reasonable accommodation for changed circumstances. The costs of revisions requested by Chemport under this Section 5.2(b) shall be borne by Chemport without any increase in the API Price.

(c) Changes Mandated by Legal Requirements. Notwithstanding anything in subsections (a) and (b) of this Section 5.2 to the contrary, (i) Chemport shall implement all changes to the API Specifications intended to maintain compliance with Legal Requirements, to bring the API Specifications into compliance with Legal Requirements or to accommodate the demands or requests of any Governmental Body; (ii) unless such changes are generally

applicable to the Facility or Chemport's manufacture of other products, the Parties shall bear equally the expense of any of such changes; and (iii) if the changes are generally applicable to the Facility or Chemport's manufacture of other products, Chemport shall bear the expense of any of such changes. Notwithstanding the foregoing, if changes to Legal Requirements generally affecting manufacturers of drugs containing the Compound significantly increase the cost for Chemport to supply API hereunder, then the Parties agree to negotiate in good faith any appropriate adjustments to this Agreement.

5.3 Storage and Handling Obligations. When storing and handling API, Third Party Materials, Nonconforming API or API-derived wastes, Chemport shall comply with, and shall maintain all storage facilities in compliance with, the API Specifications, cGMPs, Legal Requirements and the Quality Agreement.

5.4 Validations and Stability Studies.

(a) Initial Manufacturing Process Validation. Chemport shall as soon as practicable complete the Validation of the manufacturing process for the API in connection with the Expansion (the "Initial Manufacturing Process") in accordance with activities set forth in the Development and Process Validation Plan at no additional cost to Amarin. The Development and Process Validation Plan shall, among other things, include activities necessary to establish the Facility as a cGMP facility, a validation plan and appropriate protocols. Without limiting the foregoing, Chemport will provide process progress reports to Amarin no less frequently than [***], which reports shall include, without limitation, reasonable details related to construction, equipment installation and process implementation, subject to redaction of any Chemport Confidential Information. Promptly following completion of Validation of the Initial Manufacturing Process, Chemport shall deliver a final report to Amarin that includes a summary of regulatory data and documentation respecting the manufacture of the API, without disclosing any confidential process information, all in compliance with applicable FDA guidelines and any other applicable Legal Requirements but subject to redaction of any Chemport Confidential Information.

(i) The Parties shall participate in project teleconferences with each other as reasonably requested by the other Party to successfully complete the Validation of the Initial Manufacturing Process. During development and Validation of the Initial Manufacturing Process, Chemport will accommodate in person technical meetings at the Facility and technical inspections as reasonably requested by Amarin. Without limiting the foregoing, during process development and in support of API process characterization and Validation activities, Amarin will be permitted to conduct reviews of the Facility and the pertinent records maintained by Chemport, subject to restriction on access to all Chemport Confidential Information, in connection with the conduct of manufacturing, storage and testing of API, all upon Amarin's request and with reasonable notice to permit Chemport to support such technical reviews.

(ii) In conjunction with the foregoing Validation pursuant to the Development and Process Validation Plan, Chemport will produce process Validation Batches. Amarin shall be required to purchase Validation Batches of API provided that they comply with the API Specifications and Validation acceptance criteria and are otherwise in compliance with the terms of this Agreement. The establishment and Validation of the Initial Manufacturing Process shall be deemed to be complete upon the manufacture of such [***] successful, consecutive Validation Batches that comply with the API Specifications and Validation criteria and are otherwise in compliance with the terms of this Agreement and the Development and Process Validation Plan.

(iii) With the prior written consent of the other Party, a Party may engage in teleconferences, in-person meetings, Facility reviews, quality assurance audits, records reviews and other activities under this Agreement through its (or its Affiliates') employees or consultants with a bona fide need to know, but only to the extent necessary for the Party to exercise its rights and discharge its obligations under this Agreement, provided that (A) each such employee and consultant has executed a written confidentiality agreement containing use and disclosure restrictions at least as protective as those set forth in Article XIII, and (B) any Amarin consultant shall be reasonably acceptable to Chemport (such persons, "Approved Representatives").

(b) Process Validation for Improved Manufacturing Processes. The Parties acknowledge that Amarin or Chemport may from time to time desire to pursue strategies and efficiencies for improving the manufacturing processes for the API. Each Party agrees to reasonably evaluate and discuss any such suggestions for improvements that the other Party reasonably believes in good faith may result in significant cost or time savings in the manufacturing process.

(c) General. Without limiting the foregoing, Chemport shall perform at no additional cost to Amarin on an on-going basis all Validations and stability studies required by the applicable Drug Applications, the API Specifications, cGMPs or Legal Requirements in connection with the regular course of manufacturing the API for commercial supply.

(d) Duties. In performing its duties under this Section 5.4, Chemport shall perform the following tasks, consistent with the Quality Agreement:

(i) implement and operate an ICH complaint stability program;

(ii) notify Amarin's head of regulatory affairs, or his or her designee, promptly, but within not more than [***], if any batch of API fails any stability tests; and

(iii) report to Amarin's head of regulatory affairs, or his or her designee, promptly, but within not more than [***], any Nonconformity, significant atypical results, deviations or adverse trends exhibited during final release or stability testing.

(e) Manufacturing Process Review. At either Party's reasonable request, the Parties shall promptly meet, in person or telephonically, for the purpose of reviewing such matters related to manufacturing of the API as may be specified by a Party, including discussing strategies for improving the API manufacturing processes.

(f) Confidential Information. Notwithstanding anything to the contrary contained in this Agreement, Chemport may redact or limit from any deliveries of or access to data, reports or any other information to Amarin any Third Party confidential information or Chemport Confidential Information, at Chemport's sole discretion; provided, however, that Chemport may not redact or limit any Chemport Confidential Information that is reasonably necessary for Amarin to comply with all Legal Requirements. In this regard, the Parties agree that all process information related to the manufacture of API, whether contained in a DMF or otherwise, shall, subject to Section 13.4, constitute Chemport Confidential Information and shall not be disclosed to Amarin under any circumstances, notwithstanding anything herein to the contrary; provided, however, Chemport shall provide the relevant Governmental Body with all information necessary to support Amarin's Drug Application filings in a timely manner. Furthermore, for the avoidance of doubt, subject to Section 13.4, all information provided to Amarin under this Section 5.4 is Chemport Confidential Information and nothing in this Section 5.4 shall be construed as giving Amarin any right to use or disclose (A) any Chemport Intellectual Property (except as may be permitted by any express license from Chemport), or (B) any Chemport Confidential Information (except as may be permitted under Article XIII hereof).

5.5 Third Party Materials.

(a) General. Chemport shall be responsible for procuring, inspecting, testing and releasing adequate Third Party Materials that comply with cGMP and this Agreement as necessary to meet a Purchase Order for API. Chemport shall perform all testing of Third Party Materials required by the applicable API Specifications, cGMP, Legal Requirements, this Agreement and the Quality Agreement.

(b) Audits. Chemport shall be responsible for selecting all Third Party Suppliers of materials for API and periodically performing audits of each such Material Third Party Supplier as necessary to ensure compliance with Section 5.5(a). Chemport shall provide the results of any such audit, including copies of any reports prepared in connection with any such audit, within [***] of the audit's completion.

(c) Materials Certifications. Chemport shall prepare or cause to be prepared by its Third Party Suppliers all certifications as to any Third Party Materials required by cGMPs or Legal Requirements.

5.6 Quality Agreement. Within [***] following the Effective Date, the Parties shall enter into a quality agreement with such scope, terms and conditions as are customary within the pharmaceutical industry (such agreement, the "Quality Agreement"). In the event of a conflict between any of the provisions of this Agreement and the Quality Agreement, the provisions of this Agreement shall govern.

5.7 Compliance with Specifications, cGMPs and Legal Requirements. Chemport shall be responsible for identifying and implementing, in accordance with its obligations under Section 5.1, any actions required to bring Chemport, Material Third Party Suppliers and Third Party Suppliers of starting materials for the Compound into compliance with API Specifications, cGMPs and Legal Requirements. Chemport shall implement any such changes as soon as reasonably practicable (even if, in the case of cGMPs and Legal Requirements, a later effective date is specified), unless the required effective date for implementing such change falls after the effective date of any termination of this Agreement for which notice has been previously given.

Article VI
Testing and Quality Assurance

6.1 Quality Assurance; Quality Control; Retains.

(a) Chemport shall implement and perform operating procedures and controls for sampling, ICH stability, release and other testing of Third Party Materials and API, and for Validation, documentation and release of the API and such other quality assurance and quality control procedures as required by the API Specifications, cGMPs, Legal Requirements, this Agreement and the Quality Agreement. Without limiting the foregoing, Chemport shall establish an ICH stability program that collects no less than [***] data. Chemport shall consult with Amarin with respect to the details of the stability program, including analytical methods and stability container requirements.

(b) Chemport shall maintain for a period of time required by Legal Requirements, but in no event less than [***] after the expiration date of such API (i.e., a total of [***] from manufacture, subject to Section 3.5(d)), such quantities of the API from each batch of the API as are sufficient to conduct [***] full testings of the API in accordance with this Agreement.

6.2 Testing of API. Prior to release of the API, Chemport shall test the API in accordance with the Validation testing procedures described in the (a) applicable Drug Applications, (b) API Specifications, (c) cGMPs, (d) Legal Requirements, (e) Quality Agreement and (f) those procedures and in-plant quality control checks applicable to any products packaged by Chemport. Chemport shall provide Amarin with a copy of the records pertaining to such testing if reasonably requested, subject to redaction of any Chemport Confidential Information. Additionally, Chemport shall provide Amarin with a Certificate of Analysis and/or any other certificate required by any applicable Governmental Body for release of API (collectively, the "Certificates") for each batch of API. Amarin shall be under no obligation to accept any shipment of API without the accompanying Certificates. For the avoidance of doubt, all information provided to Amarin under this Section 6.2 is Chemport Confidential Information and nothing in this Section 6.2 shall be construed as giving Amarin any right to use or disclose (A) any Chemport Intellectual Property (except as may be permitted by any express license from Chemport), or (B) any Chemport Confidential Information (except as may be permitted under Article XIII hereof).

6.3 Amarin Holds, Rejections and Revocation of Acceptance.

(a) General. Amarin may test or cause to be tested the API delivered by Chemport for a Nonconformity or reasonably suspected Nonconformity (as described below in Section 6.4). During such testing, at Amarin's reasonable request, Chemport shall provide appropriate analytical reference standards for such testing to Amarin or its designee. If Amarin wishes to hold the API delivered to it by Chemport for investigation of a Nonconformity or reasonably suspected Nonconformity, Amarin shall so notify Chemport stating the basis for the hold. Amarin's failure to comply with provisions of this Section 6.3 and 6.4, including timely notification of Chemport of any Nonconformity, shall be deemed to be an irrevocable acceptance of any such relevant API by Amarin.

(b) Independent Testing. If the Parties disagree as to whether API subject to hold, rejection or revocation of acceptance is subject to a Nonconformity, Chemport's and Amarin's respective designees shall confer to review samples and/or batch records, as appropriate, and Chemport shall initiate a formal investigation. If the disagreement is not resolved within [***], then samples, batch records and other data relating to the batch in dispute shall promptly be submitted for testing and evaluation to a mutually acceptable independent Third Party (including a qualified testing laboratory to perform such testing using validated methods) mutually approved in writing by the Parties. The findings of such independent Third Party shall be binding on the Parties, absent manifest error. The expenses incurred by the Parties for the testing and evaluation by the Third Party shall be borne by Chemport unless Amarin has claimed that the API is subject to a Nonconformity, and the API in question is ultimately found not to be Nonconforming API.

(c) Interim Replacement. During the pendency of any dispute concerning whether API is subject to a Nonconformity, Chemport shall replace the shipment under dispute, at the request of Amarin, as soon as reasonably practicable.

6.4 Nonconformity.

(a) Nonconformity. If, within [***] following manufacture of a batch of API, either Party becomes aware or has a reasonable basis to believe that any batch or shipment of API may have a Nonconformity, at any time regardless of the status of Chemport's testing and quality assurance activities, such Party shall notify the other Party within [***]

of becoming aware of a Nonconformity. "Nonconformity" means a product characteristic that (i) results from Chemport's failure to manufacture, test, package, store, label, release or ship API in accordance with the API Specifications, cGMPs, ICH guidelines, Legal Requirements, this Agreement or the Quality Agreement, (ii) causes any API to fail to conform to the API Specifications, cGMPs or Legal Requirements, or (iii) constitutes an adulteration. In the event of a Nonconformity or reasonably suspected Nonconformity identified within [***] following manufacture of an affected batch of API, the Parties shall immediately (and in any case within [***]) conduct an investigation in accordance with Section 6.8 below and, until resolution of the investigation, handle the API as provided in Section 6.4(b) below.

(b) API That May Be Subject to a Nonconformity. Any batch or shipment of API that reasonably may be suspected to be subject to a Nonconformity shall be handled as follows and consistent with the Quality Agreement:

(i) such API held in inventory at Chemport shall be placed on "Hold" and shall not be shipped to Amarin or its designee, unless, upon completion of investigations pursuant to Section 6.8, such API is found to be not Nonconforming or it is directed otherwise by Amarin;

(ii) any such API shipped to Amarin or its designee and held in stock by Amarin or its designee shall maintain a "hold" or "rejected" status and shall not be released into approved inventory of Amarin or its designee until the Parties have completed any investigations pursuant to Section 6.8; and

(iii) payment for such API whether shipped or unshipped shall [***].

Upon learning of a Nonconformity, Amarin shall have the right to [***].

(c) Remedy for Nonconforming API.

(i) In the event that any quantity of API is found to be Nonconforming API prior to it being converted into Product and Amarin notifies Chemport of such Nonconformity within [***] following manufacture of such batch of API, then Amarin may, at Amarin's discretion: (1) [***] and/or [***]; *provided*, however, that, with respect to the payment payable pursuant to [***], in no event shall such payment exceed an amount equal to [***] times [***] of [***]. For clarity, once API has been delivered by Chemport under Section 3.5(a), it may not be reworked or reprocessed in the event it is found to be Nonconforming API.

(ii) In the event that any Nonconforming API is held in inventory at Chemport, then Chemport shall have such Nonconforming API destroyed.

(iii) In connection with the destruction of API, Amarin under Section 6.4(c)(i)(B)(3) or Chemport under Section 6.4(c)(ii) shall be solely responsible for compliance with all Legal Requirements in connection with the destruction and shall be liable for any Losses resulting from such destruction, and the Party not directing the destruction of such API, as the case may be, may, if it so requests, (A) be present at such destruction, or (B) receive written documentation of such destruction.

(iv) Chemport shall use commercially reasonable efforts to perform any replacement of Nonconforming API on a priority basis and shall deliver such replacement API as soon as possible.

(d) Credit/Reimbursement for Nonconforming API. In the event that Chemport is obligated to Amarin pursuant to Section 6.4(c), Chemport shall, at Amarin's discretion, reimburse or credit Amarin for (i) [***] and [***]. Amarin shall provide Chemport with such documentation as Chemport may reasonably request to confirm any of the foregoing charges, costs or expenses. Chemport shall pay any unused credit amounts under this Section as of the expiration or termination of this Agreement to Amarin within [***] after this Agreement is terminated.

6.5 Quantitative Deficiencies. In the event Amarin determines there is a quantitative deficiency in any shipment, with respect to the API volumes indicated on the applicable Purchase Order(s), Amarin shall properly document such deficiency and notify Chemport thereof in writing. Upon such notice, Amarin may, at its option: (a) pay only for actual quantities delivered, or (b) pay only for actual quantities delivered and require Chemport to rectify any such deficiency by shipping the appropriate quantities of API to or as directed by Amarin, in which case Amarin shall be obligated to pay for any such additional quantities pursuant to the terms and conditions of this Agreement. Chemport shall use commercially reasonable efforts to rectify any such deficiency on a priority basis and deliver such additional quantities of API as soon as possible.

6.6 Product Complaints Reports.

(a) Received by Chemport. Any and all complaints of which Chemport becomes aware relating to the Product shall promptly be forwarded to Amarin's head of regulatory affairs, or his or her designee, consistent with the Quality Agreement. Without limiting the foregoing, Chemport shall forward any such complaint that might be associated with an Adverse Event (as defined below in Section 6.7) no later than [***] following its receipt.

(b) Received by Amarin. Amarin shall as soon as possible inform Chemport of any and all complaints that Amarin receives which implicate Chemport's manufacturing or other processes at the Facility. Notification shall be given by telephone, with a facsimile confirmation immediately following.

6.7 Adverse Events.

(a) Definition. For the purposes of this Agreement, "Adverse Event" shall mean any adverse event associated with the use of the Product in humans, whether or not considered drug-related, including but not limited to "adverse event" as defined in ICH guidelines.

(b) Chemport Notice to Amarin. Chemport shall notify Amarin's head of regulatory affairs, or any successor department specified by Amarin, as soon as possible, but no later than [***] following its receipt, of information concerning a possible Adverse Event. Notification shall be given by telephone, with a facsimile confirmation immediately following. Chemport shall provide to Amarin all of the information Chemport has available concerning the Adverse Event and shall reasonably cooperate with any investigation conducted or directed by Amarin as set forth in Section 6.8 below.

(c) Amarin Notice to Chemport. To the extent an Adverse Event of which Amarin becomes aware implicates Chemport's manufacturing or other processes at the Facility, Amarin shall inform Chemport of such Adverse Event as soon as possible, but no later than [***] following its receipt of such information, and shall disclose to Chemport any information Amarin has regarding that Adverse Event which implicates Chemport's manufacturing or other processes at the Facility. Notification shall be given by telephone, with a facsimile confirmation immediately following.

6.8 Investigations; Chemport's Obligations.

(a) General. The Parties shall investigate all reports of Nonconformity, Product complaints, out-of-trend analytical results, out-of-trend manufacturing yields, stability failure and Adverse Events. The Parties shall act promptly and shall cooperate fully in such investigations.

(b) Direction.

(i) Investigations Related to Product or API Following Shipment. Amarin shall have the sole right, in its discretion, to control and direct any or all aspects of an investigation conducted under this Section 6.8 with respect to matters related to API following shipment by Chemport or with respect to the Product. Amarin shall advise Chemport from time to time throughout such investigation of Amarin's intentions regarding control and direction of such aspects of the investigation. Amarin shall reasonably consult with Chemport and shall reasonably afford Chemport the opportunity to provide comments or suggestions regarding such investigation, which Amarin agrees to consider in good faith.

(ii) Investigations Related to API Prior to Shipment. Chemport shall have the sole right, in its discretion, to control and direct any or all aspects of an investigation conducted under this Section 6.8 to the extent related to API prior to its shipment by Chemport. Chemport shall advise Amarin from time to time throughout such investigation of Chemport's intentions regarding control and direction of such aspects of the investigation. Chemport shall reasonably consult with Amarin and shall reasonably afford Amarin the opportunity to provide comments or suggestions regarding such investigation, which Chemport agrees to consider in good faith.

(iii) Mutual Assistance. Upon written request by a Party in connection with an investigation, the other Party shall provide all reasonably requested testing results, assistance and information to the requesting Party in connection with an investigation of any Nonconformity, Product complaint or Adverse Event, including chemical/microbial analysis of complaint samples (if available), analysis of retained samples and review of batch records. The Party not directing an investigation shall have the right to conduct at its own expense any further tests it deems appropriate regarding such investigation provided that it shall share the results with the other Party. Any information provided by a Party shall be considered such Party's Confidential Information and may be used or disclosed only as permitted under Article XIII hereof.

(c) Reporting.

(i) The Party directing an investigation shall provide to the other Party [***], and [***].

(ii) Any final report regarding a Nonconformity shall be submitted by Chemport within [***] of the notification regarding that Nonconformity given under Section 6.4 above.

(iii) Amarin shall provide to Chemport a written report of [***]. Each Party shall hold all communications related to such investigation, testing or other requested assistance in confidence, and those communications shall be subject to the terms of Article XIII hereof.

(d) Costs of Investigations. Chemport shall reimburse Amarin for [***] incurred by Amarin in connection with [***]. Amarin shall reimburse Chemport for [***] incurred by Chemport in connection with [***].

(e) Notwithstanding the foregoing, in the event it is determined in Amarin's reasonable discretion that API supplied by Chemport hereunder was not the cause of a Product complaint or Adverse Event, Chemport shall have no further obligation under this Section 6.8 except to reasonably cooperate with Amarin's investigation upon reasonable request by Amarin.

6.9 Certain Product Events.

(a) Notification and Cooperation. In the event that Amarin shall be required (or shall voluntarily decide) to initiate a recall, withdrawal or field correction of, field alert report or comparable report with respect to any Product, Amarin shall notify Chemport's authorized quality assurance officer, and Chemport shall reasonably cooperate with Amarin to implement the same.

(b) Coordination of Efforts. In the event that Chemport becomes aware of information that may warrant Amarin taking any action with respect to any Product, Chemport shall immediately provide the Amarin head of regulatory affairs such information. The Parties shall cooperate with each other in determining the necessity and nature of such action; provided, however, that Chemport shall take no action to effect the same without the written concurrence of Amarin.

(c) Contacts and Statements. With respect to any recall, withdrawal, field correction, field alert report or comparable report with respect to any Product, Amarin or its designee shall make all contacts with the applicable Governmental Body and shall be responsible for coordinating all of the necessary activities in connection with any such recall, withdrawal, field correction, field alert report or comparable report. Amarin or its designee shall make all statements to the media, including press releases and interviews for publication or broadcast. Chemport agrees to make no statement to the media, unless otherwise required by Legal Requirements, and, in any such event, Chemport shall reasonably collaborate with Amarin on the content of any such statement.

(d) Other Notice. Notwithstanding anything herein, Chemport agrees to notify Amarin as promptly as possible of any incident pertaining to the Product or API that would require notification to any Governmental Body, including, but not limited to, fire, explosion, environmental event, serious injury or physical damage at the Facility or Chemport-controlled facility related to the API Third Party Materials, or Intermediate.

Article VII
Regulatory Matters

7.1 Consents. Chemport shall obtain and hold all Consents required to be obtained by Chemport under the Legal Requirements for the performance of its obligations under this Agreement and Amarin shall reasonably cooperate with Chemport with respect thereto. At all times, Chemport shall maintain and comply with all of the Consents which may from time to time be required by any Governmental Body having jurisdiction with respect to Chemport's manufacturing operations and facilities and otherwise to be obtained by Chemport to permit the performance of its then-current obligations under this Agreement. Chemport shall bear all expenses incurred in connection with its obligations under this Section 7.1. In the event any Consent held by Chemport relating to the Facility or its ability to manufacture the API in accordance with this Agreement is hereafter suspended or revoked, or Chemport has material restrictions imposed upon it by any Governmental Body affecting the API or the Facility, Chemport shall immediately provide written notification to Amarin identifying such material restrictions, a schedule of compliance and such other information related thereto as is reasonably requested by Amarin. Without limiting the foregoing, Chemport will cooperate with Amarin in a reasonable and timely manner in preparation for pre-approval inspection of API manufactured at the Facility by any Governmental Body.

7.2 Establishment of cGMP Facility.

(a) Chemport shall use commercially reasonable best efforts to perform the work under the Development and Process Validation Plan relating to the Facility by the date or dates specified therein in order to establish the Facility as a cGMP facility by the date specified in the Development and Process Validation Plan and Amarin shall reasonably cooperate with Chemport with respect thereto.

(b) Amarin shall have the right, pursuant to the audit procedures in Section 9.2, to have its Approved Representatives undertake a quality assurance audit of Chemport's procedures and facilities for API production as soon as practicable after the date the Expansion is completed. If Amarin undertakes such an audit, Amarin shall provide Chemport with a written audit report and, if applicable, shall highlight therein areas where Amarin judges that Chemport needs to make changes to procedures or facilities in advance of any Pre-Approval Inspection. Both Parties shall cooperate in good faith to agree and implement the necessary changes. If Amarin's written audit report identifies any areas for improvement, within [***] following delivery of Amarin's audit report, Chemport shall prepare an action plan (and promptly deliver a copy of such plan to Amarin for review and comment), which plan shall address the findings of the audit report and include accomplishment dates for corrective actions. Thereafter, once the Parties mutually agree on a corrective action plan, the Parties agree to amend the Development and Process Validation Plan to include such corrective actions.

(c) Amarin agrees to cooperate with Chemport by making its Approved Representatives available for consultation and advice to Chemport, as may be reasonably requested by Chemport, regarding implementation of cGMP and related procedural systems and any other matters as may be mutually agreed.

(d) Chemport shall use reasonable best efforts to be prepared for any Pre-Approval Inspection. Amarin will cooperate with Chemport in a reasonable and timely manner in preparation for such Pre-Approval Inspection.

7.3 Compliance. In carrying out their respective obligations under this Agreement, the Parties shall comply in all respects with cGMPs and the Legal Requirements, as applicable to such Party, in effect from time to time.

7.4 Drug Application Documentation.

(a) Amarin shall draft the CMC section of the Drug Application for the Product based on information to be provided by Chemport as follows: (i) the Quality Section for API manufacturing (in the CMC section) will be drafted by Chemport in the form of a DMF that will be sent to the FDA Documentation room by Chemport; (ii) Chemport will make available to Amarin information in the DMF that does not constitute Chemport Confidential Information; and (iii) such access to the DMF will be only through a letter of access issued to Amarin by Chemport. Once the CMC section of the Drug Application for the Product is drafted by Amarin, if requested by Amarin, Chemport shall assist Amarin by critically reviewing and providing corrections to any relevant section of the Amarin's CMC in a timely fashion. Chemport agrees that Amarin may reference Chemport as the manufacturer of the API in Amarin's Drug Application and any other documentation required under any regulatory filings for the API, and Chemport will provide the relevant Government Body with all required documentation, including development and analytical reports to support such filings. Amarin shall own all regulatory files (excluding the DMFs) with respect to the API including without limitation regulatory data and documentation prepared by Chemport under this Section 7.4 respecting the manufacture of the API, including without limitation the CMC section of any Drug Application filed with the FDA related to the API. For the avoidance of doubt, (i) the DMFs shall be owned by Chemport, and (ii) all process information related to the manufacture of API, whether contained in a DMF or otherwise, shall, subject to Section 13.4, constitute Chemport Confidential Information and shall not be disclosed to Amarin under any circumstances, notwithstanding anything herein to the contrary; provided, however, Chemport shall provide the relevant Governmental Body with all information necessary to support Amarin's Drug Application filings in a timely manner.

(b) Upon reasonable request from Chemport, Amarin shall provide Chemport with information regarding Drug Applications, or discrete sections thereof, to the extent available and necessary for Chemport to perform its obligations under this Agreement; provided, however, that information provided hereunder shall not be provided or disclosed to any other Person without Amarin's prior Consent. In the event that any Governmental Body makes an inquiry of or provides any information to Chemport that is or may be related to a Drug Application, Chemport shall promptly forward such inquiry or information to Amarin.

7.5 DMFs. Chemport shall create and maintain the Drug Master Files for API in the [***] (if designated by Amarin in its reasonable discretion) and other jurisdictions agreed to by the Parties (the "DMFs"). Amarin agrees to assist

Chemport by making its Approved Representatives available for consultation and advice to Chemport, as may be reasonably requested by Chemport, regarding preparation and maintenance of the DMFs. Chemport hereby grants to Amarin the right to reference the DMFs in any relevant Drug Application or other documentation to the extent such reference is necessary for the approval and maintenance of a Drug Application. The Approved Representatives may share with Amarin any information they receive or obtain in connection with their activities under this Section 7.5. Additionally, from time to time during the Term, Chemport shall provide such information as Amarin may reasonably request related to the DMFs, which shall be handled by Amarin as Chemport Confidential Information, subject to Article XIII. Chemport shall own all regulatory files with respect to the API including without limitation the DMFs.

7.6 Regulatory Changes. The Parties will promptly notify each other of any material revisions, amendment of or additions to the DMFs and cGMPs and will confer with each other with respect to the best means to comply with such requirements.

7.7 Regulatory Inspections.

(a) Procedures. If Chemport is notified that API or the portion of the Facility relating to the supply of API will be subject to an inspection by any Governmental Body, Chemport shall:

(i) within [***] advise Amarin's head of regulatory affairs, or his or her designee, by telephone and facsimile and provide all relevant information known to Chemport regarding such inspection;

(ii) reasonably cooperate with and allow any such inspection to the extent required by Legal Requirements;

(iii) direct all inquiries related to API, Product, any Drug Application or Amarin's Confidential Information covered by Article XIII of this Agreement to Amarin;

(iv) have a consultant with the required expertise present for such inspections at Chemport's sole cost and expense. Chemport will provide a copy of the 483 inspection observations upon conclusion of the inspection and the 483 responses to Amarin when prepared and sent to the inspecting Governmental Body;

(v) within [***] (within [***] if any serious or critical deficiencies are identified by the Governmental Body) send Amarin a copy of any inspection report observations issued by any Governmental Body related to the manufacture, generation, processing, storage, transportation, distribution, treatment, disposal or other management of API or Third Party Materials;

(vi) provide each proposed response to any inspection reports prepared in accordance with this Section 7.7 not less than [***] before the required response date and consider any comments or suggestions received from Amarin in good faith; and

(vii) respond to all inspection report observations by any Governmental Body in a timely manner and take all appropriate corrective actions required or recommended by such Governmental Body.

Notwithstanding the foregoing provisions of this Section 7.7(a), nothing shall require Chemport to disclose information to Amarin specifically relating to any other customer of Chemport or those customers' products to which the inspection relates.

(b) Notification. If any Governmental Body shall take any action which shall require a response or action by Chemport with respect to API, Product, API Specifications, Third Party Materials, the Facility or any operating procedure affecting the API, Chemport agrees [***] to notify Amarin of the required response or action and, in the case of API, Product and/or API Specifications, shall proceed only with the prior advice and written Consent of Amarin, which shall not be unreasonably withheld or delayed. Notwithstanding anything contained in this Agreement to the contrary, Chemport shall not initiate or participate in any communications with any Governmental Body concerning the API, Product or the API Specifications unless required to do so by Legal Requirements or requested to do so by Amarin and only after consultation with Amarin.

7.8 Other Regulatory Matters. Chemport shall provide to each Governmental Body and, at Amarin's request, shall provide to Amarin, all documents and information requested by each such Governmental Body in support of Chemport's and Amarin's regulatory filings, including, without limitation, all relevant DMFs. Copies of all documents to be provided to any Governmental Body shall be provided to Amarin at least [***] in advance of delivery to such Governmental Body, if possible, or otherwise as soon as practicable thereafter.

7.9 Confidential Information. Notwithstanding anything to the contrary contained herein, Chemport may redact or limit from any deliveries of or access to data, reports or any other information, any Third Party confidential information or Chemport Confidential Information, at Chemport's sole discretion; provided, however, that Chemport may not redact or limit any Chemport Confidential Information that is reasonably necessary for Amarin to comply with all Legal Requirements. In this regard, the Parties agree that all process information related to the manufacture of API, whether contained in a DMF or otherwise, shall, subject to Section 13.4, constitute Chemport Confidential Information and shall not be disclosed to Amarin under any circumstances, notwithstanding anything herein to the contrary; provided, however, Chemport shall provide the relevant Governmental Body with all information necessary to support Amarin's Drug Application filings in a timely manner. Furthermore, for the avoidance of doubt, subject to Section 13.4, all information provided to Amarin under this Article VII is Chemport Confidential Information and nothing in this Article VII shall be construed as giving Amarin any right to use or disclose (A) any Chemport Intellectual Property (except as may be permitted by any express license from Chemport), or (B) any Chemport Confidential Information (except as may be permitted under Article XIII hereof).

Article VIII
Intellectual Property

8.1 Ownership.

(a) Chemport Ownership. Amarin acknowledges and agrees that Chemport owns all rights in and to the Chemport Intellectual Property, including all Intellectual Property rights in and to the API and the documentation, specifications and processes associated with the API. Except as expressly provided in Section 8.3 below, nothing in this Agreement shall be deemed to transfer or convey, expressly or by implication, any license or any other right, title or interest in or to the Chemport Intellectual Property.

(b) Amarin Ownership. Chemport acknowledges and agrees that Amarin owns all rights in and to the Amarin Intellectual Property, including all Intellectual Property rights in and to the Product, the Drug Applications, and the documentation, specifications and processes associated with the Product that is not Chemport Intellectual Property. Chemport does not have, by virtue of this Agreement or otherwise, a license or any other right, title or interest in or to the Amarin Intellectual Property.

8.2 New Developments.

(a) API Product Developments. All Intellectual Property relating to the API or the development or manufacture of the API, that is conceived, reduced to practice, authored or otherwise invented, discovered, generated or developed in whole or in part by Chemport in the course of activities under this Agreement, whether patentable or not, and any authorship of works relating to the API that are created by Chemport, including but not limited to any trademarks, trade dress, trade secrets or copyrights, shall be "API Product Developments."

(b) Ownership of API Product Developments. Subject to the rights and licenses granted in Section 8.3 below, Chemport shall own all right, title and interest in and to all API Product Developments and all rights to Intellectual Property arising therefrom.

(c) Patents. Notwithstanding any obligation of confidentiality between Chemport and Amarin under Section 13.3 hereto or any other agreement, Chemport, at its own expense, may elect to file and prosecute appropriate patent applications and maintain patents issuing therefrom covering such API Product Development. Upon Chemport's reasonable request and at its expense, Amarin shall take such reasonable actions as Chemport deems necessary or appropriate to assist Chemport in obtaining patent or other proprietary protection in Chemport's name with respect to all API Product Developments. If Chemport declines to pursue a patent for an API Product Development, Chemport shall be obligated to assign its rights to pursue such patent to Amarin and shall provide reasonable assistance if Amarin decides to file a patent application for an API Product Development.

8.3 Grant of License to API (including API Product Developments). Subject to the terms and conditions of this Agreement, Chemport hereby grants Amarin (a) a worldwide, non-exclusive, royalty-free, non-transferable (except in connection with a permitted assignment under Section 16.4), non-sublicensable license to use the API Product Developments for the manufacture and sale of Product using API supplied by Chemport, and (b) a worldwide, non-exclusive, royalty-free, non-transferable (except in connection with a permitted assignment under Section 16.4), non-sublicensable license to use the Chemport Intellectual Property (other than the API Product Developments) for the manufacture and sale of Product using API supplied by Chemport. This license shall terminate upon the later of (i) the expiration or termination of this Agreement or (ii) such time that Amarin is no longer in possession of API

supplied by Chemport, including API that has been incorporated into Product that has not reached expiry. For the avoidance of doubt, regardless of the termination or expiration of this Agreement, Amarin shall have a license to use the Chemport Intellectual Property (including API Product Developments) for the manufacture and sale of the Product for so long as necessary to sell all inventory that incorporates API (including API Product Developments) provided by Chemport under this Agreement. The license granted in this Section 8.3 shall be referred to as the "Amarin License."

8.4 Infringement.

(a) Amarin shall promptly notify Chemport of any suspected or threatened infringement, misappropriation or other unauthorized use of the Chemport Intellectual Property licensed by Chemport to Amarin under the Amarin License that comes to Amarin's attention. The notice shall set forth the facts of such suspected or threatened infringement in reasonable detail. Chemport shall have the sole right, but not the obligation, to institute, prosecute and control, at its expense, any action or proceeding against the Third-Party infringer of such Chemport Intellectual Property. If Chemport institutes an action against such infringer, Amarin shall give Chemport reasonable assistance and authority to control, file and prosecute the suit as necessary at Chemport's expense. Amarin shall have the right to participate in the applicable action or proceeding with its own counsel at its own expense and without reimbursement hereunder. If Amarin elects to so participate, Chemport shall provide Amarin with an opportunity to consult regarding such action or proceeding.

(b) If Chemport elects not to bring any action or proceeding for infringement, misappropriation or other unauthorized use of the Chemport Intellectual Property licensed by Chemport to Amarin under the Amarin License, then it shall promptly advise Amarin of its decision, and Amarin thereafter shall have the right, but not the obligation, to institute, prosecute and control, at its expense, any action or proceeding against the Third-Party infringer of such Chemport Intellectual Property. If Amarin institutes an action against such infringer, Chemport shall give Amarin reasonable assistance and authority to control, file and prosecute the suit as necessary at Amarin's expense, and shall join such action if reasonably requested by Amarin or required by applicable Legal Requirements. Chemport shall have the right to participate in the applicable action or proceeding with its own counsel at its own expense and without reimbursement hereunder (except for any out-of-pocket costs and expenses incurred by Chemport following its joinder as a party to such action or proceeding pursuant to Amarin's reasonable request or as required by applicable Legal Requirements). If Chemport elects to participate (but is not joined as a party to such action or proceeding), Amarin shall provide Chemport with an opportunity to consult regarding such action or proceeding. Amarin shall retain any damages or other monetary awards that it recovers in pursuing any action under this Section 8.4(b).

(c) In the event that either Party exercises the rights conferred in this Section 8.4 and recovers any damages or other sums in such action or proceeding or in settlement thereof, such damages or other sums recovered shall first be applied to all out-of-pocket costs and expenses incurred by the Parties in connection therewith (including attorneys fees), unless such Party is expressly not entitled to reimbursement under this Section 8.4. If such recovery is insufficient to cover all such costs and expenses of both Parties, the controlling Party's costs shall be paid in full first before any of the other Party's costs. Each Party seeking reimbursement under this Section 8.4 shall furnish promptly to the other Party appropriate documentation of its out-of-pocket costs and expenses incurred.

8.5 Data. As between Chemport and Amarin, Amarin shall be and remain the sole and exclusive owner of any and all data and information, in any form, relating to: (a) the business of Amarin; (b) licensees, customers and suppliers of Amarin; (c) the Product and the development and manufacture thereof (excluding Chemport's data and information related to the API); and (d) the API Specifications. All information provided to Amarin by Chemport under this Article VIII shall be handled by Amarin as Chemport Confidential Information, subject to Article XIII.

Article IX
Information; Access; Audit Rights

9.1 Provision of Information.

(a) Data. Chemport shall provide to Amarin copies (in electronic or hard-copy form, as requested by Amarin) of or access to data as may be reasonably requested from time to time by Amarin on a bona fide need-to-know basis, except as may be restricted for confidential information or trade secrets. Chemport shall provide final reports for batch failures, including recommendation for API disposition for all investigations involving (i) foreign matter or

particulate contamination; or (ii) any test results indicating non-compliance with the applicable Drug Applications, cGMPs or the API Specifications.

(b) Annual Report. Chemport shall prepare and provide to Amarin a written annual report no later than [***] following the end of each Calendar Year, documenting, subject to redaction of Chemport Confidential Information, (i) the prior Calendar Year's batch records; (ii) packaging changes; (iii) process changes; (iv) changes in API testing methods performed pursuant to Article VI hereof; (v) changes in API Specifications; (vi) batches of API rejected or aborted; (vii) any other discrepancies that require reporting pursuant to cGMP or Legal Requirements; (viii) "trends" in the manufacture of API during the prior Calendar Year; and (ix) ICH stability data summary.

9.2 Audit and Inspection Rights. During the Term of this Agreement and thereafter during any applicable records retention period(s) under Section 9.3, Approved Representatives shall have the right, upon a prior written consent of Chemport, not to be unreasonably withheld or delayed, to audit and inspect those portions of the Facility (or the facility of a Material Third Party Supplier or Subcontractor, as the case may be) used in, and those documents and records related to, the manufacture, generation, storage, testing, treatment, holding, transportation, distribution or other handling or receiving of the API and Third Party Materials. Such audits may be conducted [***] each [***]; provided, however, that Amarin may conduct additional "for cause" audits during a [***] to the extent Chemport supplies Nonconforming API or in the event of Product complaints or Adverse Events caused by Nonconforming API. Chemport may redact from such deliveries to Amarin any Third Party confidential information or Chemport Confidential Information. During such inspections, Approved Representatives shall have the right to audit and inspect all inventory of API and Third Party Materials contained at the Facility (or the facility of a Material Third Party Supplier or Subcontractor, as the case may be). Chemport agrees to reasonably cooperate and assist Amarin (and to require any Material Third Party Supplier or Subcontractor to cooperate and assist Amarin) in connection with any audits or inspections pursuant to this Section 9.2. Audits or inspections under this Section 9.2 shall occur during business hours and shall be scheduled by Approved Representatives at least [***] in advance; provided, however, that, in the event of an Adverse Event or any proposed or actual inspection by the FDA or other Governmental Body (whether of Chemport or a Material Third Party Supplier or Subcontractor) or other similar event or emergency involving any API or Third Party Materials, Approved Representatives shall have the right at any time, upon written notice to Chemport (or any Material Third Party Supplier or Subcontractor) of [***], to conduct an audit or inspection of those affected portions of the Facility (or the facility of such Material Third Party Supplier or Subcontractor, as the case may be) used in the manufacture, generation, storage, testing, treatment, holding, transportation, distribution or other handling or receiving of API and Third Party Materials. Chemport shall ensure that Approved Representatives have access to Material Third Party Supplier's and Subcontractor's facilities in the manner set forth in this Section 9.2. Chemport shall as soon as practicable take any corrective action reasonably requested by Amarin in connection with this Section 9.2.

9.3 Record Retention. Each Party shall maintain, in accordance with and for the period required under the applicable Drug Application, cGMPs and Legal Requirements, complete and adequate records pertaining to all activities in connection with, and facilities used for, the manufacture, generation, storage, testing, treatment, holding, transportation, distribution or other handling or receiving of the API, Third Party Materials and Product.

9.4 Confidential Information. Notwithstanding anything to the contrary contained in this Agreement, Chemport may redact or limit from any deliveries of or access to data, reports or any other information any Third Party confidential information or Chemport Confidential Information, at Chemport's sole discretion; provided, however, that Chemport may not redact or limit any Chemport Confidential Information that is reasonably necessary for Amarin to comply with all Legal Requirements. In this regard, the Parties agree that all process information related to the manufacture of API, whether contained in a DMF or otherwise, shall, subject to Section 13.4, constitute Chemport Confidential Information and shall not be disclosed to Amarin under any circumstances, notwithstanding anything herein to the contrary; provided, however, Chemport shall provide the relevant Governmental Body with all information necessary to support Amarin's Drug Application filings in a timely manner. Furthermore, for the avoidance of doubt, all information provided to Amarin under this Article IX is, subject to Section 13.4, Chemport Confidential Information and nothing in this Article IX shall be construed as giving Amarin any right to use or disclose (A) any Chemport Intellectual Property (except as may be permitted by any express license from Chemport), or (B) any Chemport Confidential Information (except as may be permitted under Article XIII hereof).

Article X
Representations and Warranties

10.1 Representations and Warranties of Chemport. Chemport represents and warrants that:

(a) Compliance. The manufacture, generation, processing, distribution, transport, treatment, storage, disposal and other handling of any Third Party Materials and API by Chemport shall be in accordance with and conform to the API Specifications, cGMPs, ICH guidelines, all Legal Requirements, this Agreement and the Quality Agreement. The API shall comply with the applicable Drug Applications, cGMPs, API Specifications, ICH guidelines and Legal Requirements; shall be free from defects in materials and workmanship; and shall not be adulterated or misbranded within the meaning of applicable Legal Requirements.

(b) Status; Enforceability. Chemport is a validly existing corporation in good standing under the laws of the jurisdiction of its incorporation; the execution, delivery and performance of this Agreement by Chemport has been duly authorized by all requisite corporate action; this Agreement constitutes a legal, valid and binding obligation of Chemport, enforceable against Chemport in accordance with the terms hereof; and the execution, delivery and performance of this Agreement by Chemport will not violate or conflict with any other agreement or instrument to which Chemport is a party.

(c) Certain Persons. Chemport has not used, and will not use, in any capacity associated with or related to the manufacture of the API, the services of any Persons who have been, or are in the process of being, (i) debarred under 21 U.S.C. § 335a(a) or (b) or any comparable Legal Requirements, or (ii) excluded from participation in the Medicare program, any state Medicaid program or any other health care program. Furthermore, neither Chemport nor any of its officers, employees or consultants has been convicted of an offense under (x) either a federal or state law that is cited in 21 U.S.C. § 335(a) as a ground for debarment, denial of approval or suspension, (y) any other law cited in any comparable Legal Requirements as a ground for debarment, denial of approval or suspension. Chemport shall notify Amarin immediately upon learning of any circumstance that would cause this certification under this Section 10.1(c) to become false or inaccurate.

(d) Regulatory Consents. Chemport has or will have all Consents necessary to timely perform its obligations hereunder and to manufacture the API used in Product for commercial sale.

(e) Maintenance of Facility. During the Term of this Agreement, Chemport shall maintain the Facility, required local licenses, the equipment used to manufacture the API, Chemport Intellectual Property and any applicable contracts necessary to manufacture the API in accordance with the API Specifications, Legal Requirements, cGMPs, the Quality Agreement and Chemport's standard operating procedures.

(f) Negative Pledge. The transfer of the API by Chemport to Amarin is and shall be rightful and free and clear of any liens or encumbrances.

(g) Security Measures. Chemport shall maintain reasonable security policies at the Facility and shall use commercially reasonable efforts to have security measures in place to protect the integrity of the API, Third Party Materials, data and works-in-process at the Facility.

(h) Non-Infringement. To Chemport's best knowledge, Chemport's performance of its obligations under this Agreement will not infringe upon, nor cause Amarin's use of the API to infringe upon, the Intellectual Property rights of any Third Party.

10.2 Representations and Warranties of Amarin. Amarin represents and warrants that:

(a) Status; Enforceability. Amarin is a validly existing corporation in good standing under the laws of the jurisdiction of its incorporation; the execution, delivery and performance of this Agreement by Amarin has been duly authorized by all requisite corporate action; this Agreement constitutes the legal, valid and binding obligation of Amarin, enforceable against Amarin in accordance with the terms hereof; and the execution, delivery and performance of this Agreement by Amarin will not violate or conflict with any other agreement or instrument to which Amarin is a party.

(b) Certain Persons. Amarin has not used, and will not use, in any capacity associated with or related to the Product, the services of any Persons who have been, or are in the process of being, (i) debarred under 21 U.S.C. § 335a(a) or (b) or any comparable Legal Requirements, or (ii) excluded from participation in the Medicare program, any state Medicaid program or any other health care program. Furthermore, neither Amarin nor any of its officers, employees or consultants has been convicted of an offense under (x) either a federal or state law that is cited in 21 U.S.C. §

335(a) as a ground for debarment, denial of approval or suspension, (y) any other law cited in any comparable Legal Requirements as a ground for debarment, denial of approval or suspension. Amarin shall notify Chemport immediately upon learning of any circumstance that would cause this certification under this Section 10.2(b) to become false or inaccurate.

(c) Regulatory Consents. Amarin has all Consents necessary to perform its obligations hereunder and will, prior to commercial sale of Product, have all Consents necessary for the commercial sale of Product once Product is approved by FDA or any other Governmental Body.

(d) Non-infringement. To Amarin's best knowledge, Amarin's commercial sale of Product will not infringe upon the Intellectual Property rights of any Third Party.

10.3 Disclaimer. OTHER THAN AS EXPRESSLY PROVIDED FOR IN THIS AGREEMENT, NEITHER PARTY MAKES ANY WARRANTIES, EITHER EXPRESS OR IMPLIED, AND THE PARTIES EXPRESSLY DISCLAIM ALL IMPLIED WARRANTIES, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, TITLE AND NONINFRINGEMENT.

Article XI
Liability and Indemnification

11.1 Indemnity by Chemport. Chemport shall defend, indemnify and hold harmless Amarin and Amarin's Affiliates and licensees and distributors and its and their respective directors, officers, employees and agents from and against all Losses to the extent arising out of or resulting from (a) any breach, nonperformance or failure to comply with any of Chemport's covenants, agreements, obligations, representations or warranties under this Agreement or the terms of this Agreement; or (b) negligence, recklessness, gross negligence or wrongful intentional acts or omissions by, or strict liability of, Chemport or Chemport Affiliates, their respective directors, officers, employees, agents or Subcontractors.

11.2 Indemnity by Amarin. Amarin shall defend, indemnify and hold harmless Chemport and Chemport's Affiliates and its and their respective directors, officers, employees and agents from and against all Losses to the extent arising out of or resulting from (a) any breach, nonperformance or failure to comply with any of Chemport's covenants, agreements, obligations, representations or warranties under this Agreement or the terms of this Agreement; or (b) negligence, recklessness, gross negligence or wrongful intentional acts or omissions by, or strict liability of, Amarin or Amarin Affiliates, their respective directors, officers, employees, agents or contractors.

11.3 Procedures. Any person that may be entitled to indemnification under this Agreement (an "Indemnified Party") shall give written notice to the Person obligated to indemnify it (an "Indemnifying Party") with reasonable promptness upon becoming aware of any claim or other facts upon which a claim for indemnification will be based. The notice shall set forth such information with respect thereto as is then reasonably available to the Indemnified Party. The Indemnifying Party shall have the right to undertake the defense of any such claim with counsel reasonably satisfactory to the Indemnified Party, and the Indemnified Party shall cooperate in such defense and make available all records, materials and witnesses reasonably requested by the Indemnifying Party at the Indemnifying Party's expense. If the Indemnifying Party shall have assumed the defense of the claim with counsel reasonably satisfactory to the Indemnified Party, the Indemnifying Party shall not be liable to the Indemnified Party for any legal expenses subsequently incurred by the Indemnified Party in connection with the defense thereof. The Indemnifying Party shall not be liable for any claim settled without its Consent, which Consent shall not be unreasonably withheld. The Indemnifying Party shall obtain the written Consent of the Indemnified Party, which shall not be unreasonably withheld, prior to ceasing to defend, settling or otherwise disposing of any claim if, as a result thereof, the Indemnified Party would become subject to injunctive or other equitable relief or if the Indemnified Party may reasonably object to such disposition of such claim based on a continuing adverse effect on the Indemnified Party.

11.4 Special Indemnity. In the event this Agreement is terminated by Amarin pursuant to Section 15.5(a), Chemport shall pay to Amarin the amount of [***], which shall be Amarin's sole and exclusive remedy with respect thereto, and in the event this Agreement is terminated by Amarin pursuant to Section 15.5(g), Chemport shall pay to Amarin the amount of [***], which shall be Amarin's sole and exclusive remedy with respect thereto.

11.5 Limitation of Liability. Subject to Section 11.6, in no event, regardless of the form of the claim or cause of action, whether based on contract, warranty, infringement, tort, strict liability or otherwise, shall a Party's cumulative liability for claims under or relating to this Agreement, including, but not limited to, liquidated damages for delay in delivery or Nonconformity, exceed the aggregate amount of [***].

11.6 No Special Damages. Notwithstanding anything to the contrary contained herein, except for breaches of confidentiality obligations, the Parties shall not be liable to each other for any special, indirect, incidental or consequential damages (including for lost profits).

Article XII
Insurance

12.1 Coverage Requirements. Each Party shall maintain in full force and effect beginning no later than [***] and during the remaining Term of this Agreement and for a period of [***] after expiration or termination of this Agreement, worker's compensation, property, general liability and product liability insurance coverage in such amounts and with such scope of coverages as are adequate to cover such Party's obligations under this Agreement and as are customary in the industry for companies of like size and activities and taking into account the nature of the API to be manufactured under this Agreement and the Product. Without limiting any of the foregoing, (a) each Party's product liability insurance coverage limits shall be no less than [***]; (b) Chemport's insurance shall include coverage for [***]; and (c) Chemport's policy(ies) shall include [***]. Each Party shall provide evidence of such insurance to the other Party and ensure that the other Party will receive no less than [***] notice of any cancellation, non-renewal or material change in the policy(ies).

Article XIII
Confidentiality

13.1 Definition of "Amarin Confidential Information". As used herein, the term "Amarin Confidential Information" shall mean all confidential business and technical communications, documents and other information, in each case not constituting Chemport Confidential Information, Chemport Intellectual Property or data, whether in written, oral or other form, which Amarin or an Amarin Affiliate furnishes or discloses to Chemport or which Chemport otherwise learns in connection with the negotiation or performance of this Agreement (whether relating to Amarin, an Amarin Affiliate or any Third Party for which Amarin has an obligation of confidentiality), including the API Specifications and the terms of this Agreement and any information disclosed by Amarin prior to the Effective Date.

13.2 Definition of "Chemport Confidential Information". As used herein, the term "Chemport Confidential Information" shall mean (a) all confidential business information, and (b) technical communications, documents or other information, in each case not constituting Amarin Confidential Information, Amarin Intellectual Property or data, whether in written, oral or other form, of Chemport or a Chemport Affiliate that are disclosed to Amarin by Chemport or a Chemport Affiliate or Amarin otherwise learns in connection with the negotiation or performance of this Agreement (whether relating to Chemport, a Chemport Affiliate or any Third Party for which Chemport has an obligation of confidentiality), including the terms of this Agreement and any information disclosed by Chemport prior to the Effective Date. The fact that a Party is required by a provision of this Agreement to disclose certain information to the other Party shall not have any effect regarding whether such information is Amarin Confidential Information or Chemport Confidential Information, as the case may be, and all use and disclosure of such Confidential Information is subject to this Article XIII. In responding to such a required disclosure, a Party may redact information relating to Third Parties from any documents deliverable to the other Party that are not relevant to the subject matter of this Agreement.

13.3 Treatment of Confidential Information. Both during the Term of this Agreement and thereafter, Amarin Confidential Information and Chemport Confidential Information (collectively for this Section 13.3 "Confidential Information") shall be treated in accordance with the requirements of this Article XIII.

(a) Nondisclosure and Non-Use. A Party receiving Confidential Information of the other Party shall (i) maintain in confidence such Confidential Information to the same extent such Party maintains its own proprietary information of similar kind and value (but at a minimum each Party shall use commercially reasonable efforts to maintain Confidential Information in confidence); (ii) not disclose such Confidential Information to any Third Party without

prior written Consent of the disclosing Party, except, in the case of Amarin, for disclosures to Amarin's licensees and commercial partners for the Product who agree to be bound by obligations of non-disclosure and non-use at least as stringent as those contained in this Article XIII; and (iii) not use such Confidential Information for any purpose except those purposes permitted by this Agreement.

(b) Exceptions. Notwithstanding any other provision of this Agreement, the receiving Party may disclose Confidential Information of the disclosing Party to a Third Party: (i) to the extent and to the Persons as required by an applicable Legal Requirements, legal process or court order, or an applicable disclosure requirement of any Governmental Body, the U.S. Securities and Exchange Commission, the Nasdaq market or any other securities exchange or market; or (ii) to the extent necessary to exercise the rights granted to the receiving Party under this Agreement in filing or prosecuting patent applications, prosecuting or defending litigation or otherwise establishing rights or enforcing obligations under this Agreement, or conducting clinical trials or seeking regulatory approval of the Product; provided, however, that the receiving Party shall first have given prompt notice to the disclosing Party to enable the disclosing Party to seek any available exemptions from or limitations on any applicable disclosure requirement and shall reasonably cooperate in such efforts by the disclosing Party. Chemport shall reasonably cooperate with Amarin in providing prospective commercial partners with access to the Facility during normal business hours and allowing the prospective partners to perform reasonable due diligence related to the manufacture and supply of API hereunder to the extent such access to the Facility or information does not interfere with the daily operation of Chemport's business, and subject to Chemport's right to deny access to or disclosure of Chemport Confidential Information at Chemport's sole and absolute discretion. Notwithstanding, the Parties agree that all process information related to the manufacture of API, whether contained in a DMF or otherwise, shall, subject to Section 13.4, constitute Chemport Confidential Information and shall not be disclosed to Amarin or any prospective commercial partners under any circumstances.

(c) Terms of Agreement. The Parties agree that the existence of and the material terms of this Agreement shall be considered Confidential Information of both Parties, subject to the special authorized disclosure provisions set forth below in this Section 13.3(c) (in lieu of the authorized disclosure provisions set forth in Section 13.3(b), to the extent of any conflict) and without limiting the generality of the definition of Confidential Information set forth in Sections 13.1 and 13.2. If either Party desires to make a public announcement concerning this Agreement or the terms hereof, such Party shall give reasonable prior advance notice of the proposed text of such announcement to the other Party for its prior review and approval. A Party shall not be required to seek the permission of the other Party to repeat any information as to the existence and terms of this Agreement that has already been publicly disclosed by such Party in accordance with the foregoing or by the other Party. Either Party may disclose the terms of this Agreement to such Party's existing investors, directors and professional advisors and to potential investors, acquirors or merger partners and their professional advisors who are bound by written or professional obligations of non-disclosure and non-use that are at least as stringent as those contained in this Article XIII or are customary for such purpose. Chemport acknowledges that Amarin or its Affiliates may be obligated to file a copy of this Agreement with the U.S. Securities and Exchange Commission with its next quarterly report on Form 10-Q, annual report on Form 10-K or current report on Form 8-K or with any registration statement filed with the U.S. Securities and Exchange Commission pursuant to the Securities Act of 1933, as amended, and Amarin shall be entitled to make such filings.

13.4 Excluded Information. Notwithstanding any provision herein to the contrary, the requirements of this Article XIII shall not apply to any information of either Party which:

(a) at the time of disclosure hereunder is generally available to the public;

(b) after disclosure hereunder becomes generally available to the public, except through breach of this Article XIII by the receiving Party or its Affiliates;

(c) was not acquired directly or indirectly from the disclosing Party or its Affiliates and which the receiving Party lawfully had in its possession prior to disclosure by the disclosing Party without confidentiality, nondisclosure and non-use obligations;

(d) is independently developed by employees or agents of the receiving Party without the use of the Confidential Information of the disclosing Party; or

(e) becomes available to the receiving Party from a Third Party that is not legally prohibited from disclosing such Confidential Information, provided such information was not acquired by such Third Party directly or indirectly from the disclosing Party or its Affiliates.

13.5 Return of Confidential Information. At any time upon the request of the other Party, to the extent such Confidential Information is not reasonably necessary to enable a Party to perform its obligations under this Agreement, or upon expiration or termination of this Agreement, the Party receiving Confidential Information will cease its use and, upon request, within thirty (30) days either return or destroy (and certify as to such destruction) all Confidential Information of the other Party, including any copies or other embodiments thereof, except that the receiving Party may retain a copy for archive purposes. The return and/or destruction of such Confidential Information as provided above shall not relieve the receiving Party of its other obligations under this Article XIII.

13.6 Redaction of Chemport Confidential Information. Notwithstanding Chemport's right to redact or limit Chemport Confidential Information from deliveries of or access to data, reports or any other information, Chemport may not redact or limit any Chemport Confidential Information that is reasonably necessary for Amarin to comply with all Legal Requirements. In this regard, the Parties agree that all process information related to the manufacture of API, whether contained in a DMF or otherwise, shall, subject to Section 13.4, constitute Chemport Confidential Information and shall not be disclosed to Amarin under any circumstances, notwithstanding anything herein to the contrary; provided, however, Chemport shall provide any relevant Governmental Body with all information necessary to support Amarin's Drug Application filings in a timely manner. Furthermore, for the avoidance of doubt, subject to Section 13.4, all information provided to Amarin under this Agreement is Chemport Confidential Information and nothing in this Agreement shall be construed as giving Amarin any right to use or disclose (A) any Chemport Intellectual Property (except as may be permitted by any express license from Chemport), or (B) any Chemport Confidential Information (except as may be expressly permitted under this Agreement).

Article XIV
Force Majeure Event

14.1 General. Except for any obligation to pay money, neither Party shall be held liable or responsible to the other Party nor be deemed to be in default under, or in breach of any provision of, this Agreement for failure or delay in fulfilling or performing any obligation of this Agreement when such failure or delay is due to a Force Majeure Event, and without the fault or negligence of the Party so failing or delaying. For purposes of this Agreement, a "Force Majeure Event" is defined as: acts of God; war; civil commotion; destruction of production facilities or materials by fire, flood, earthquake, explosion or storm; labor disturbances; epidemic; failure of public utilities and similar events which are beyond the reasonable control of the Party affected. In the event of a Force Majeure Event, Amarin or Chemport, as the case may be, shall immediately notify the other Party of such inability and of the period for which such inability is expected to continue. The Party giving such notice shall thereupon be excused from such of its obligations under this Agreement as it is thereby disabled from performing for so long as it is so disabled. To the extent possible, each Party shall use reasonable efforts to minimize the duration of any Force Majeure Event.

14.2 Termination Due to Event of Force Majeure; Transition. If, as a result of the conditions referred to in Section 14.1, a Party is unable to fully perform its obligations for a period of [***], the other Party shall have the right to terminate this Agreement upon [***] prior notice to the non-performing Party.

Article XV
Term; Termination; Remedies

15.1 Term. This Agreement shall commence on the Effective Date and, unless earlier terminated by either Party in accordance with this Article XV, will continue until the seventh (7th) anniversary of the approval of the Drug Application by the FDA (the "Initial Term") and shall renew automatically for successive five (5) year renewal terms unless either Party notifies the other Party of its intent to not renew by providing written notice to the other Party no less than two (2) years prior to the expiration of the Initial Term or applicable renewal term. The Initial Term together with any renewal term(s) is the "Term."

15.2 Termination for Breach. This Agreement may be terminated by either Party in the event of the material breach by the other Party of the terms and conditions hereof; provided, however, the other Party shall first give to the breaching Party written notice of the proposed termination or cancellation of this Agreement, specifying the grounds therefor. Upon receipt of such notice, the breaching Party shall have sixty (60) days to respond by curing such breach. If the breaching Party does not cure such breach within such cure period, then (a) if Chemport is the breaching Party, Amarin (i) shall have the right to terminate this Agreement and (ii) shall have the remedies set forth

in Section 15.6; or (b) if Amarin is the breaching Party, Chemport shall (i) have the right to terminate this Agreement and (ii) shall have the remedies set forth in Section 15.8.

15.3 Insolvency; Bankruptcy. To the extent permitted by Legal Requirements, each Party will have the right to terminate this Agreement immediately upon notice to the other Party, if any of the following occurs: (a) such other Party is declared bankrupt or insolvent, (b) such other Party generally fails to pay its debts as they become due, (c) there is an assignment for the benefit of such other Party's creditors, (d) a receiver is appointed or there is a voluntary or involuntary petition filed or an action or proceeding commenced for bankruptcy, reorganization, dissolution or winding up of such other Party that is not dismissed within sixty (60) days, or (e) there is a foreclosure or sale of a material part of such other Party's assets by or for the benefit of any creditor or governmental agency.

15.4 Discontinuance or Suspension of Product Program. Amarin may terminate this Agreement upon thirty (30) days' written notice to Chemport if Amarin, in its sole and absolute discretion, discontinues or indefinitely suspends the development and/or commercialization of the Product. Upon the termination of this Agreement pursuant to this Section 15.4, Amarin's sole obligation shall be for it to reimburse Chemport for all documented direct costs and expenses properly and reasonably incurred by Chemport pursuant to this Agreement up to the effective date of such termination in connection with Amarin's then-outstanding obligation to purchase quantities of API forecasted with respect to the binding portion of an applicable [***] Forecast; provided, however, that Chemport shall use commercially reasonable efforts to mitigate such costs and expenses by cancelling any cancelable orders for Third Party Materials, returning returnable Third Party Materials, and/or using non-returnable Third Party Materials for its own or its other customers' behalf. For avoidance of doubt, if Amarin terminates this Agreement pursuant to this Section 15.4, Amarin shall be obligated to purchase the quantities set forth in any Purchase Orders and quantities set forth in any binding portion of a [***] Forecast, but not obligated to purchase any minimum purchase requirements set forth in Section 2.2.

15.5 Termination by Amarin. Without limiting any other Section of this Article XV, Amarin may terminate this Agreement upon thirty (30) days' written notice to Chemport upon the occurrence of any of the following:

(a) Failure to Validate Manufacturing Process. Chemport fails to complete the Validation of the Initial Manufacturing Process on or before the Expansion completion date set forth in Section 4.1.

(b) Failure to Achieve Acceptance of Pre-Approval Inspection. Chemport (i) receives at any time correspondence from FDA indicating that the Facility or facility of a Third Party Supplier is not approved for the manufacture of API, or (ii) fails to obtain official correspondence from FDA stating that the Facility has been approved for the manufacture of API on or before the [***] after the first FDA inspection of the Facility relating to the Expansion.

(c) Failure to Supply Unrelated to Force Majeure. In the event of the continued failure of Chemport to deliver API to Amarin, Amarin shall have the right to terminate this Agreement upon thirty (30) days' prior written notice to Chemport. "Continued" for purposes of determining a continued failure to supply shall be a failure to deliver at least [***] of the API required to be delivered over a [***] period.

(d) Supply of Nonconforming API. Chemport delivers Nonconforming API pursuant to [***] or more Purchase Orders in any [***] period.

(e) Late Shipment. Chemport ships API pursuant to [***] or more Purchase Orders after the applicable Shipment Date during any [***] period.

(f) Failure to Obtain or Maintain Consents. Chemport fails to obtain, maintain and comply with all Consents required for the performance of its obligations under this Agreement.

(g) Failure to Ship Commercial Batches. Chemport fails to deliver [***] batches of API (each batch being [***]) to Amarin's carrier by the Shipment Date(s) specified in the relevant Purchase Order(s), which Shipment Date(s) shall be within [***] from the completion date of the Expansion.

15.6 Effect of Termination by Amarin. In the event Amarin terminates this Agreement pursuant to Sections 14.2, 15.2, 15.3 or 15.5, (a) Amarin shall have the right to terminate, in whole or in part, any Purchase Order issued under this Agreement; (b) Amarin shall be relieved of its requirement to purchase quantities of API associated with any binding portion of a [***] Forecast; and (c) Amarin shall be relieved of its the minimum purchase requirements set forth in Section 2.2.

15.7 Termination by Chemport. Without limiting any other Section of this Article XV, Chemport may terminate this Agreement upon thirty (30) days' written notice to Amarin upon the occurrence of any of the following:

(a) Failure to Obtain Approval of the Drug Application. Amarin's failure to obtain approval of the Drug Application for the Product from the FDA by [***].

(b) Failure to Place Purchase Orders. Amarin's failure to place Purchase Orders within [***] of the date on which the Chemport Approvals are obtained.

(c) Failure to Accept API Unrelated to a Force Majeure Event. Amarin's continued failure to accept conforming API delivered by Chemport unrelated to a Force Majeure Event. "Continued" for purposes of determining a continued failure to accept conforming API shall be a failure to accept at least [***] of the API delivered over a [***] period.

(d) Failure to Pay. Amarin's failure to pay Chemport invoiced amounts for conforming API (that is not subject to an active investigation of Nonconformity or otherwise disputed in good faith by Amarin) within [***] from the applicable due dates for [***] consecutive Purchase Orders.

(e) Failure to Order Minimum Quantities. Amarin's failure to order the relevant minimum annual quantities of API for [***] consecutive [***]. For purposes of determining the quantities ordered by Amarin, (i) all quantities subject to Purchase Orders placed in such Calendar Year, (ii) all quantities of Validation batches of API purchased pursuant to Section 5.4(a) in such Calendar Year, (iii) all quantities ordered from a Secondary Supplier due to Chemport's failure to supply API hereunder in such Calendar Year and (iv) all quantities ordered from a Secondary Supplier due to a Force Majeure Event in such Calendar Year shall be included in such determination.

15.8 Effect of Termination by Chemport. In the event Chemport terminates this Agreement pursuant to Sections 14.2, 15.2, 15.3 or 15.7, (a) Chemport may, upon [***] written notice, require Amarin to [***] and (b) Chemport shall, otherwise, be relieved of any of its obligations to supply any quantities of API under this Agreement.

15.9 Termination of Related Agreement. This Agreement may be terminated by either Party upon written notice to the other Party (notwithstanding the 30-day notice requirement described above) upon the termination of that certain agreement entered into between the Parties on the date of this Agreement related to Amarin's investment.

Article XVI
Miscellaneous

16.1 Notices. In addition to the other specific procedures for notification provided herein, all notices, demands, requests and other communications made hereunder shall be in writing and shall be given either by personal delivery, by facsimile or by internationally recognized overnight courier (with charges prepaid) and shall be deemed to have been given or made: (a) if personally delivered, on the day of such delivery; (b) if sent by facsimile, on the day it is sent or, if not sent on a business day, the next business day; or (c) if sent by overnight courier, on the business day following the date deposited with such overnight courier service, in each case pending the designation of another address, addressed as follows:

If to Amarin:

Amarin Pharmaceuticals Ireland Ltd.
c/o Byrne Wallace; Attention: [***]
2 Grand Canal Square
Dublin 2
Ireland
Telephone +353 1 691 5000
Fax +353 1 691 5010

and

Amarin Pharmaceuticals Ireland Ltd.
c/o Amarin Pharma, Inc.
Mystic Packer Building, Suite 300
12 Roosevelt Avenue
Mystic, CT 06355
USA
Attention: Vice President, Corporate Development

Telephone: +1 860-572-4979
Fax: +1 860-572-4940

With a copy (which shall not constitute notice) to:

Dan L. O'Korn
Smith, Anderson, Blount, Dorsett, Mitchell
& Jernigan, L.L.P.
150 Fayetteville Street, 25th Floor (zip: 27601)
P.O. Box 2611
Raleigh, North Carolina 27602-2611
Facsimile: (919) 821-6800

If to Chemport:

Chemport Inc.
15-1 Dongsu-dong, Naju-si
Jeollanam-do 520-330, Korea

Attention: [***], CTO/Senior Managing Director
Fax: +82-61-330-9770
Email: [***]

With a copy (which shall not constitute notice) to:

Chemport Inc.
2-1704 Ace Hightech City, 55-20
Munrae-dong 3-ga, Yeongdeungpo-gu
Seoul 150-834 Korea

Attention:	[***], CFO/Director
Fax:	+82-2-3439-2266
Email:	[***]

16.2 Independent Contractors. Each Party shall be treated as an independent contractor of the other. Neither Party shall be deemed to be a co-venturer, partner, employee or a legal representative of the other Party for any purpose. Neither Party shall have the authority to enter into any contracts in the name of or on behalf of the other Party or incur any charges or expenses for or in the name of the other Party.

16.3 Entire Understanding. The Parties agree, on their own and their respective Affiliates' behalf, that this Agreement, including Schedules hereto, and any other document identified herein, constitutes the entire agreement between the Parties and their Affiliates relating to the subject matter hereof, and all prior agreements or arrangements, written or oral, between the Parties and their Affiliates relating to the subject matter hereof are hereby superseded and merged with this Agreement.

16.4 Assignment. This Agreement will be binding upon and inure to the benefit of the Parties, their successors and permitted assigns. Neither Party shall delegate, transfer, convey, assign or pledge this Agreement, in whole or in part, or any of its rights or obligations under this Agreement, without the prior written Consent of the other Party in each instance, and any such action without Consent shall be void and have no effect. However, notwithstanding the foregoing, a Change of Control of either Party shall not be deemed to be an assignment of this Agreement and shall not be subject to the other Party's Consent.

16.5 Dispute Resolution. If the Parties fail to resolve any claim, dispute or controversy of whatever nature arising out of or relating to this Agreement (other than one relating to the validity, enforceability, infringement or misappropriation of Intellectual Property rights, which shall not be subject to this Section 16.5), the Parties shall refer the dispute, to their respective officers designated below or such other officers as the Parties may designate in writing from time to time, for attempted resolution by good faith negotiations within [***] after so submitting the dispute. The designated officers are as follows:

For Amarin:

Amarin Pharmaceuticals Ireland Ltd.
c/o Amarin Pharma, Inc.
Mystic Packer Building, Suite 300
12 Roosevelt Avenue
Mystic, CT 06355
USA
Attention: President
Telephone: +1 860-572-4979
Fax: +1 860-572-4940

For Chemport:

Chemport Inc.
15-1 Dongsu-dong, Naju-si
Jeollanam-do 520-330, Korea

Attention: [***], CTO/Senior Managing Director
Fax: +82-61-330-9770
Email: [***]

With a copy to:

Chemport Inc.
2-1704 Ace Hightech City, 55-20
Munrae-dong 3-ga, Yeongdeungpo-gu
Seoul 150-834 Korea

Attention:	[***], CFO/Director
Fax:	+82-2-3439-2266
Email:	[***]

If such dispute is not resolved by the end of the [***] period, then either Party shall be entitled to refer the matter to be finally settled by arbitration to be held in accordance with the then-current Rules of Arbitration and Conciliation of the International Chamber of Commerce by three (3) arbitrators to be appointed in accordance with the said Rules. The Parties agree that any such unresolved dispute, and any claim or dispute related to the validity of this arbitration clause, may be resolved solely by binding arbitration under this Section 16.5. The arbitration shall take place in London, England if the claim giving rise to such arbitration is brought by Chemport and the arbitration shall take place in Singapore if the claim giving rise to such arbitration is brought by Amarin. In each case, the proceedings shall be conducted and all documentation shall be presented in the English language. The award of the arbitrators shall be final and without appeal. Any competent court shall be able to order enforcement of the award. Each Party will bear its own attorneys' fees and other costs and expenses incurred pursuant to this Section 16.5. For avoidance of doubt, the foregoing shall not prohibit or delay a Party from seeking appropriate injunctive or other equitable relief.

16.6 Subcontractors. Chemport may utilize Subcontractors with appropriate expertise and experience in the performance of its obligations under this Agreement; provided, however, that Amarin must give its written Consent in each instance prior to the use of Subcontractors by Chemport (such Consent not to be unreasonably withheld or delayed). Nothing in this Section 16.6 shall relieve Chemport from any obligation under this Agreement.

16.7 Amendment. This Agreement, including any Schedule hereto, may not be amended or modified in any manner except by an instrument in writing signed by a duly authorized officer of each Party.

16.8 Severability. If and to the extent that any court of competent jurisdiction holds any provision (or any part thereof) of this Agreement to be invalid or unenforceable, such holding shall in no way affect the validity or enforceability of the remainder of this Agreement, and the invalid or unenforceable provision shall be fully severed from this Agreement, and there shall automatically be added in lieu thereof a provision as similar in terms and intent to such severed provision as may be legal, valid and enforceable.

16.9 Waiver. Any failure of a Party to comply with any obligation, covenant, agreement or condition herein contained may be expressly waived, in writing only, by the other Party hereto, and such waiver shall be effective only in the specific instance and for the specific purpose for which made or given.

16.10 Survival. Articles I (to the extent required to enforce other surviving rights or obligations), VIII, IX, X, XI, XII, XIII, XV, XVI and Sections 6.1(b), 6.3, 6.4, 6.5, 6.6, 6.7, 6.8, 6.9, 7.5, 7.7, and 7.9, and any other provision which by its terms specifically shall so state, together with any obligations accrued hereunder at the time of termination or expiration, shall survive the termination or expiration of this Agreement.

16.11 Drafting Ambiguities. Each Party to this Agreement and its counsel have reviewed and revised this Agreement. The rule of construction to the effect that any ambiguities are to be resolved against the drafting Party shall not be employed in the interpretation of this Agreement or any amendment or Schedules hereto.

16.12 Headings; Schedules; Counterparts.

(a) Headings. The headings of the Sections of this Agreement are for reference purposes only, are not part of this Agreement and shall not in any way affect the meaning or interpretation of this Agreement.

(b) Schedules. All Schedules and Exhibits delivered pursuant to this Agreement shall be deemed part of this Agreement and incorporated herein by reference as if fully set forth herein. In the event that any Schedule conflicts with any of the terms or provisions of this Agreement, the terms and provisions of this Agreement shall prevail.

(c) Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed to be an original but all of which together shall constitute one and the same instrument. Facsimile signatures shall be treated as original signatures.

16.13 Governing Law. This Agreement and all matters arising out of or relating to this Agreement shall be governed, construed and enforced in accordance with the laws of the State of New York, USA, without regard to principles of conflicts of law. The Parties agree that the provisions of the United Nations Convention on Contracts for the International Sale of Goods shall not apply.

16.14 Remedies. Unless otherwise expressly provided in this Agreement, none of the remedies set forth in this Agreement are intended to be exclusive, and each Party shall have available to it all remedies available under law or in equity or in any other agreement between the Parties.

16.15 Injunctive Relief. In the event that either Chemport or Amarin breaches or threatens to breach any provision of Article VIII or Article XIII of this Agreement, the Parties agree that irreparable harm to the other Party should be presumed, and the damages to such Party would probably be very difficult to ascertain and would be inadequate. Accordingly, in the event of such circumstances, each of Chemport and Amarin agree that, in addition to any other right and remedies available at law or in equity, the other Party shall have the right to seek injunctive relief from any court of competent jurisdiction.

16.16 Standard Forms. In all communications, Amarin and Chemport may employ their standard forms, but nothing in those forms shall be construed to be in addition to or modify or amend the terms and conditions of this Agreement, and, in the case of any conflict herewith, the terms and conditions of this Agreement shall control.

16.17 Further Assurances. Each Party agrees to execute, acknowledge and deliver such further instruments and to do all such other acts as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

16.18 Counterparts. This Agreement may be executed in two counterparts and by facsimile or PDF signature, each of which shall be deemed an original and which together shall constitute one instrument.

16.19 English Language. The English language version of this Agreement will be controlling on the Parties. All information, documents, reports, notices, writings and communications to be provided by one Party to the other Party hereunder will be provided in the English language.

[Remainder of page intentionally left blank.]

IN WITNESS WHEREOF, each of the Parties hereto has caused this Agreement to be duly executed as of the date first written above.

AMARIN PHARMACEUTICALS IRELAND LTD.

By: /s/ Thomas G. Lynch
Name: Thomas G. Lynch
Title: Director

CHEMPORT INC.

By: /s/ Young Joo Kim
Name: Young Joo Kim
Title: CEO/President
5/25/2011

SCHEDULE 3.1

PRICING SCHEDULE

Price Schedule

[***]

SCHEDULE 3.1(e)

API PRICE ADJUSTMENT

[***]

SCHEDULE 4.1

EXPANSION PLANS

[***]

SCHEDULE 4.5

SECOND EXPANSION PLANS

[***]

SCHEDULE 5.1

API SPECIFICATIONS[1]

[***]

[1] [***]

SCHEDULE 6.2

FORM OF CERTIFICATE OF ANALYSIS

[***]

Exhibit 10.36

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED AND REPLACED WITH "[***]". SUCH IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

AMENDMENT TO API COMMERCIAL SUPPLY AGREEMENT

This AMENDMENT TO API COMMERCIAL SUPPLY AGREEMENT (the "Amendment") is made as of this 4 day of April, 2012 (the "Amendment Effective Date"), by and between Amarin Pharmaceuticals Ireland Ltd., a corporation organized under the laws of Ireland and having its principal office at First Floor, Block 3, The Oval, Shelbourne Road, Ballsbridge, Dublin 4, Ireland ("Amarin"), and Chemport Inc., a corporation organized under the laws of South Korea and having its principal offices at 15-1, Dongsu-dong, Naju-si, Jeollanam-do 520-330 Korea ("Chemport").

WHEREAS, the Parties entered into that certain API Commercial Supply Agreement as of May 25, 2011 (the "Agreement"); and

WHEREAS, the Parties wish to amend the Agreement as set forth herein.

NOW THEREFORE, in consideration of the premises and mutual covenants herein below, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. Capitalized terms used but not defined herein shall have the meanings given to them in the Agreement.

2. A new Section 9.5 is hereby added to the Agreement and shall hereafter read as follows:

9.5 Amarin Representative. Amarin shall be allowed to have, at its expense, an employee of Amarin or a third party consultant present at all locations [***] for the purpose of [***]. Such employee or third party consultant shall execute a reasonable confidentiality agreement intended to protect Confidential Information of Chemport. Chemport will reasonably cooperate in enabling such employee or consultant of Amarin to carry out his or her activities [***]. The Amarin employee or consultant shall be obligated to follow reasonable rules and procedures made known to such employee and consultant and that apply generally to personnel of Chemport. Chemport agrees to [***]. This Section 9.4 shall expire upon approval of the Drug Application by the FDA.

3. Section 11.4 of the Agreement is deleted in its entirety and replaced with the following:

11.4 Special Indemnity. In the event this Agreement is terminated by Amarin pursuant to Sections 15.5(a) or (h), Chemport shall pay to Amarin the amount of [***], which shall be Amarin's sole and exclusive remedy with respect thereto, and in the event this Agreement is terminated by Amarin pursuant to Section 15.5(g), Chemport shall pay to Amarin the amount of [***], which shall be Amarin's sole and exclusive remedy with respect thereto.

4. A new subsection (h) is hereby added to Section 15.5 of the Agreement and shall hereafter read as follows:

(h) [***]. In Amarin's reasonable judgment, Chemport [***] on Schedule 15.5(h) hereto at the Facility on or before [***]; provided, however, that notwithstanding anything in this Section 15.5 to the contrary, such termination shall take immediate effect upon written notice from Amarin.

5. Schedule 15.5(h) attached hereto is hereby incorporated into the Agreement as Schedule 15.5(h).

6. This Amendment and any other future amendment of the Agreement may be executed in two (2) or more counterparts, each of which shall be an original, but all of which together shall constitute one and the same instrument. To evidence the fact that it has executed this Amendment and any other future amendment of the Agreement, a Party may send a copy of its executed counterpart to the other Parties by facsimile transmission or by email transmission in portable document format, or similar format. Signatures of the Parties transmitted by facsimile or by email transmission in portable document format, or similar format, shall be deemed to be their original signatures for all purposes.

7. Except as expressly provided in this Amendment, all other provisions of the Agreement shall remain unmodified and in full force and effect.

[signature page follows]

IN WITNESS WHEREOF, the Parties have caused their duly authorized representative to execute this Amendment effective as of the Amendment Effective Date.

AMARIN PHARMACEUTICALS IRELAND LTD.

By: /s/ Thomas G. Lynch
Name: Thomas G. Lynch
Title: Director + Officer

CHEMPORT INC.

By: /s/ Young Joo Kim
Name: Young Joo Kim
Title: CEO/President

SCHEDULE 15.5(H)

[***]

Exhibit 10.37

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED AND REPLACED WITH "[***]". SUCH IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

SECOND AMENDMENT TO API COMMERCIAL SUPPLY AGREEMENT

This SECOND AMENDMENT TO API COMMERCIAL SUPPLY AGREEMENT (the "Amendment") is made as of this 19th day of July, 2012 (the "Amendment Effective Date"), by and between Amarin Pharmaceuticals Ireland Ltd., a corporation organized under the laws of Ireland and having its principal office at 2 Pembroke House, Upper Pembroke Street, #28-32, Dublin 2, Ireland ("Amarin"), and Chemport Inc., a corporation organized under the laws of South Korea and having its principal offices at 15-1, Dongsu-dong, Naju-si, Jeollanam-do 520-330 Korea ("Chemport").

WHEREAS, the Parties entered into that certain API Commercial Supply Agreement as of May 25, 2011 (the "Original Agreement");

WHEREAS, the Parties amended the Original Agreement pursuant to that certain Amendment to API Commercial Supply Agreement dated April 4, 2012 (together with the Original Agreement, the "Agreement"); and

WHEREAS, the Parties wish to further amend the Agreement as set forth herein.

NOW THEREFORE, in consideration of the premises and mutual covenants herein below, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. Capitalized terms used but not defined herein shall have the meanings given to them in the Agreement.

2. Section 4.1 is hereby deleted in its entirety and replaced with the following:

4.1 Capacity. Within [***] months after the Effective Date, Chemport shall expand the Facility's capacity to supply annually [***] metric tons of API (with [***]) as further detailed in Schedule 4.1 (the "Expansion"). Following completion of the Expansion, Chemport shall maintain at all times during the Term the capacity to supply Amarin [***] of API each Calendar Year ("Chemport's Initial Minimum Capacity"). Chemport's capacity as further expanded in accordance with this Agreement, together with Chemport's Initial Minimum Capacity, shall be referred to herein as "Chemport's Minimum Capacity."

3. Section 4.2 is hereby deleted in its entirety and replaced with the following:

4.2 Completion. The Expansion will be deemed to be completed for purposes of this Agreement if (i) all of the requirements set forth in Schedule 4.1 have been satisfied, (ii) Chemport has manufactured three (3) successful, consecutive process validation (consistent with ICH guidelines) batches (each batch shall be in a quantity of [***]) of API (each a "Validation Batch") in the expanded Facility that satisfy the requirements of this Agreement, and (iii) Amarin or mutually agreed upon Third Party has reviewed the completed process validation report and agrees that it is suitabale to support the approval of the Drug Application. The entire unredacted Process Validation report can be reviewed by aforementioned Third Party, and Amarin can only review redacted report (redactions will only apply to Chemport confidential process information). Any delays related to review and acceptance of the Process Validation report by Amarin or Third Party shall not constitute a delay in Chemport's obligations under this Agreement.

4. Schedule 5.1 of the Agreement is deleted in its entirety and shall be replaced with the Schedule 5.1 attached hereto.

5. Section 11.4 of the Agreement is deleted in its entirety and replaced with the following:

11.4 Special Indemnity. In the event this Agreement is terminated by Amarin pursuant to Sections 15.5(a) or (h), Chemport shall pay to Amarin the amount of [***], which shall be Amarin's [***], and in the event this Agreement is terminated by Amarin pursuant to Section 15.5(g), Chemport shall pay to Amarin the amount of [***], which shall [***].

6. The address for Amarin set forth in Section 16.1 of the Agreement is hereby changed to the following:

If to Amarin:

Amarin Pharmaceuticals Ireland Ltd.
c/o Byrne Wallace; Attention: Thomas Maher
Upper Pembroke Street, #28-32
Dublin 2
Ireland
Telephone +353 1 691 5507
Fax + 353 1 691 5010 DX 18 Dublin

and

Amarin Pharmaceuticals Ireland Ltd.
c/o Amarin Pharma, Inc.
1430 Route 206, Suite 200
Bedminster, NJ 07921
USA
Attention: Senior Vice President, Corporate Development
Telephone: 908 719 1315
Fax: 908 719 3012

With a copy (which shall not constitute notice) to:

Dan L. O'Korn
Hutchison PLLC
5410 Trinity Road, Suite 400
Raleigh, North Carolina 27607
Facsimile: (919) 859-1841

7. The address for Amarin set forth in Section 16.5 of the Agreement is hereby changed to the following:

Amarin Pharmaceuticals Ireland Ltd.
c/o Amarin Pharma, Inc.
1430 Route 206, Suite 200
Bedminster, NJ 07921
USA
Attention: Senior Vice President, Corporate Development
Telephone: 908 719 1315
Fax: 908 719 3012

8. This Amendment and any other future amendment of the Agreement may be executed in two (2) or more counterparts, each of which shall be an original, but all of which together shall constitute one and the same instrument. To evidence the fact that it has executed this Amendment and any other future amendment of the Agreement, a Party may send a copy of its executed counterpart to the other Parties by facsimile transmission or by email transmission in portable document format, or similar format. Signatures of the Parties transmitted by facsimile or by email transmission in portable document format, or similar format, shall be deemed to be their original signatures for all purposes.

9. Except as expressly provided in this Amendment, all other provisions of the Agreement shall remain unmodified and in full force and effect.

[signature page follows]

IN WITNESS WHEREOF, the Parties have caused their duly authorized representative to execute this Amendment effective as of the Amendment Effective Date.

AMARIN PHARMACEUTICALS IRELAND LTD.

By: /s/ Conor Dalton

Name: Conor Dalton

Title: Chief Administrative Officer

CHEMPORT INC.

By: /s/ Young Joo Kim

Name: Young Joo Kim

Title: CEO/President

SCHEDULE 5.1

[***]

Exhibit 10.38

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED AND REPLACED WITH "[***]". SUCH IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

PURCHASE AND SALE AGREEMENT

BY AND BETWEEN

AMARIN PHARMACEUTICALS IRELAND LIMITED

AMARIN CORPORATION PLC

AND

BIOPHARMA SECURED DEBT FUND II HOLDINGS CAYMAN LP

EFFECTIVE AS OF

DECEMBER 6, 2012

PURCHASE AND SALE AGREEMENT

THIS PURCHASE AND SALE AGREEMENT (this ***"Agreement"***) is made and entered into as of December 6, 2012 (the ***"Effective Date"***), by and between **AMARIN PHARMACEUTICALS IRELAND LIMITED**, a company incorporated under the laws of Ireland (registered number 408912) having its registered office at 88 Harcourt Street, Dublin 2, and its permitted successors and assigns (***"Seller"***), **AMARIN CORPORATION PLC**, a public limited company incorporated under the laws of England and Wales, and its permitted successors and assigns (***"Parent"*** and, together with Seller, the "***Amarin Parties***") and **BIOPHARMA SECURED DEBT FUND II HOLDINGS CAYMAN LP**, a Cayman Islands exempted limited partnership, and its permitted successors and assigns (***"Purchaser"***). Purchaser, Seller and Parent are sometimes referred to individually as a ***"Party"*** and collectively as the ***"Parties."*** Capitalized terms used but not otherwise defined will have the respective meanings given to such terms in **Annex A** attached hereto.

BACKGROUND

WHEREAS, the Amarin Parties desire additional funding to develop and commercialize the Product in the Territory and Purchaser desires, on the terms and conditions set forth herein, to provide Seller with such additional funding; and

WHEREAS, upon and subject to the terms and conditions contained herein, Seller desires to sell, convey, transfer and assign to Purchaser, and Purchaser desires to purchase and accept from Seller, all of Seller's right, title and interest in, to and under the Purchased Receivables.

NOW, THEREFORE, in consideration of the premises and mutual covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

ARTICLE 1

PURCHASE AND SALE OF PURCHASED RECEIVABLES

1.1 PURCHASE AND SALE OF PURCHASED RECEIVABLES. On the terms and subject to the conditions set forth in this Agreement, Seller will sell, convey, transfer and assign to Purchaser, and Purchaser agrees to purchase and accept from Seller, on the Closing Date, all of Seller's right, title and interest in, to and under the Purchased Receivables, free and clear of any and all Encumbrances (other than Permitted Encumbrances).

1.2 PURCHASE PRICE; USE OF PROCEEDS.

(a) The aggregate purchase price for the Purchased Receivables is $100,000,000.00 (the ***"Purchase Price"***). The Purchase Price will be paid on the Closing Date by wire transfer in immediately available U.S. dollar funds to an account to be designated in writing by Seller prior to the Closing.

(b) Seller will use the proceeds of the Purchase Price for Funded Activities. Seller will pay all providers of Funded Activities, whether Third-Person providers or Seller's employees or Affiliates. Purchaser will have no obligation or responsibility to pay any portion of the Purchase Price to any providers of Funded Activities or anyone else, besides Seller as set forth in Section 1.2 (a).

1.3 MANNER OF EFFECTIVE SALE. The sale, conveyance, transfer, assignment and delivery of the Purchased Receivables by Seller to Purchaser will be effected by Purchaser and Seller executing the Bill of Sale.

1.4 CLOSING AND CLOSING DATE. The purchase and sale provided for in this Agreement (the ***"Closing"***) will take place at the offices of Akin Gump Strauss Hauer & Feld LLP, 1 Bryant Park, New York, NY 10036, commencing at 9:00 a.m. (local time) on the second Business Day following the satisfaction or waiver of all conditions set forth in Section 1.5 and Section 1.6, or at such other place, time and date as the Parties may mutually agree; provided that the Closing Date shall in no event occur earlier than December 19, 2012 and no later than

December 27, 2012. The Parties will undertake in good faith all such actions and efforts reasonably required in an effort to effect the Closing within the period specified in the preceding sentence. The date of the Closing is referred to as the ***"Closing Date."***

1.5 CONDITIONS TO PURCHASER'S OBLIGATIONS.

(a) Seller shall have delivered to Purchaser the Bill of Sale, duly executed by Seller.

(b) Seller shall have delivered to Purchaser the Intellectual Property Charge Agreements, duly executed by Seller.

(c) An authorised officer of each of the Amarin Parties shall have delivered to Purchaser certificates, duly executed:

(i) (A) attaching copies, certified by such officer as true and complete, of resolutions of the board of directors of such Amarin Party authorizing and approving the execution, delivery and performance by such Amarin Party of the Transaction Documents and the transactions contemplated herein and therein; (B) setting forth the incumbency of the officer or officers of such Amarin Party who have executed and delivered the Transaction Documents, including therein a signature specimen of each officer or officers; (C) attaching copies, certified by such officer as true and complete, of each of the certificate of incorporation (and any certificates of change of name) and memorandum and articles of association of such Amarin Party as in effect on the Closing Date; and (D) where applicable, attaching copies, certified by such officer as true and complete, of long form good standing certificates of the appropriate Governmental Authority of such Amarin Party's jurisdiction of incorporation, stating that such Amarin Party is in good standing under the laws of such jurisdiction; and

(ii) (A) as to the accuracy in all material respects of each of such Amarin Party's representations and warranties in this Agreement as of the Closing Date (other than those made as of a specified date earlier than the Closing Date); (B) as to the accuracy in all material respects of each of such Amarin Party's representations and warranties in this Agreement as of a specified date earlier than the Closing Date; and (C) as to such Amarin Party's compliance with and performance of in all material respects each of its covenants and obligations to be performed or complied with at or before the Closing Date.

(d) Seller shall sign or deliver to Purchaser such other certificates, documents and financing statements and make such filings within the applicable statutory time periods as Purchaser may reasonably request in order to perfect the ownership interests in the Purchased Receivables and the security interests in the Collateral (a) in accordance with the UCC to the extent such security interest can be perfected by the filing of a financing statement or by filing with the United States Patent and Trademark Office and (b) as required under the laws of Ireland to the extent such security interest can be perfected; provided that for the avoidance of doubt, Seller shall not be obligated to undertake any filings or other actions with respect to any jurisdictions outside of the United States other than filings required in Ireland and with the European Patent Office.

(e) There shall not have been issued and be in effect any Judgment of any Governmental Entity enjoining, preventing or restricting the consummation of the transactions contemplated by this Agreement.

(f) There shall not have been instituted or be pending any action or proceeding by any Governmental Entity or any other Person (i) challenging or seeking to make illegal, to delay materially or otherwise directly or indirectly to restrain or prohibit the consummation of the transactions contemplated hereby, (ii) seeking to obtain material damages in connection with the transactions contemplated hereby or (iii) seeking to restrain or prohibit Purchaser's purchase of the Purchased Receivables.

(g) Purchaser shall have received an opinion of Cooley LLP, special counsel to Seller, in form and substance as agreed to by the Parties on the date hereof**.**

(h) Purchaser shall have received an opinion of Byrne Wallace, special counsel to Seller, covering matters customary for similar transactions in form and substance reasonably acceptable to Purchaser.

(i) Seller shall have delivered to Purchaser Form C1s signed on behalf of Seller in connection with Section 4.8 and Section 4.9 of this Agreement, the Irish Intellectual Property Charge Agreement and any other intellectual property charge agreement which is registerable in the CRO, in the form to be agreed between Purchaser and Seller.

(j) In the event that (or in the event that it is anticipated that) the Closing Date will occur more than 19 calendar days after the date of this Agreement, authority to file the Form C1s signed on behalf of the Seller in connection with this Agreement.

(k) All intellectual property registrations as Purchaser determines are necessary to perfect the security interest in the Collateral in the EPO, the Irish Patents Office and the European Trade Marks and Design Registration Office in connection with the European Patents.

1.6 CONDITIONS TO SELLER'S OBLIGATIONS.

(a) Purchaser shall have delivered to Seller the Bill of Sale, duly executed by Purchaser.

(b) Purchaser shall have delivered to Seller the Intellectual Property Charge Agreements, duly executed by Purchaser.

(c) The general partner of Pharmakon Advisors, LP, the investment manager of Purchaser ("***Pharmakon***"), shall sign and deliver to Seller certificates dated as of the Closing Date:

(i) as to the power and authority of Pharmakon to execute, on behalf of Purchaser, the Transaction Documents to which Purchaser is or is to be a party;

(ii) (A) as to the accuracy in all material respects of each of Purchaser's representations and warranties in this Agreement as of the Closing Date (other than those made as of a specified date earlier than the Closing Date); (B) setting forth the incumbency of the authorized person of Pharmakon who has executed and delivered the Transaction Documents, including therein a signature specimen of such authorized person; (C) as to the accuracy in all material respects of each of Purchaser's representations and warranties in this Agreement as of a specified date earlier than the Closing Date; and (D) as to Purchaser's compliance with and performance of in all material respects each of its covenants and obligations to be performed or complied with at or before the Closing Date.

(d) There shall not have been issued and be in effect any Judgment of any Governmental Entity enjoining, preventing or restricting the consummation of the transactions contemplated by this Agreement.

(e) There shall not have been instituted or be pending any action or proceeding by any Governmental Entity or any other Person (i) challenging or seeking to make illegal, to delay materially or otherwise directly or indirectly to restrain or prohibit the consummation of the transactions contemplated hereby, (ii) seeking to obtain material damages in connection with the transactions contemplated hereby or (iii) seeking to restrain or prohibit Purchaser's purchase of the Purchased Receivables.

1.7 RETAINED RIGHTS; NO ASSUMED OBLIGATIONS; SELLER AUTHORITY. Notwithstanding any provision in this Agreement to the contrary:

(a) Purchaser is acquiring only the Purchased Receivables and does not, by purchase of the Purchased Receivables hereunder, acquire any other assets of Seller or its Affiliates other than the Purchased Receivables;

(b) Purchaser does not, by purchase of the Purchased Receivables hereunder, assume any Liability of Seller or any of its Affiliates. All such Liabilities will be retained by and remain Liabilities of Seller or its Affiliates; and

(c) Except as otherwise expressly provided herein, Seller has sole authority and responsibility for the research, development, commercialization and exploitation of Product, including regulatory compliance, intellectual property protection, manufacturing, marketing, clinical development, distribution, sales, product liability and reimbursement with respect thereto.

ARTICLE 2

PAYMENTS; RECORDS AND AUDITS

2.1 PAYMENTS DUE TO PURCHASER.

(a) (i) Until such time as Seller or its Affiliates have paid the Threshold Amount or otherwise met the requirements of Section 2.1(e) or Section 2.1(h), then subject to the Quarterly Cap in Section 2.1(b), Seller will, or will cause its Affiliates to, during the Payment Period, as applicable, pay Purchaser the scheduled quarterly amount set forth in the corresponding table below (each, a ***"Scheduled Quarterly Amount"***):

(1) each Calendar Quarter occurring	**Scheduled Quarterly Amount (in the event it is not a Quarterly Cap Event Quarter)**
in the last two Calendar Quarters of 2013	$2,500,000
in 2014	$8,000,000
in 2015	$10,000,000
in 2016	$15,000,000
in the first Calendar Quarter of 2017 (in the event no prior Quarterly Cap Event Quarter)	$13,000,000

(2) each Calendar Quarter occurring	**Scheduled Quarterly Amount (in the event there is or has been a Quarterly Cap Event Quarter)**
in the first Calendar Quarter of 2017 (in the event of a prior or current Quarterly Cap Event Quarter)	The lesser of (1) the Outstanding Threshold Amount and (2) [***]
in the second Calendar Quarter of 2017 and thereafter (only in the event of a prior Quarterly Cap Event Quarter)	The lesser of (1) the Outstanding Threshold Amount and (2) [***]

(ii) Until such time as the Threshold Amount has been paid, the Scheduled Quarterly Amount will be calculated and payable by Seller or its Affiliates on a Calendar Quarter basis during the Payment Period, and Seller will, or will cause its Affiliates to, pay the Scheduled Quarterly Amount to Purchaser within [***] after the end of such Calendar Quarter. In any event, Seller or its Affiliate, in connection with or as a result of any Scheduled Quarterly Amount payment shall notify Purchaser when Seller believes the Threshold Amount has been reached.

(b) Each Calendar Quarter during the Payment Period, the Scheduled Quarterly Amount payable by Seller and its Affiliates pursuant to Section 2.1(a) will be subject to [***] (each, a ***"Quarterly Cap"***), amounts in excess of which will not constitute a Scheduled Quarterly Amount and, thus, will not be payable by Seller or its Affiliates to Purchaser pursuant to Section 2.1(a). The attainment of a Quarterly Cap in any Calendar Quarter during the Payment Period shall hereinafter be referred to as a "***Quarterly Cap Event Quarter***"

(c) [RESERVED]

(d) In the event of a Quarterly Cap Event Quarter, then, beginning with the first Calendar Quarter of 2017, Seller shall perform a true-up for the Scheduled Quarterly Amount for the total of each of the preceding Quarterly Cap Event Quarter amounts unpaid, to the extent applicable. Such true-up shall reconcile the actual Scheduled Quarterly Amount for each applicable Calendar Quarter with the Scheduled Quarterly Amount calculated pursuant to Section 2.1(b) (including, without limitation, a reconciliation of actual deductions with respect to Net Sales with the deductions that were accrued or estimated with respect thereto). Seller shall provide to Purchaser such reconciliation no later than [***] after the end of the first Calendar Quarter of 2017. If Seller is required to make a payment to Purchaser to effect such reconciliation, then subject to the rate adjustments in Section 2.1(e) and to the limitation in Section 2.1(h), Seller or its Affiliates shall provide such payment to Purchaser along with such reconciliation. Seller shall provide to Purchaser, along with the reconciliation, all documentation reasonably necessary to explain or support the reconciliation (as well as such other information as Purchaser shall reasonably request), in a form to be mutually agreed. Any reconciling payment made pursuant to this Section 2.1(d) shall be made without interest pursuant to Section 2.4.

(e) Seller or its Affiliates shall have the option to prepay all or any portion of Scheduled Quarterly Amounts due hereunder at any time during the Payment Period upon written notice (specifying the Scheduled Quarterly Amount with respect to which such prepayment is made, or if not specified such prepayment shall be deemed made for the next Scheduled Quarterly Amount) and tender of payment to Purchaser; provided that if Seller determines to pay the Outstanding Threshold Amount, then Seller shall provide written notice to Purchaser of the exercise of this option not less than [***] prior to the Outstanding Threshold Amount payment date (the ***"Termination Date"***). Upon payment of the Outstanding Threshold Amount on the Termination Date, neither Seller nor any of its Affiliates will have any obligation to pay to Purchaser any additional Scheduled Quarterly Amount pursuant to this Section 2.1 and this Agreement shall terminate

(f) All payments from Seller or its Affiliates under this Section 2.1 and any other payment made by Seller or its Affiliates to Purchaser under this Agreement will be made in U.S. dollars by wire transfer of immediately available funds, free and clear of all Encumbrances and without offset or reduction by Seller or its Affiliates of any kind (except pursuant to the reconciliation procedures under this Section 2.1 or pursuant to Section 2.4), to such account as Purchaser notifies Seller in writing.

(g) Seller will, and will cause its Affiliates to, hold in trust for the benefit of Purchaser any portion of Net Sales constituting Scheduled Quarterly Amounts in the applicable Calendar Quarter until such funds are paid to Purchaser within the time period provided therefor hereunder.

(h) Neither Seller nor any of its Affiliates will have any obligation to pay to Purchaser any Scheduled Quarterly Amount pursuant to this Section 2.1 once Purchaser has actually received an aggregate amount of such payments equal to the Threshold Amount or Seller or its Affiliates have satisfied in full the obligations under Section 4.9(m) or Section 4.14.

2.2 DELIVERABLES DUE TO PURCHASER.

(a) Within [***] of the end of each Calendar Quarter during the Payment Period, Seller will send a written report to Purchaser showing (i) the Net Sales for the Calendar Quarter in question (and for that Calendar Year to date), showing in reasonably specific detail how calculated, (ii) a breakdown of such Net Sales by Product and country,

(iii) any Quarterly Cap applicable to such Scheduled Quarterly Amount, (iv) whether, in connection with or as a result of such Scheduled Quarterly Amount payment, Seller believes the Threshold Amount has been reached, certified by an executive officer of Seller as true and complete in all material respects (the ***"Quarterly Report"***). Within [***] of the end of each Calendar Year , Seller or its Affiliate will deliver to Purchaser a reasonably detailed annual report, certified by an executive officer of Seller as true and complete in all material respects, setting forth, with respect to such calendar year, (A) the Clinical Updates, (B) the Commercial Updates and (C) the Intellectual Property Updates (the ***"Annual Report"***); provided that in the event there is a material change in a Calendar Quarter to a previously provided Annual Report, then within [***] of the applicable quarter, Seller shall provide a supplemental report in reasonable detail describing such material change to the most recently provided Annual Report. Seller shall also provide Purchaser with such additional information regarding the updates included in each Annual Report as Purchaser may reasonably request from time to time.

(b) Within [***] after the end of each of the first three Calendar Quarters of a Calendar Year during the Payment Period, the Amarin Parties will provide Purchaser with copies of the unaudited consolidated balance sheets of Parent and its consolidated subsidiaries for the corresponding Calendar Quarter, the related unaudited consolidated statements of income and cash flows for such Calendar Quarter and the notes to such financial statements (the ***"Unaudited Financial Statements"***) certified by an executive officer of Seller as true and complete in all material respects (except as permitted by Form 10-Q of the Securities Exchange Act of 1934, as amended). Each set of the Unaudited Financial Statements shall be the Confidential Information of the Amarin Parties.

(c) Not less than [***] prior to the beginning of each Calendar Quarter during the Payment Period, Seller will provide Purchaser with a written statement describing [***].

(d) Within [***] after the end of each Calendar Quarter during the Payment Period, Seller will provide Purchaser with a written statement, which describes [***].

(e) Within [***] after the end of each Calendar Year during the Payment Period, the Amarin Parties will provide Purchaser with copies of the audited consolidated balance sheets of Parent and its consolidated subsidiaries for such Calendar Year, the related audited consolidated statements of income and cash flows for such Calendar Year, the notes to such financial statements, the report on such audited information by Deloitte & Touche LLP (or such other independent certified public accounting firm as Parent determines) [***]

2.3 RECORDS; AUDIT RIGHTS.

(a) Seller will, and will cause its Affiliates to, consistent with their respective internal financial control and reporting practices and procedures, keep and maintain, for a period of [***] from the end of an applicable [***], accounts and records of all data reasonably required to verify calculations and related payments of Scheduled Quarterly Amounts, to verify and calculate the amounts to be paid to Purchaser under this Agreement, and to verify the expenses for which the Purchase Price proceeds were used. Seller shall also cause any counterparty to any out-license or sub-license of the Seller or the Seller's Affiliates to prepare and maintain reasonably complete and accurate records of the information to be used in calculating Scheduled Quarterly Amounts and the expenses for which the Purchase Price proceeds were used, if any.

(b) During the Term and for [***] thereafter, during normal business hours and upon at least [***] prior written notice to Seller, but no more frequently than one time per [***] without cause, as determined by Purchaser in its reasonable discretion, and no more than one time with respect to each Calendar Quarter during the Payment Period, Purchaser has the right to audit, through an independent certified public accountant selected by Purchaser and acceptable to Seller (which acceptance will not be unreasonably withheld, conditioned or delayed), those accounts and records of Seller and Seller's Affiliates as may be reasonably necessary to verify the accuracy of the Quarterly Reports and the amounts received by Purchaser or the use of Purchase Price proceeds (provided, however, that, prior to conducting any such audit, such accountant will have entered into a confidentiality agreement in form and substance reasonably satisfactory to Seller). Purchaser's independent certified public accountant will keep confidential all information obtained during such audit and will issue a written report to Purchaser and to Seller with only: (i) the actual amount of Net Sales made during the [***] in question, (ii) the resulting over- or under-payment of Scheduled Quarterly Amounts to Purchaser that occurred during, the [***] in question; and (iii) the details of any discrepancies between the Scheduled Quarterly Amounts that were paid and the Scheduled Quarterly Amounts that should have been paid. The determination of the actual amount of Scheduled Quarterly Amounts to be paid to

Purchaser under this Agreement with respect to any [***] will be binding and conclusive on the Parties upon the expiration of [***] following the end of such [***], unless an audit of such [***] has been initiated before the expiration of such [***] period and is on-going, in which case, such determination will be binding and conclusive on the Parties upon completion of such audit. Without limiting the generality of the preceding sentence, in the event that the Parties dispute the results of any audit performed pursuant to this Section 2.3, then the Parties shall, within [***], agree upon a nationally recognized U.S. independent auditor who has no engagement with either of the Parties within the prior [***], to review the results of the audit and the calculations and data of Seller. The designated independent auditor shall make a binding determination on the Parties by selecting the results of one of the Parties, without adjustment or compromise. The costs and expenses of the engagement of the independent auditor selected to resolve the dispute will be allocated in accordance with Section 2.3(c) below.

(c) Purchaser is solely responsible for all the expenses of the independent certified accountant, unless the independent certified public accountant's report shows any underpayment by Seller exceeding [***] of the payment it owed Purchaser for any of the [***] then being reviewed. If the independent certified public accountant's report shows that Seller underpaid by more than [***], Seller is responsible for the reasonable expenses incurred by Purchaser for the independent certified public accountant's services. Any payment owed by one Party to another as a result of the audit shall be made within [***] of the receipt of the audit report, free and clear of any and all Encumbrances. In addition, any payment under this Section 2.3 shall bear interest in accordance with Section 2.4.

2.4 INTEREST. In the event a payment under this Agreement is not made when due hereunder, the amount of such outstanding payment will accrue interest (from the date such payment is due through and including the date on which full payment is made) at an annual rate equal to [***]. Payment of accrued interest will accompany payment of the outstanding payment.

2.5 NO OTHER COMPENSATION. Purchaser and Seller hereby agree that the terms of this Agreement fully define all consideration, compensation and benefits, monetary or otherwise, to be paid, granted or delivered by Purchaser to Seller and by Seller to Purchaser in connection with the transactions contemplated herein. Neither Seller nor Purchaser have previously paid or entered into any other commitment to pay, whether orally or in writing, any Seller or Purchaser employee, directly or indirectly, any consideration, compensation or benefits, monetary or otherwise, in connection with the transactions contemplated herein.

ARTICLE 3

REPRESENTATIONS AND WARRANTIES

3.1 REPRESENTATIONS AND WARRANTIES OF THE AMARIN PARTIES. The Amarin Parties, jointly and severally, represent and warrant to Purchaser as follows:

(a) Organization. Seller is an Irish company duly incorporated and validly existing under the laws of Ireland. Parent is a public limited company duly incorporated and validly existing under the laws of England and Wales. Each Amarin Party is, where applicable, in good standing in every jurisdiction in which the failure to do so would reasonably be expected to result, individually or in the aggregate, in a Material Adverse Effect.

(b) Ownership Rights. Seller is the sole owner of all legal and equitable title to the Purchased Receivables, entitled to exercise its rights in connection therewith, free and clear of all Encumbrances, other than Permitted Encumbrances, such that, upon consummation of this Agreement, Purchaser will become entitled to receive, free and clear of all Encumbrances, other than Permitted Encumbrances, the Purchased Receivables. Seller has not pledged, sold, transferred, conveyed, assigned or delivered any interest in the Purchased Receivables to any other Person, or agreed to do so, and Seller has the full right, power and authority to sell, transfer, convey, assign and deliver the Purchased Receivables to Purchaser, free and clear of all Encumbrances, other than the Permitted Encumbrances. Upon the sale, transfer, conveyance, assignment and delivery of the Purchased Receivables to Purchaser pursuant to this Agreement, Purchaser will be the sole owner of all legal and equitable title to the Purchased Receivables, free and clear of any Encumbrances, other than the Permitted Encumbrances. Upon the filing of an appropriate UCC financing statement, the filings of particulars of Section 4.8 and Section 4.9 of this Agreement in the CRO and the filing of an appropriate patent security agreement in the PTO, there will have been duly filed all financing statements or other similar instruments or documents necessary under the applicable UCC (or any comparable law) of all applicable jurisdictions in the United States and all patent security agreements to

perfect and maintain the perfection of Purchaser's ownership interest in the Purchased Receivables and of the security interest in the Purchased Receivables granted by Seller to Purchaser pursuant to Section 4.8, in each case, in the United States.

(c) Authorization. Each Amarin Party has all requisite power, right and authority and all material licenses, authorizations, consents and approvals of all Governmental Authorities required to carry on its business as it is presently carried on by such Amarin Party, to enter into, execute and deliver this Agreement, the other Transaction Documents to which it is a party and the other documents to be delivered by such Amarin Party pursuant to Section 1.5, to sell, assign, transfer, convey and deliver the Purchased Receivables to Purchaser and to perform all of the covenants, agreements, and obligations to be performed by such Amarin Party under the Transaction Documents. The Transaction Documents to which each Amarin Party is a party have been duly executed and delivered by an authorized officer of such Amarin Party and each constitutes such Amarin Party's valid and binding obligation, enforceable against such Amarin Party in accordance with its respective terms, subject to bankruptcy, insolvency, reorganization or similar laws affecting the rights of creditors generally and to equitable principles (whether considered in a Proceeding in equity or at law).

(d) No Conflicts. Neither the execution and delivery of this Agreement or the other Transaction Documents by either Amarin Party nor the performance or consummation of this Agreement or the other Transaction Documents to which such Amarin Party is a party or the transactions contemplated hereby or thereby by such Amarin Party will: (i) contravene or conflict with, result in a Breach or violation of, constitute a default or accelerate the performance under (with due notice or lapse of time or both), in any respect, the terms of (A) to Seller's Knowledge, any Applicable Law, (B) any provisions of the certificate of incorporation (or any certificate of change of name) or memorandum and articles of association (or other organizational or constitutional documents) of such Amarin Party, or (C) the Senior Notes or any material contract, agreement, or other arrangement to which either Amarin Party or any of their respective Affiliates is a party or by which either Amarin Party or any of their respective Affiliates or any of their respective assets is bound or committed; or (ii) result in the creation or imposition of any Encumbrance (except as provided in this Agreement) on the Purchased Receivables or the Additional Collateral.

(e) No Consent. The execution and delivery by each Amarin Party of this Agreement and the other Transaction Documents, and the performance by such Amarin Party of its obligations and the consummation by each Amarin Party of any of the transactions contemplated hereby and thereby, do not require any consent, approval, license, order, authorization or declaration from, notice to, action or registration by or filing with any Governmental Authority or any other Person, except for (i) the filing of proper financing statements under the UCC, (ii) the filing of duly prepared intellectual property security agreements with the PTO, (iii) filings required by federal securities laws or stock exchange rules; (iv) the filings of particulars of Section 4.8 and Section 4.9 of this Agreement and the Irish Intellectual Property Charge Agreement in the CRO and (v) the filing of particulars of Section 4.8 and Section 4.9 of this Agreement and particulars of the Irish Intellectual Property Charge Agreement in the Irish Patents Office, the EPO and the European Trade Marks and Design Registration Office in connection with the European Patents.

(f) Solvency. Immediately after consummation of the transactions contemplated by the Transaction Documents, (i) the fair saleable value of Seller's assets will be greater than the sum of its debts and other obligations, including contingent liabilities, (ii) the present fair saleable value of Seller's assets will be greater than the amount that would be required to pay its probable liabilities on its existing debts and other obligations, including contingent liabilities, as they become absolute and matured, (iii) Seller will be able to realize upon its assets and pay its debts and other obligations, including contingent obligations, as they mature, (iv) Seller will not have unreasonably small capital with which to engage in its business, as currently conducted, and (v) Seller does not have present plans or intentions to incur debts or other obligations or liabilities beyond its ability to pay such debts or other obligations or liabilities as they become absolute and matured.

(g) No Litigation. There is no Proceeding against either Amarin Party, or to the Knowledge of Seller, investigation, pending or, to the Knowledge of Seller, threatened against either Amarin Party, or its Affiliates, at law or in equity (including that challenges the validity, ownership or enforceability of any of the Vascepa Product Rights), which, in each case, (i) if adversely determined, would reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect, or (ii) challenges, or may have the effect of preventing, delaying, making illegal or otherwise interfering with, any of the transactions contemplated by any of the Transaction Documents.

(h) Compliance with Laws. No Amarin Party is (i) in violation of, or has violated or has been given written notice of any violation, or, to the Knowledge of Seller, is under investigation with respect to, or has been threatened to be charged with, any violation of, any Applicable Law that would reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect, or (ii) subject to any Applicable Law that would reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect.

(i) In-Licensees and Sublicensees.

(i) *Existing In-Licenses; No Other In-Licenses*. Except as set forth on Schedule 3.1(i), there are no In-Licenses (any In-License set forth on Schedule 3.1(i), an "***Existing In-License***"). A true, correct and complete copy of each Existing In-License has been provided to the Purchaser by Seller prior to the date hereof. Except as set forth on Schedule 3.1(i), Seller and the respective counterparty thereto have not made or granted any amendment or waiver of any provision of any Existing In-License. To the Knowledge of Seller, the development, discovery, manufacture, importation, sale, offer for sale or use of the Product did not and does not require Seller to obtain any In-License in addition to the Existing In-Licenses in order to avoid or resolve any infringement or misappropriation of intellectual property rights or other rights of any other Person.

(ii) *Validity and Enforceability of the In-Licenses*. Each of the Existing In-Licenses is a valid and binding obligation of Seller and the counterparty thereto. Each of the Existing In-Licenses is enforceable against each counterparty thereto in accordance with its terms, except as may be limited by applicable Bankruptcy Laws or by general principles of equity (whether considered in a proceeding in equity or at law). The Seller has not received any notice in connection with an Existing In-License challenging the validity, enforceability or interpretation of any provision of such agreement.

(iii) *No Liens or Assignments by Seller*. Except as set forth in Schedule 3.1(i), Seller has not, except for Permitted Liens or as contemplated hereby, conveyed, assigned or in any other way transferred or granted any liens upon or security interests with respect to all or any portion of the Collateral.

(iv) *No Termination*. The Seller has not (A) given notice to a counterparty of the termination of any Existing In-License (whether in whole or in part) or any notice expressing any intention or desire to terminate any Existing In-License or (B) received from a counterparty thereto any notice of termination of any Existing In-License (whether in whole or in part) or any notice expressing any intention or desire to terminate any Existing In-License.

(v) *No Breaches or Defaults*. There is and has been no breach or default under any provision of any Existing In-License either by Seller or, to the Knowledge of Seller, by the respective counterparty (or any predecessor thereof) thereto, which breach or default would or would reasonably be expected to materially impact Purchaser's right to receive Scheduled Quarterly Amounts, and there is no event that upon notice or the passage of time, or both, would reasonably be expected to give rise to any breach or default either by Seller or, to the Knowledge of Seller, by the respective counterparty to such agreement, which breach or default would or would reasonably be expected to materially impact Purchaser's right to receive Scheduled Quarterly Amounts.

(vi) *Payments Made*. The Seller has made all payments to the respective counterparty required under each Existing In-License as of the date hereof.

(vii) *No Assignments*. The Seller has not consented to any assignment by the counterparty thereto of any of such counterparty's rights or obligations under any Existing In-License and, to the Knowledge of Seller, such counterparty has not assigned any of its rights or obligations under such Existing In-License to any Person.

(viii) *No Indemnification Claims*. The Seller has not notified the respective counterparty to any Existing In-License or any other Person of any claims for indemnification under any Existing In-License nor has Seller received any claims for indemnification under any Existing In-License.

(ix) *No Infringement*. The Seller has not received any written notice from, or given any written notice to, any counterparty to any Existing In-License regarding any infringement of any of the Vascepa Patent Rights. To the Knowledge of the Seller, [***].

(j) Sublicenses; Out-Licenses. Other than the Manufacturing Agreements, Seller has not entered into or executed a sublicense or other out-license with any other Person in respect of any Vascepa Product Rights or the Product.

(k) Manufacturing Agreements. Schedule 3.1(k) sets forth a list of the manufacturing and supply agreements entered into by Seller with Third Persons for the supply of Product and active pharmaceutical ingredient incorporated therein (the "***Manufacturing Agreements***"). Seller has delivered to Purchaser true, correct and complete copies of each Manufacturing Agreement.

(i) *Validity and Enforceability of the Manufacturing Agreements*. Each of the Manufacturing Agreements is a valid and binding obligation of Seller and the counterparties thereto. The Manufacturing Agreements are enforceable against each of the parties thereto in accordance with their respective terms, except as may be limited by applicable Bankruptcy Laws or by general principles of equity (whether considered in a proceeding in equity or at law). The Seller has not received any notice in connection with a Manufacturing Agreement challenging the validity, enforceability or interpretation of any provision of such agreement, which challenge if successful would or would reasonably be expected to materially impact Purchaser's right to receive Scheduled Quarterly Amounts.

(ii) *No Breaches or Defaults*. There is and has been no breach or default under any provision of any Manufacturing Agreement either by Seller or, to the Knowledge of Seller, by the respective counterparty (or any predecessor thereof) thereto, which material breach or default would or would reasonably be expected to materially impact Purchaser's right to receive Scheduled Quarterly Amounts, and there is no event that upon notice or the passage of time, or both, would reasonably be expected to give rise to any breach or default either by Seller or, to the Knowledge of Seller, by the respective counterparty to such agreement, which breach or default would or would reasonably be expected to materially impact Purchaser's right to receive Scheduled Quarterly Amounts.

(iii) *Payments Made*. The Seller has made all payments to the respective counterparty required under each Manufacturing Agreement as of the date hereof, except where such failure to pay would or would reasonably be expected to materially impact Purchaser's right to receive Scheduled Quarterly Amounts.

(iv) *Amendments or Waivers*. The Seller and the respective counterparty thereto have not made or granted any amendment or waiver of any provision of any Manufacturing Agreement, which amendment or waiver would or would reasonably be expected to materially impact Purchaser's a right to receive Scheduled Quarterly Amounts.

(v) *No Indemnification Claims*. The Seller has not notified the respective counterparty to each Manufacturing Agreement or any other Person of any claims for indemnification under any Manufacturing Agreement nor has Seller received any claims for indemnification under any Manufacturing Agreement.

(l) Compliance

(i) Seller is not in violation of, and to the Knowledge of the Seller, the Seller is not under investigation with respect to, nor has the Seller been threatened to be charged with or given notice of any violation of, any law or Judgment applicable to the Seller, which violation would reasonably be expected to adversely affect the Seller's rights in or to any Vascepa Product Rights or Purchaser's rights with respect to Scheduled Quarterly Amounts hereunder.

(ii) Except as would not reasonably be expected to have a Material Adverse Effect, all applications, submissions, information and data related to the Product submitted or utilized as the basis for any request to any Governmental Entity by or on behalf of the Seller were true and correct in all material respects as of the date of such submission or request, and any updates, changes, corrections or modification to such applications, submissions, information or data required under applicable laws or regulations have been submitted or will be submitted in a timely manner to the necessary Governmental Entities.

(iii) Seller has not committed any act, made any statement or failed to make any statement that would reasonably be expected to provide a basis for the FDA or any other Governmental Entity to invoke its policy with respect to "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities", or similar policies, set forth in any applicable laws or regulations, except as would not reasonably be expected to have a Material Adverse Effect.

(m) Intellectual Property

(i) Schedule 3.1(m) lists all of the Patents included within the Vascepa Patent Rights. Except as set forth on Schedule 3.1(m), Seller is the registered owner of all of the Vascepa Patent Rights. Schedule 3.1(m) specifies as to each listed patent or patent application (A) the jurisdictions by or in which each such Vascepa Patent Right has issued as a patent or a patent application has been filed, including the respective patent or application numbers, and

(B) any other Person owning or having an interest in such Vascepa Patent Right, including the nature of such interest.

(ii) The Vascepa Patents Rights are the only Patents that are owned or controlled by Seller, or under which Seller is empowered to grant licenses, the subject matter of which is necessary or useful in the development, manufacture, use, marketing, promotion, sale or distribution of the Product.

(iii) Except as set forth in Schedule 3.1(m), Seller has not received written notice of, and is not a party to, any pending, and to the Knowledge of Seller there are no threatened, litigations, interferences, reexaminations, oppositions or like procedures involving any of the Vascepa Patent Rights.

(iv) All of the issued Patents within the Vascepa Patent Rights are in full force and effect and have not lapsed, expired or otherwise terminated. Seller has not received any written notice relating to the lapse, expiration or other termination of any of the issued patents within the Vascepa Patent Rights, or alleging that, and Seller has not received any written legal opinion that alleges that, an issued patent within any of the Vascepa Patent Rights is invalid or unenforceable.

(v) Seller has not received any written notice that there is any, and, to the Knowledge of Seller, there is no, Person who is or claims to be an inventor under any of the Vascepa Patent Rights who is not a named inventor thereof.

(vi) Seller has not and, to the Knowledge of Seller, no counterparty to an Existing In-License has received any written notice of any claim by any Person challenging inventorship or ownership of, the rights of Seller in and to, or the patentability, validity or enforceability of, any of the Vascepa Patent Rights, or asserting that the development, manufacture, importation, sale, offer for sale or use of the Product infringes or will infringe such Person's patents or other intellectual property rights.

(vii) To the Knowledge of Seller, [***].

(viii) To the Knowledge of Seller, [***].

(ix) Seller or the counterparty to each In-License has paid all maintenance fees, annuities and like payments required as of the date hereof with respect to any of the Vascepa Patent Rights.

(n) No Brokers Fees. Neither Seller nor any of its Affiliates has retained any Person to whom any brokerage commission, finder's fee or other like payment is or will be due in connection with this Agreement or the other Transaction Documents to which Seller is a party or the consummation of the transactions contemplated hereby or thereby.

(o) Subordination. The claims and rights of Purchaser created by any Transaction Document in, to and under the Purchased Receivables are not and shall not, at any time, be subordinated to any creditor of Seller or any other Person or Governmental Authority.

(p) UCC Representations and Warranties. Seller's exact legal name is, and for the shorter of its existence as a company or the immediately preceding ten (10) years has been, " AMARIN PHARMACEUTICALS IRELAND LIMITED" The Seller is, and for the shorter of its existence as a company or the immediately preceding ten (10) years has been, incorporated under the laws of Ireland.

(q) Senior Notes; No Encumbrances. The Senior Notes, and the obligations of each Amarin Party in connection therewith, are not secured by any assets of Seller or any Affiliate of Seller. Each Amarin Party is in material compliance with all of its obligations under the Senior Notes. Without limiting the generality of any of the representations or warranties of the Amarin Parties herein, no Encumbrance exists on the Collateral other than Permitted Encumbrances.

(r) [***]

(s) [***]

3.2 REPRESENTATIONS AND WARRANTIES OF PURCHASER. Purchaser represents and warrants to Seller, as of the Closing Date, as follows:

(a) Organization. Purchaser is a Cayman Islands exempted limited partnership, duly formed and validly existing under the laws of the Cayman Islands.

(b) Authorization. Purchaser has all necessary power, right and authority and all licenses, authorizations, consents and approvals of all Governmental Authorities required to carry on its business as it is presently carried on by Purchaser, to enter into, execute and deliver this Agreement and the other Transaction Documents to which it is a party and to perform all of the covenants, agreements, and obligations to be performed by Purchaser hereunder and under the Transaction Documents to which it is a party. This Agreement and the other Transaction Documents to which it is a party have been duly executed and delivered by Purchaser and each constitutes Purchaser's valid and binding obligation, enforceable against Purchaser in accordance with its respective terms, subject to bankruptcy, insolvency, reorganization or similar laws affecting the rights of creditors generally and to equitable principles.

(c) No Conflicts. Neither the execution and delivery of this Agreement or any other Transaction Documents by Purchaser nor the performance or consummation of this Agreement or any other Transaction Documents to which it is a party or the transactions contemplated hereby or thereby by Purchaser will contravene or conflict with, result in a Breach or violation of, constitute a default or accelerate the performance under (with due notice or lapse of time or both), in any respect, the terms of: (i) to Purchaser's Knowledge, any Applicable Law; (ii) any material contract, agreement, or other arrangement to which Purchaser is a party or by which Purchaser or any of its assets is bound or committed; or (iii) the applicable organizational or constitutional documents of Purchaser.

(d) No Consent. Other than the filing of any documentation contemplated by Sections 4.7 and 4.9, no consent, approval, license, order, authorization, registration, declaration or filing with any Governmental Authority or any other Person is required by Purchaser in connection with the execution and delivery by Purchaser of this Agreement or the other Transaction Documents to which it is a party, the performance by Purchaser of its obligations under this Agreement and any other Transaction Document to which it is a party or the consummation by Purchaser of any of the transactions contemplated hereby or thereby.

(e) No Brokers Fees. Neither Purchaser nor any of its Affiliates has retained any Person to whom any brokerage commission, finder's fee or other like payment is or will be due in connection with this Agreement or the other Transaction Documents to which Purchaser is a party or the consummation of the transactions contemplated hereby or thereby.

3.3 NO GUARANTEES. The Parties acknowledge and agree that (a) Purchaser is assuming all market risk associated with Product and, as such, will have no recourse against Seller or any of Seller's Affiliates based on the failure of the sales of Product to meet its or any other Person's projections, and (b) nothing in this Agreement shall be construed to constitute a guarantee by Seller regarding the commercial viability or economic potential of any Product in the marketplace.

3.4 DISCLAIMER OF WARRANTIES. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT OR ANY OTHER TRANSACTION DOCUMENT, EACH PARTY EXPRESSLY DISCLAIMS, WAIVES, RELEASES, AND RENOUNCES ANY WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY, NONINFRINGEMENT OR FITNESS FOR A PARTICULAR PURPOSE.

ARTICLE 4

COVENANTS OF SELLER; SECURITY INTEREST

The Amarin Parties covenant and agree with Purchaser that for the duration of the Term, such Amarin Party (as applicable) will perform the obligations set forth below:

4.1 SELLER'S RESPONSIBILITIES.

(a) The Amarin Parties will use commercially reasonable efforts to pursue the Funded Activities.

(b) Without limiting the generality of clause (a) above, the Amarin Parties will, each Calendar Quarter, allocate to the promotion and marketing of Product in the Territory, a commercially reasonable level of resources (both monetary and personnel).

(c) The Amarin Parties agree to reasonably fund the expenses associated with the discovery, development and Commercialization of Product, including the Funded Activities.

(d) With respect to each Product, the Amarin Parties will use commercially reasonable efforts to avoid supply channel shortages. The Amarin Parties will use commercially reasonable efforts to expand the supply of Product if necessary to provide Net Sales such that the Scheduled Quarterly Amount for an upcoming calendar quarter, as set forth in Section 2.1(a), would not be expected to exceed [***].

(e) With respect to the performance of this Agreement and the activities contemplated hereby, the Amarin Parties will, and will cause their respective Affiliates to, comply in all material respects with all Applicable Law, except where compliance therewith is contested in good faith by appropriate proceedings.

(f) Seller will, and will cause its Affiliates to, use commercially reasonable efforts to maintain the Regulatory Approvals and all other FDA, FFDCA and other Governmental Authority approvals, including complying will any and all requirements for post-marketing follow-up studies and information reporting.

(g) The Amarin Parties will, and will cause its Affiliates to, use commercially reasonable efforts to maintain its relationships with Third Person manufacturers and suppliers.

(h) Seller will, and will cause its Affiliates to, use commercially reasonable efforts to obtain consents from any licensee or sublicensee of Vascepa Patent Rights necessary to provide Purchaser with copies of royalty reports delivered by such licensee or sublicensee to Seller.

4.2 INTELLECTUAL PROPERTY MATTERS.

(a) Seller shall promptly inform the Purchaser of any suspected infringement by a Third Person of any Vascepa Patent Right. The Seller shall provide to the Purchaser a copy of any written notice of any suspected infringement of any Vascepa Patent Rights delivered or received by the Seller, as well as copies of material correspondence related thereto, as soon as practicable and in any event not more than [***] following such delivery or receipt.

(b) Seller shall promptly inform the Purchaser of any Third Person that, to Seller's Knowledge, is seeking market entry for any generic version of Vascepa, including the filing of an ANDA or a Paragraph IV patent certification by a Third Party. The Seller shall provide to the Purchaser a copy of any written notice of any Third Person seeking market entry for a generic version of Vascepa (including a Paragraph IV Notification) delivered or received by the Seller, as well as copies of material correspondence related thereto, as soon as practicable and in any event not more than [***] following such delivery or receipt.

(c) Prior to initiating, or permitting the initiation of, an Enforcement Action regarding any suspected infringement by a Third Person of any Vascepa Patent Right, the Seller shall provide the Purchaser with [***] of such Enforcement Action.

(d) If the Seller recovers monetary damages from a Third Person in an action brought for such Third Person's infringement of any of the Vascepa Patent Rights, where such damages, whether in the form of judgment or settlement, result from such infringement of such Vascepa Patent Rights, such recovery will be allocated first to the reimbursement of any expenses incurred by the Seller or a Permitted Licensee in such litigation, and any remaining amounts that are not awarded as a multiple of compensatory damages for willful infringement will be treated as Net Sales of the Product. All costs and expenses (including attorneys' fees and expenses) incurred by a party hereto in connection with any Enforcement Action shall be borne by such party.

(e) [***]

4.3 COMMERCIALIZATION OF THE PRODUCT. Seller hereby agrees to use its commercially reasonable efforts to promptly Commercialize the Product and use its commercially reasonable efforts to maximize Net Sales of the Product in a manner that would satisfy payments of the Scheduled Quarterly Amounts.

4.4 RESTRICTIVE COVENANTS. Each Amarin Party will not, nor shall it permit any Affiliate to, without the prior written consent of Purchaser:

(a) incur, create, issue, assume, Guarantee, suffer to exist or otherwise become liable for or with respect to, or become responsible for, the payment or performance of, contingently or otherwise, whether present or future, Indebtedness in an amount greater than the product of (x) [***] and (y) the sum of EBITDA for the [***] immediately preceding such incurrence, creation, issuance, assumption, Guarantee, existence, liability or responsibility, other than Permitted Indebtedness;

(b) declare or pay any cash dividend or make any cash distribution on its capital stock, other than dividends or distributions by Seller to Parent, unless, [***];

(c) amend, restate, supplement or otherwise modify its certificate of incorporation (and any certificate of change of name) or memorandum and articles of association (or other organizational or constitutional documents) in any respect except for such amendments, restatements, supplements or modifications that: (i) do not affect the adversely interests of Purchaser in any material respect under this Agreement or in the Collateral (other than changes to the organizational documents of Parent to remove any limit on Parent's ability to incur Indebtedness contained therein) and (ii) could not reasonably be expected to have a Material Adverse Effect;

(d) create, grant or suffer to exist any Encumbrance on any of the Collateral other than as required under this Agreement and other than Permitted Encumbrances;

(e) [***]; or

(f) commit to do or engage in any of the foregoing (other than any such commitments as are contingent upon repayment in full of the Outstanding Threshold Amount or otherwise obtaining a consent from the Purchaser).

4.5 NOTICES. Seller shall provide Purchaser with a prompt written update (but no later than within [***] following any significant development with respect to the information to be included in (a) a Clinical Update or (b) a Commercial Update and shall provide no later than [***] after the end of each fiscal quarter an Intellectual Property Update; provided that notice hereunder shall be deemed delivered to Purchaser upon Seller's issuance of any press release with respect to such information.

4.6 RELEVANT INFORMATION. In addition to, and not in limitation of, the other provisions of this Agreement, Seller will provide Purchaser with written notice as promptly as practicable (and in any event within [***]) after obtaining Knowledge of any of the following:

(a) the occurrence of a Bankruptcy Event;

(b) any material Breach by either Amarin Party of any covenant, agreement or other provision of this Agreement or any other Transaction Document;

(c) any Event of Default or any event, which after the giving of notice or the passage of time would become an Event of Default or that any representation or warranty made by the Amarin Parties in this Agreement or any other Transaction Document or in any certificate delivered to Purchaser pursuant hereto or thereto that is qualified by materiality shall prove to be untrue, inaccurate or incomplete on the date as of which made, or that any representation or warranty made by Seller in this Agreement or any other Transaction Document that is not qualified by materiality shall prove to be untrue, inaccurate or incomplete in any material respect on the date as of which made; or

(d) any event, occurrence or development that would reasonably be expected, individually or in the aggregate, to result in a Material Adverse Effect.

4.7 TRUE SALE. Purchaser and Seller intend and agree that the sale, conveyance, assignment and transfer of the Purchased Receivables shall constitute a true sale by Seller to Purchaser of the Purchased Receivables that is absolute and irrevocable and that provides Purchaser with the full benefits and detriments of beneficial ownership of the Purchased Receivables, and neither Purchaser nor Seller intends the transactions contemplated hereunder to be a financing transaction, borrowing or a loan from Purchaser to Seller. Each Party further agrees that it will treat the

sale of the Purchased Receivables as a sale of an "account" in accordance with the UCC. Seller disclaims any beneficial ownership interest in the Purchased Receivables upon execution of this Agreement and each of Seller and Purchaser waives any right to contest or otherwise assert that this Agreement is other than a true, absolute and irrevocable sale and assignment by Seller to Purchaser of the Purchased Receivables under Applicable Law, which waiver will be enforceable against the applicable Party in any bankruptcy, insolvency or similar proceeding relating to such Party, except to the extent required by GAAP or the rules of the SEC. Seller authorizes and consents to Purchaser filing, including with the Secretary of State of the State of Delaware, one or more UCC financing statements (and continuation statements with respect to such financing statements when applicable) or other instruments and notices, in such manner and in such jurisdictions as in Purchaser's determination may be necessary or appropriate to evidence the purchase, acquisition and acceptance by Purchaser of the Purchased Receivables hereunder and to perfect and maintain the perfection of Purchaser's ownership in the Purchased Receivables and the security interest in the Purchased Receivables granted by Seller to Purchaser pursuant to Section 4.8; provided, however, that Purchaser will provide Seller with a reasonable opportunity to review any such financing statements (or similar documents) prior to filing. For greater certainty, Purchaser will not file this Agreement in connection with the filing of any such financing statements (or similar documents). For sake of clarification, the foregoing statements in this Section 4.7 shall not bind either party regarding the reporting of the transactions contemplated hereby for GAAP or SEC reporting purposes.

4.8 PRECAUTIONARY SECURITY INTEREST IN PURCHASED RECEIVABLES. Without limiting Section 4.9 and as set forth in Section 4.7, it is the intent and expectation of both Seller and Purchaser that the sale, conveyance, assignment and transfer of the Purchased Receivables be a true, irrevocable and absolute sale by Seller to Purchaser for all purposes. Notwithstanding the foregoing, in an abundance of caution to address the possibility that, notwithstanding that Seller and Purchaser expressly intend and expect for the sale, conveyance, assignment and transfer of the Purchased Receivables hereunder to be a true and absolute sale and assignment for all purposes, in the event that such sale and assignment will be characterized as a loan or other financial accommodation and not a true sale or such sale will for any reason be ineffective or unenforceable as such, as determined in a judicial, administrative or other proceeding (any of the foregoing being a "***Recharacterization***"), then this Agreement will be deemed to constitute a security agreement under the UCC and other Applicable Law. For this purpose and without being in derogation of the intention of Seller and Purchaser that the sale of the Purchased Receivables will constitute a true sale thereof, effective as of the Closing Date, Seller does hereby grant to Purchaser a continuing security interest of first priority in all of Seller's right, title and interest in, to and under the Purchased Receivables, whether now or hereafter existing, and any and all "proceeds" thereof (as such term is defined in the UCC), in each case, for the benefit of Purchaser as security for the prompt and complete payment of a loan deemed to have been made in an amount equal to the Purchase Price together with the performance when due of all of Seller's obligations now or hereafter existing under this Agreement and the other Transaction Documents, which security interest will, upon the filing of a duly prepared financing statement in the appropriate filing office and filing particulars of the security interest in the CRO, be perfected and prior to all other Encumbrances thereon, other than Permitted Encumbrances, to the extent that such security interest in the Collateral can be perfected under the UCC by the filing of financing statement in such filing office or making such other filings. Purchaser will have, in addition to the rights and remedies which it may have under this Agreement, all other rights and remedies provided to a secured creditor after default under the UCC and other Applicable Law, which rights and remedies will be cumulative. Seller hereby authorizes Purchaser, as secured party, to file the UCC financing statements and Form C1 contemplated hereby. In the case of any Recharacterization, each of Seller and Purchaser represents and warrants as to itself that each remittance of payments of the Scheduled Quarterly Amount, in respect of the payments of the Scheduled Quarterly Amount or any other payment owed by Seller to Purchaser under this Agreement, will have been in payment of a debt incurred by Seller in the ordinary course of business or financial affairs of Seller and Purchaser, and made in the ordinary course of business or financial affairs of Seller and Purchaser.

4.9 SECURITY INTEREST IN ADDITIONAL COLLATERAL; REMEDIES.

(a) Seller hereby grants to Purchaser a security interest in all of Seller's right, title and interest in, to and under the Additional Collateral, to secure the prompt and complete payment and performance when due of all obligations of Seller hereunder and under the other Transaction Documents, which security interest will upon:

(i) filing of a duly prepared financing statement in the appropriate filing office (and the filing of the U.S. Patent Security Agreement in the PTO);

(ii) filing of particulars of the security interest in the CRO; and

(iii) filing in the Irish Patents Office, the European Trade Marks and Design Registration Office and the EPO in connection with the European Patents.

be perfected and prior to all other Encumbrances thereon, other than Permitted Encumbrances, to the extent that such security interest in the Collateral can be perfected under the UCC by the filing of a financing statement in such filing office or by making such other filings.

(b) Seller will notify Purchaser in writing [***] to any change in, or amendment or alteration to, (i) its legal name, (ii) its form or type of organizational structure or jurisdiction of organization, or (iii) its Federal Employer Identification Number. Seller agrees not to effect or permit any such change referred to above unless all filings have been made under the UCC or otherwise requested by Purchaser that are required or advisable in order for Purchaser to continue at all times following such change to have a valid, legal and perfected Encumbrance (prior and superior in right and interest to any other Person) in all the Collateral.

(c) Without limiting the generality of Section 9.4(a), Seller will execute any and all further documents, financing statements, agreements and instruments, and take all further action that may be required under Applicable Law, or that Purchaser may reasonably request, in order to grant, create, preserve, enforce, protect and perfect the validity and priority of the security interests and other Encumbrances created by this Agreement in the Collateral. Without limiting the foregoing, Seller will do or cause to be done all acts and things that may be required, or that Purchaser from time to time may reasonably request, to assure and confirm that Purchaser holds duly created and enforceable and perfected Encumbrances upon the Collateral (including any property or assets that are acquired or otherwise become Collateral after the date of this Agreement), in each case, as contemplated by, and with the lien priority required under, this Agreement; provided that (a) Seller shall not be obligated to undertake any filings or other actions with respect to any jurisdictions outside of the United States other than Ireland and the European Patent Office, and (b) no control agreements with respect to any deposit accounts or securities accounts shall be required.

(d) Upon the request of Purchaser at any time after the occurrence and during the continuance of an Event of Default, Seller will permit Purchaser or any advisor, auditor, consultant, attorney or representative acting for Purchaser, upon reasonable notice to Seller and during normal business hours, to make extracts from and copy the books and records of Seller (and its Affiliates, as applicable) relating to the Collateral, and to discuss any matter pertaining to the Collateral with the officers and employees of Seller (and its Affiliates, as applicable).

(e) Seller will not, and will cause its Affiliates not to directly or indirectly, sell, transfer, assign, lease, license, sublicense, convey or otherwise directly or indirectly dispose of any of the Collateral or any interest therein, except as permitted by this Agreement and except for Permitted Encumbrances. This Section 4.9(e) shall in no way limit Purchaser's rights or remedies upon the occurrence of a Change of Control.

(f) Upon the occurrence and during the continuance of an Event of Default, Purchaser will have in any jurisdiction in which enforcement hereof is sought, in addition to all other rights and remedies granted in this Agreement, at law or in equity (including as set forth in Section 4.9(m)) with respect to the Collateral, the rights and remedies of a secured party under the UCC (whether or not in effect in the jurisdiction where such rights are exercised) or other Applicable Law.

(g) Seller agrees that, upon the occurrence and during the continuance of an Event of Default, Purchaser will have the right, subject to Applicable Law and subsection (n) below, to sell or otherwise dispose of all or any part of the Collateral, at public or private sale, for cash, upon credit or for future delivery as Purchaser shall deem appropriate. Each purchaser at any such sale shall hold the property sold absolutely, free from any claim or right on the part of Seller.

(h) Purchaser will give Seller [***] written notice of the time and place of any such proposed sale. Any such notice will (i) in the case of a public sale, state the time and place fixed for such sale, (ii) in the case of a private sale, state the day after which such sale may be consummated, (iii) contain the information specified in Section 9-613 of the UCC, (iv) be authenticated and (v) be sent to the parties required to be notified pursuant to Section 9-611(c) of the UCC; provided that, if Purchaser fails to comply with this sentence in any respect, its liability for such failure shall be limited to the liability (if any) imposed on it as a matter of law under the UCC. Seller agrees that such written notice will satisfy all requirements for notice to Seller that are imposed under the UCC or other Applicable Law with

respect to the exercise of Purchaser's rights and remedies hereunder upon default. Purchaser will not be obligated to make any sale or other disposition of any Collateral if it shall determine not to do so, regardless of the fact that notice of sale or other disposition of such Collateral shall have been given. Purchaser may, without notice or publication, adjourn any public or private sale or cause the same to be adjourned from time to time by announcement at the time and place fixed for sale, and such sale may, without further notice, be made at the time and place to which the same was so adjourned.

(i) Any public sale will be held at such time or times within ordinary business hours and at such place or places as Purchaser may fix and state in the notice of such sale. At any sale or other disposition, the Collateral, or portion thereof, to be sold may be sold in one lot as an entirety or in separate parcels, as Purchaser may (in its sole and absolute discretion) determine. If any of the Collateral is sold, leased, or otherwise disposed of by Purchaser on credit, the obligations secured by the security interests granted herein shall not be deemed to have been reduced as a result thereof unless and until payment in full is received thereon by Purchaser.

(j) At any such public (or, to the extent permitted by Applicable Law, private) sale made pursuant hereto, Purchaser may bid for or purchase, free (to the extent permitted by Applicable Law) from any right of redemption, stay, valuation or appraisal on the part of Seller, the Collateral or any part thereof offered for sale, and Purchaser may make payment on account thereof by using any or all of the obligations secured by the security interests granted herein as a credit against the purchase price, and Purchaser may, upon compliance with the terms of sale, hold, retain and dispose of such property without further accountability to Seller therefor.

(k) As an alternative to exercising the power of sale herein conferred upon it, Purchaser may proceed by a suit or suits at law or in equity to foreclose upon the Collateral and, subject to subsection (n) below, to sell the Collateral or any portion thereof pursuant to a judgment or decree of a court or courts having competent jurisdiction or pursuant to a proceeding by a court-appointed receiver.

(l) To the extent permitted by Applicable Law, Seller hereby waives all rights of demand, redemption, stay, valuation and appraisal that Seller now has or may at any time in the future have under any rule of law or statute now existing or hereafter enacted.

(m) Without limiting the generality of Section 4.9(f), upon the occurrence and during the continuance of an Event of Default, Purchaser may accelerate the Outstanding Threshold Amount, which upon such acceleration, shall become due and payable to Purchaser; provided that upon an Event of Default specified in clause (d) of the definition thereof, automatically and without any notice to Seller, the Outstanding Threshold Amount, will be due and payable to Purchaser (except as set forth in Section 4.9(n) below). Presentment, demand, protest or notice of any kind are hereby expressly waived. Further, if an Event of Default shall occur and be continuing, Purchaser may, subject to any restrictions set forth in this Section 4.9, foreclose or otherwise realize upon the Collateral in such portions or in full as Purchaser sees fit in its sole discretion.

(n) Without limiting the generality of the foregoing, if there is an occurrence and during the continuance of an Event of Default described in subsection (d) of that definition (a Bankruptcy Event), and if there is a sale or other disposition of all or any part of the Collateral by Purchaser pursuant to subsection (g) or subsection (k) above, then, in such case, Purchaser hereby agrees to accept from the proceeds of such a sale or other disposition an amount equal to the Outstanding Threshold Amount.

4.10 IN-LICENSES.

(a) Seller shall act in a commercially reasonable manner with respect to its obligations under each of the In-Licenses. Promptly, and in any event within [***], after receipt of any (written or oral) notice from a counterparty to such In-License or its Affiliates of an alleged breach under any In-License, Seller shall give notice thereof to the Purchaser, including delivering the Purchaser a copy of any such written notice. To the extent commercially reasonable, Seller shall undertake efforts to cure any breaches by it under any In-License and shall give written notice to the Purchaser upon curing any such breach. Promptly, and in
any event within [***] following Seller's notice to a counterparty to any material In-License of an alleged material breach under such In-License, Seller shall give notice thereof to the Purchaser, including delivering the Purchaser a copy of any such written notice.

(b) Seller shall promptly (and in any event within [***]) provide the Purchaser with (i) executed copies of each new material In-License, (ii) executed copies of each material amendment, supplement, modification or waiver of any provision of an In-License and (iii) copies of all material reports, documents, and other materials provided by Seller to the counterparty to each In-License or provided by the counterparty to each In-License to Seller.

(c) Seller shall provide Purchaser with written notice following a counterparty's material breach of its obligations under any material In-License.

(d) Seller shall provide the Purchaser with written notice following the termination of any material In-License.

4.11 MANUFACTURING AGREEMENTS.

(a) Seller shall act in a commercially reasonable manner with respect to its obligations under each of the Manufacturing Agreements. Promptly, and in any event within [***], after receipt of any (written or oral) notice from any of the parties thereto of an alleged breach by Seller under a Manufacturing Agreement, Seller shall give notice thereof to the Purchaser, including delivering the Purchaser a copy of any such written notice. To the extent commercially reasonable, Seller shall undertake efforts to cure any breaches by it under any Manufacturing Agreement and shall give written notice to the Purchaser upon curing any such breach.

(b) Promptly (and in any event within [***]) after Seller becomes aware of, or comes to believe in good faith that there has been, a material breach of any Manufacturing Agreement by the counterparty thereto, Seller shall provide notice of such breach to the Purchaser. In addition, Seller shall provide to the Purchaser a copy of any written notice of material breach or alleged material breach of any material Manufacturing Agreement delivered by Seller to the counterparty thereto as soon as practicable and in any event not less than [***] following such delivery.

(c) Seller shall promptly (and in any event within [***]) provide the Purchaser with (i) executed copies of each new Manufacturing Agreement, and (ii) executed copies of each material amendment, supplement, modification or waiver of any provision of a Manufacturing Agreement.

(d) Seller (i) shall use commercially reasonable efforts to determine [***] forecasted amount of Product and (ii) will notify Purchaser within [***] if it cannot secure agreement from manufacturers to supply a [***] forecasted amount of Product, it being understood that such obligation in clause (ii) is solely an obligation to provide such notice.

(e) Seller shall provide the Purchaser with written notice following the termination of any Manufacturing Agreement.

4.12 OUT-LICENSES.

(a) Subject to Section 4.14 and compliance with this Section 4.12, Seller may license (but not assign or otherwise convey title to, except pursuant to Section 9.3) all or a portion of the Vascepa Product Rights to a Third Person (a "***Permitted Licensee***") to research, develop, manufacture, promote, market, use, sell, offer for sale, import or distribute Product(s) in all or any portion of the Territory without the Purchaser's prior written consent (any such license, a "***Permitted License***").

(b) Seller shall promptly (and in any event within [***]) provide the Purchaser with (i) executed copies of each executed Permitted License, (ii) executed copies of each material amendment, supplement, modification or waiver of any provision of a Permitted License and (iii) copies of all material reports, documents, and other materials provided by Seller to the counterparty to each Permitted License provided or by the counterparty to any Permitted License to Seller.

(c) Any license contemplated by Section 4.12(a) shall [***].

(d) The Seller shall provide the Purchaser with written notice following a counterparty's material breach of its obligations under any Permitted License.

(e) The Seller shall provide the Purchaser with written notice following the termination of any Permitted License.

4.13 SENIOR NOTES.

(a) Seller shall comply in all material respects with its obligations under the Senior Notes and shall not take any action or forego any action that would reasonably be expected to constitute a material breach thereof. Promptly, and in any event within [***], after receipt of any (written or oral) notice from any of the holders of Senior Notes of an alleged breach by Seller under the Senior Notes, Seller shall give notice thereof to the Purchaser, including delivering the Purchaser a copy of any such written notice. The Seller shall use its commercially reasonable efforts to cure any breaches by it under the Senior Notes and shall give written notice to the Purchaser upon curing any such breach.

(b) If Seller fails, or expects to fail, to satisfy any of its obligations under the Senior Notes, including any payment obligations owed to the holders of the Senior Notes, when such obligations are due, Seller shall immediately notify the Purchaser of the specifics regarding such failure or expected failure.

4.14 CHANGE OF CONTROL.

(a) Upon the consummation of a Change of Control on or before December 31, 2013, automatically and without any notice to Seller, an amount equal to, when taken together with the cumulative amount of cash paid by Seller (or its Affiliates, as applicable) and actually received by Purchaser under this Agreement immediately prior to the closing of such occurrence that would constitute a Change of Control, $140,000,000 will be due and payable to Purchaser. Presentment, demand, protest or notice of any kind are hereby expressly waived.

(b) Upon the consummation of a Change of Control after December 31, 2013, automatically and without any notice to Seller, an amount equal to the Outstanding Threshold Amount will be due and payable to Purchaser. Presentment, demand, protest or notice of any kind are hereby expressly waived.

(c) Upon payment of the amount specified in Section 4.14(a) or 4.14(b), as applicable, neither Seller nor any of its Affiliates will have any obligation to pay to Purchaser any additional Scheduled Quarterly Amount pursuant to Section 2.1 and this Agreement shall terminate.

ARTICLE 5

CONFIDENTIALITY

5.1 DEFINITION OF CONFIDENTIAL INFORMATION. For purposes of this Agreement, the term ***"Confidential Information"*** of a Party means any information furnished by or on behalf of such Party to the other Party or its Affiliates pursuant to this Agreement or learned through observation during visit(s) to the other Party's facilities, in each case which information (a) is of the nature that is typically known to be of a confidential nature, or (b) if disclosed in tangible form, is marked "Confidential" or with other similar designation to indicate its confidential or proprietary nature, or (c) if disclosed orally, is indicated orally to be confidential or proprietary at the time of such disclosure. Without limiting the generality of the foregoing, except as provided in the immediately succeeding sentence, all reports and information provided or accessed pursuant to Sections 2.2 or 2.3, and all copies of agreements provided by Seller pursuant to this Agreement, will be deemed the Confidential Information of Seller. Notwithstanding the foregoing, a Party's Confidential Information will not include information that, in each case as demonstrated by written documentation or other competent evidence: (i) was already known to the receiving Party, other than under an obligation of confidentiality, at the time of disclosure; (ii) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party; (iii) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement; (iv) was subsequently lawfully disclosed to the receiving Party by a Third Person having no obligation of which the receiving Party is aware to the disclosing Party or its Affiliates; or (v) is independently developed by the receiving Party without the benefit of Confidential Information of the disclosing Party.

5.2 OBLIGATIONS. Except as authorized in this Agreement or except upon obtaining the other Party's prior written permission to the contrary, each Party agrees that during the Term and for [***] thereafter it will: (a) maintain in confidence, and not disclose to any Person, the other Party's Confidential Information; (b) not use the other Party's Confidential Information for any purpose, except as contemplated in this Agreement; and (c) protect the other

Party's Confidential Information in its possession by using the same degree of care as it uses to protect its own Confidential Information (but no less than a reasonable degree of care).

Notwithstanding anything to the contrary in this Agreement, a Party will be entitled to injunctive relief to restrain the Breach or threatened Breach by the other Party of this Article 5 without having to prove actual Damages or threatened irreparable harm. Such injunctive relief will be in addition to any rights and remedies available to the aggrieved Party at law, in equity, and under this Agreement for such Breach or threatened Breach.

5.3 PERMITTED DISCLOSURES.

(a) Permitted Persons. A Party may disclose the other Party's Confidential Information, without the other Party's prior written permission, to:

(i) its and its Affiliates' members, trustees, managers, directors, employees, partners, agents, consultants, attorneys, accountants, shareholders, investors, banks and other financing sources, and permitted assignees, purchasers, transferees or successors-in-interest under Section 9.3 in each case, who need to know such Confidential Information to provide financing to the Party or to assist the Party in evaluating the transactions contemplated hereby or in fulfilling its obligations or exploiting its rights hereunder (or to determine their interest in providing such financing or assistance) and who are, prior to receiving such disclosure, bound by written or professional confidentiality and non-use obligations no less stringent than those contained herein; or

(ii) permitted assignees, purchasers, transferees, or successors-in-interest (or potential assignees, purchasers, transferees, or successors-in-interest) under Section 9.3 who need to know such Confidential Information in connection with such assignment, sale, or transfer (or potential assignment, sale, or transfer) and who are bound by written or professional confidentiality and non-use obligations no less stringent than those contained herein.

(b) Legally Required. A Party may disclose the other Party's Confidential Information, without the other Party's prior written permission, to any Person to the extent such disclosure is necessary to comply with Applicable Law, applicable stock exchange requirements, or an order or subpoena from a court of competent jurisdiction; provided that the compelled Party, to the extent it may legally do so, will give reasonable advance notice to the other Party of such disclosure and, at such other Party's reasonable request and expense, the compelled Party will use its reasonable efforts to secure confidential treatment of such Confidential Information prior to its disclosure (whether through protective orders or otherwise). Notwithstanding the foregoing, if a Party receives a request from an authorized representative of a Tax authority for a copy of this Agreement, that Party may provide a copy of this Agreement to such Tax authority representative without advance notice to, or the permission or cooperation of, the other Party.

5.4 TERMS OF AGREEMENT. Except to the extent allowed under Section 5.3 or as otherwise permitted in accordance with this Section 5.4, neither Party will make any public announcements concerning this Agreement or the terms hereof, without the prior written consent of the other Party and each Party agrees that it will each treat the contents and terms of this Agreement and the consideration for this Agreement as Confidential Information of the other Party. Consistent with Section 5.3(b), Purchaser and Seller agree to use reasonable efforts to provide the other with a copy of any required SEC or other filing regarding this Agreement or its terms to review prior to filing and to consider any comments of the other Party in good faith, and to the extent either Party has to file or disclose this Agreement with the SEC, such Party will consider in good faith the other Party's comments with respect to confidential treatment of this Agreement's terms and will redact this Agreement in a manner allowed by the SEC to protect sensitive terms, and will be permitted to file this Agreement, as so redacted, with the SEC. For purposes of clarity, each Party is free to discuss with Third Persons the information regarding this Agreement and Parties' relationship disclosed in such SEC filings and any other authorized public announcements.

ARTICLE 6

TERM AND TERMINATION

6.1 TERM OF AGREEMENT; TERMINATION. This Agreement will commence as of the Effective Date and will continue until all of Purchaser's right to receive any payments on account of the Purchased Receivables set forth in this Agreement and all other amounts to which Purchaser may be entitled to receive as payment hereunder have

expired, unless earlier terminated pursuant to the mutual written agreement of the Parties or pursuant to Section 2.1(e) (the ***"Term"***). Upon expiration or earlier termination of the Term, this Agreement shall terminate.

6.2 SURVIVAL. Notwithstanding anything to the contrary in this Article 6, the following provisions shall survive termination of this Agreement: Sections 2.1(g), 2.3, 2.4, 3.3, 3.4, this Section 6.3, Article 5 (Confidentiality), Article 7 (Tax Matters), Article 8 (Parent Guaranty) Article 9 (Miscellaneous) and Annex A (to the extent necessary for the interpretation of any surviving provisions). Termination of this Agreement shall not relieve any Party of liability in respect of breaches of this Agreement by any Party on or prior to termination.

6.3 RELEASE OF LIENS.

(a) The security interests granted hereby and the other Transaction Documents shall be automatically released upon the payment of the Outstanding Threshold Amount or, in connection with a Change of Control, upon the payment of the amounts specified in Section 4.14;

(b) Upon such release or any release of Collateral or any part thereof expressly permitted by and in accordance with the provisions of this Agreement, Purchaser hereby authorizes Seller to file any UCC termination statements and releases necessary to effect such termination, and Purchaser will execute and deliver to Seller any additional documents or instruments as Seller shall reasonably request to evidence such termination.

(c) In the event Purchaser shall foreclose on the Collateral in accordance with Section 4.9, then, Purchaser agrees that it will license the Vascepa Product Rights to any Permitted Licensee on the same terms as set forth in the then existing Permitted License of such Permitted Licensee. Purchaser agrees that it will promptly enter into any agreements and documents with Seller and/or such Permitted Licensee as reasonably requested by Seller to provide for the foregoing.

(d) For the avoidance of doubt, and in no way limiting Seller's obligations to make payments in respect of the Purchased Receivables, the Parties acknowledge and agree that Seller shall have the right to use its cash and other Proceeds in connection with the operation of its business in the ordinary course.

ARTICLE 7

TAX MATTERS

The Parties agree that no deduction or withholding of any Tax is required under any provision of U.S. federal, state or local or foreign law in respect of any payment under this Agreement. If any applicable provision of U.S. federal, state or local or foreign law requires any deduction or withholding of any Tax in respect of any payment under this Agreement, then Seller shall make such deduction or withholding and shall timely pay the full amount to the relevant Governmental Authority in accordance with applicable law, and Seller shall pay an additional amount to Purchaser such that the net after-tax payment to Purchaser is equal to the amount to which Purchaser would have been entitled if no such amount was deducted or withheld. Seller shall indemnify and hold harmless, on an after-tax basis, Purchaser, its direct and indirect partners, employees, agents, representatives and affiliates against (a) any Tax (including interest or penalties on or with respect to such a Tax) imposed on or with respect to, or measured by, any payment under this Agreement, and (ii) any loss (including but not limited to any Tax, interest, penalties, attorneys' fees and accountants' fees) as a result of any claim by any Governmental Authority resulting from the failure or asserted failure of Seller to deduct and withhold any Tax that should have been deducted or withheld from any payment under this Agreement.

ARTICLE 8

PARENT GUARANTY

Parent hereby unconditionally and irrevocably Guarantees, as primary obligor and not merely as surety, the complete and timely performance by Seller of its obligations under this Agreement, including, but not limited to, the complete and timely performance by Seller of its obligation to make payments in respect of the Purchased Receivables pursuant to the terms of this Agreement (the ***"Guaranteed Obligations"***). Parent hereby acknowledges

and agrees that Purchaser may proceed directly against the Parent in the event of nonperformance by Seller, for any reason, of the Guaranteed Obligations. Parent hereby waives any circumstance which might constitute a legal or equitable discharge of a surety or guarantor, including, but not limited to: (a) notice of acceptance of this guaranty; (b) presentment and demand concerning the liabilities of Parent; (c) notice of any dishonor or default by, or disputes with, Purchaser; and (d) any right to require that any action or proceeding be brought against Seller or any other Person, or to require that Purchaser seek enforcement of any performance against Seller or any other Person, prior to any action against Parent under the terms of this Agreement.

ARTICLE 9

MISCELLANEOUS

9.1 ENTIRE AGREEMENT. This Agreement (including the Bill of Sale and this Agreement's other exhibits and schedules) sets forth all the covenants, promises, agreements, warranties, representations, conditions and understandings between and among the Parties and supersedes and terminates all prior agreements and understandings between or among the Parties relating to the subject matter hereof. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as set forth in this Agreement (including the Bill of Sale and this Agreement's other exhibits and schedules).

9.2 AMENDMENTS. This Agreement may be amended or supplemented only by a written agreement signed by an authorized officer of each Party (or, with respect to any Party that is a trust, its trustee).

9.3 BINDING AGREEMENT; SUCCESSORS AND ASSIGNS. The terms, conditions and obligations of this Agreement will inure to the benefit of and be binding upon the Parties hereto and their respective permitted successors and assigns thereof. Neither this Agreement nor any rights or obligations hereunder may be sold, assigned, hypothecated or otherwise transferred in whole or in part by any Party, by operation of law or otherwise, without the prior written consent of the other Party; provided, however, that Seller may consummate a transaction constituting (a) a Change of Control provided that it is conditioned upon the applicable payment described in Section 4.14 being paid to Purchaser, or (b) Permitted License, in either case without prior written consent. Subject to the terms of, and compliance with, Article 5, Purchaser may sell, assign, hypothecate or otherwise transfer all or any part of the Purchased Receivables (i.e., payment amounts and no other rights or obligations) to any one or more Persons upon prior written notice to Seller.

9.4 FURTHER ASSURANCES.

(a) Seller and Purchaser covenant and agree, at any time or from time to time after the Closing Date, to execute and deliver such other documents, certificates, agreements, instruments and other writings and to take such other actions as may be necessary or desirable, or reasonably requested by the other Party, in each case, without further consideration but at the expense of Seller, in order to vest and maintain in Purchaser good and marketable title in, to and under the Purchased Receivables free and clear of any and all Encumbrances (other than Permitted Encumbrances), and to consummate the other transactions contemplated hereby, including the perfection under the applicable UCC (or any comparable law) of all applicable jurisdictions in the United States and Ireland and maintenance of perfection of Purchaser's ownership interest in the Purchased Receivables, the back-up security interest in the Purchased Receivables granted by Seller to Purchaser pursuant to Section 4.8 and the security interest in the Additional Collateral granted by Seller to Purchaser pursuant to Section 4.9. Notwithstanding the foregoing, (a) Seller shall not be obligated to undertake any filings or other actions with respect to any jurisdictions outside of the United States other than the Republic of Ireland, and the European Patent Office, and (b) no control agreements with respect to any deposit accounts or securities accounts shall be required.

(b) During the Term, Purchaser will hold in trust for the benefit of Seller any over-payment of Scheduled Quarterly Amounts received by Purchaser and identified as such in the audit report described in Section 2.3(c) until such funds, if any, are paid to Seller pursuant to Section 2.3(c).

9.5 COUNTERPARTS AND FACSIMILE EXECUTION. This Agreement may be executed in two or more counterparts, each of which will be an original, but all of which together will constitute one and the same instrument. To evidence the fact that it has executed this Agreement, a Party may send a copy of its executed

counterpart to the other Parties by facsimile or other electronic transmission. In such event, such Party will forthwith deliver to the other Parties the counterpart of this Agreement executed by such Party.

9.6 INTERPRETATION. When a reference is made in this Agreement to Articles, Sections or Exhibits, such reference will be to an Article, Section or Exhibit to this Agreement unless otherwise indicated. The words "include," "includes," and "including" when used herein will be deemed in each case to be followed by the words "without limitation" and will not be construed to limit any general statement which it follows to the specific or similar items or matters immediately following it. The headings and captions in this Agreement are for convenience and reference purposes only and will not be considered a part of or affect the construction or interpretation of any provision of this Agreement. Unless specified otherwise, all statements of, or references to, monetary amounts in this Agreement are in U.S. dollars. Provisions that require that a Party or the Parties "agree," "consent," or "approve" or the like will require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise. Words of any gender include the other gender. Neither Party hereto will be or be deemed to be the drafter of this Agreement for the purposes of construing this Agreement against one Party or any other.

9.7 WAIVER. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver will be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. No waiver by any Party of any term or condition of this Agreement, in any one or more instances, will be deemed to be or construed as a waiver of the same or any other term or condition of this Agreement on any future occasion.

9.8 RELATIONSHIP OF THE PARTIES. The Parties acknowledge and agree that the relationship between Purchaser and Seller under this Agreement is intended to be that of buyer and seller, and nothing in this Agreement is intended to be construed so as to suggest that either Purchaser or Seller (except as expressly set forth herein) is obligated to provide, directly or indirectly, any advice, consultations or other services to the other Party. The Parties further acknowledge and agree that Purchaser is purchasing the Purchased Receivables solely in its capacity as an investor. Each Party is an independent contractor relative to the other Party under this Agreement, and this Agreement is not a partnership agreement and nothing in this Agreement will be construed to establish a relationship of co-partners or joint venturers between the Parties. Seller will have no responsibility for the hiring, termination or compensation of Purchaser's employees or for any employee benefits for such employee and Purchaser will have no responsibility for the hiring, termination or compensation of Seller's or any of its Affiliate's employees or for any employee benefits of such employee. No employee or representative of Seller or any of Seller's Affiliates will have any authority to bind or obligate Purchaser and no employee or representative of Purchaser will have any authority to bind or obligate Seller, for any sum or in any manner whatsoever. No employee or representative of Seller or any of Seller's Affiliates will have any authority to create or impose any contractual or other Liability on Purchaser without Purchaser's prior written approval and no employee or representative of Purchaser will have any authority to create or impose any contractual or other Liability on Seller without Seller's prior written approval.

9.9 NOTICES. All notices, consents, waivers, requests and other communications hereunder will be in writing and will be delivered in person, sent by overnight courier (e.g., Federal Express) or sent by confirmed facsimile transmission, to following addresses of the Parties:

If to Purchaser:

c/o Biopharma Secured Debt Fund II Holdings Cayman LP
c/o Walkers Corporate Services Limited
Walker House
87 Mary Street, George Town
Grand Cayman KY1-9005
Cayman Islands

Fax No.: [***]
Tel.No.: [***]
Attention: Pedro Gonzalez de Cosio

with a copy (which will not constitute notice) to:

Pharmakon Advisors LP
110 East 59th Street, #3300
New York, NY 10022
Attention: Pedro Gonzalez de Cosio
Telephone: [***]
Facsimile: [***]

Akin Gump Strauss Hauer& Feld LLP
One Bryant Park
New York, NY 10036-6745
Attention: Geoffrey E. Secol
Telephone: [***]
Facsimile: [***]

If to Seller:

Amarin Pharmaceuticals Ireland Limited
2 Pembroke House
Upper Pembroke Street 28-32
Dublin 2, Ireland
and
Amarin Pharmaceuticals Ireland Limited
Amarin Corporation plcc/o Amarin Pharma, Inc.
1430 Route 206, Suite 200
Bedminster, NJ 07921
Attention: Chief Executive Officer
Fax: [***]
Phone: [***]
with a copy (which will not constitute notice) to each of:

Amarin Corporation
1430 Route 206, Suite 200
Bedminster, NJ 07921
Attention: Joe Kennedy
Fax: [***]
Phone: [***]

Cooley LLP
3175 Hanover St.
Palo Alto, CA 94304
Attention: Glen Sato
Telephone: [***]
Facsimile: [***]

or to such other address or addresses as Purchaser or Seller may from time to time designate by notice as provided herein. Any such notice will be deemed given (a) when actually received when so delivered personally or by overnight courier, (b) if mailed, other than during a period of general discontinuance or disruption of postal service due to strike, lockout or otherwise, on the fifth day after its postmarked date thereof, or (c) if sent by confirmed facsimile transmission, on the date sent if such day is a Business Day or the next following Business Day if such day is not a Business Day.

9.10 GOVERNING LAW; SUBMISSION TO JURISDICTION; WAIVER OF JURY TRIAL.

(a) THIS AGREEMENT AND ANY PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY (WHETHER IN CONTRACT, TORT OR OTHERWISE) WILL BE GOVERNED BY, AND CONSTRUED, INTERPRETED AND ENFORCED IN ACCORDANCE WITH THE INTERNAL SUBSTANTIVE LAWS OF THE STATE OF NEW YORK, WITHOUT GIVING EFFECT TO THE PRINCIPLES OF CONFLICTS OF LAW THEREOF OTHER THAN SECTION 5-1401 OF THE GENERAL OBLIGATIONS LAW OF THE STATE OF NEW YORK, AND THE OBLIGATIONS, RIGHTS AND REMEDIES OF THE PARTIES HEREUNDER WILL BE DETERMINED IN ACCORDANCE WITH SUCH LAWS.

(b) ANY PROCEEDING WITH RESPECT TO THIS AGREEMENT OR ANY OTHER TRANSACTION DOCUMENT WILL BE BROUGHT IN THE COURTS OF THE STATE OF NEW YORK LOCATED IN THE BOROUGH OF MANHATTAN, THE CITY OF NEW YORK OR OF THE UNITED STATES OF AMERICA FOR THE SOUTHERN DISTRICT OF NEW YORK, AND EACH PARTY HEREBY ACCEPTS FOR ITSELF

AND IN RESPECT OF ITS RESPECTIVE PROPERTY, GENERALLY AND UNCONDITIONALLY, THE EXCLUSIVE JURISDICTION OF THE AFORESAID COURTS.

(c) EACH PARTY HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, TRIAL BY JURY IN ANY ACTION OR DISPUTE ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY (WHETHER IN CONTRACT, TORT OR OTHERWISE).

(d) EACH PARTY HEREBY IRREVOCABLY WAIVES ANY OBJECTION, INCLUDING ANY OBJECTION TO THE LAYING OF VENUE OR BASED ON THE GROUNDS OF FORUM NON CONVENIENS, WHICH IT MAY NOW OR HEREAFTER HAVE TO THE BRINGING OF ANY SUCH ACTION OR PROCEEDING IN SUCH RESPECTIVE JURISDICTIONS.

(e) EACH PARTY IRREVOCABLY CONSENTS TO THE SERVICE OF PROCESS OF ANY OF THE AFOREMENTIONED COURTS IN ANY SUCH ACTION OR PROCEEDING BY THE SENDING OF COPIES THEREOF BY FEDERAL EXPRESS OR OTHER OVERNIGHT COURIER COMPANY, TO SUCH PARTY AT ITS ADDRESS SPECIFIED BY SECTION 9.9, SUCH SERVICE TO BECOME EFFECTIVE FOUR DAYS AFTER DELIVERY TO SUCH COURIER COMPANY.

(f) NOTHING HEREIN WILL AFFECT THE RIGHT OF ANY PARTY TO SERVE PROCESS IN ANY OTHER MANNER PERMITTED BY LAW.

9.11 EQUITABLE RELIEF. Each of the Parties hereto acknowledges that each other Party may have no adequate remedy at law if a Party fails to perform any of its obligations under this Agreement in any material respect. In such event, the Parties agree that, in addition to any other rights the Parties may have (whether at law or in equity), in the event of any material Breach or threatened material Breach by any Party of any covenant, obligation or other provision set forth in this Agreement, any non-Breaching Party may be entitled (in addition to any other remedy that may be available to it) to seek (a) a decree or other of specific performance or mandamus to enforce the observance and performance of such covenant, obligation or other provision, and (b) an injunction restraining such material Breach or threatened material Breach.

9.12 NO THIRD-PARTY BENEFICIARIES. All rights, benefits and remedies under this Agreement are solely intended for the benefit of the Parties (including their permitted successors and assigns), and no other Person other than the Parties will have any rights whatsoever to (a) enforce any obligation contained in this Agreement, (b) seek a benefit or remedy for any Breach of this Agreement, or (c) take any other action relating to this Agreement under any legal theory, including but not limited to, actions in contract, tort (including but not limited to negligence, gross negligence and strict liability), or as a defense, set-off or counterclaim to any action or claim brought or made by the Parties (or any of their permitted successors and assigns).

9.13 SEVERABILITY. If any provision hereof should be held invalid, illegal or unenforceable in any jurisdiction, the Parties will negotiate in good faith a valid, legal and enforceable substitute provision that most nearly reflects the original intent of the Parties and all other provisions hereof will remain in full force and effect in such jurisdiction and will be liberally construed in order to carry out the intentions of the Parties as nearly as may be possible. Such invalidity, illegality or unenforceability will not affect the validity, legality or enforceability of such provision in any other jurisdiction. Nothing in this Agreement will be interpreted so as to require a Party to violate any Applicable Law.

9.14 EXPENSES.

(a) Each Party will be responsible for and bear all of its own costs and expenses with regard to the negotiation and execution of this Agreement and the other Transaction Documents by the Parties.

(b) In any Proceeding between the Parties arising out of or involving this Agreement or any other Transaction Document, the prevailing party will be entitled to recover, in addition to any other relief awarded, all expenses it incurs in that Proceeding, including reasonable attorneys' fees and expenses.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement as of the Effective Date.

PURCHASER:

BIOPHARMA SECURED DEBT FUND II HOLDINGS CAYMAN LP

By: Pharmakon Advisors, LP, its investment manager

By: Pharmakon Management I, LLC, its general partner

By: /s/ Pedro Gonzalez de Cosio
Name: Pedro Gonzalez de Cosio
Title: Managing Member

SELLER:

AMARIN PHARMACEUTICALS IRELAND LIMITED

By: /s/ John F. Thero
Name: John F. Thero
Title: Director

PARENT:

AMARIN CORPORATION PLC

By: /s/ Joseph S. Zakrzewski
Name: Joseph S. Zakrzewski
Title: CEO

[Signature Page to Purchase and Sale Agreement]

ANNEX A

DEFINED TERMS

"Additional Collateral" means all of Seller's right, title and interest in, to and under the following property, whether now owned or hereafter acquired, wherever located:

(a) all Vascepa Product Rights and all of Seller's rights and privileges with respect thereto;

(b) all Regulatory Approvals;

(c) all Supporting Obligations (as such term is defined in the UCC) in respect of the foregoing and all collateral security and guarantees given by any Person with respect to any of the foregoing;

(d) all of Seller's books and records relating to any and all of the foregoing; and

(e) all Proceeds (as such term is defined in the UCC) and products of and to any and all of the foregoing.

"Affiliate" means, with respect to an entity, any business entity controlling, controlled by, or under common control with such entity, but only so long as such control exists. For the purposes of this definition, ***"controlling"***, ***"controlled"***, and ***"control"*** mean the possession, directly (or indirectly through one or more intermediary entities), of the power to direct the management or policies of an entity, including through ownership of 50% or more of the voting securities of such entity (or, in the case of an entity that is not a corporation, ownership of 50% or more of the corresponding interest for the election of the entity's managing authority).

"ANCHOR Clinical Indication" means the use of the Product as a treatment for patients with high (≥200 and <500mg/dL) triglyceride levels who are also on statin therapy.

"ANCHOR Clinical Trials" means the clinical trials of the Product intended to support the registration of the Product in the ANCHOR Clinical Indication or any new clinical trials implemented with respect to the ANCHOR Clinical Indication.

"Applicable Law" means, with respect to any Person, all provisions of (a) all constitutions, statutes, laws, rules, regulations, ordinances and orders of Governmental Authorities, (b) any authority, consent, approval, license, permit (or the like) or exemption (or the like) of any Governmental Authority, and (c) any orders, decisions, judgments, writs and decrees issued or entered by any Governmental Authority; in each case, applicable to such Person or any of its properties or assets.

"Bankruptcy Event" means, with respect to either Amarin Party, the occurrence of any of the following:

(a) Such Amarin Party will voluntarily commence any case, proceeding or other action (i) under any existing or future law of any jurisdiction, domestic or foreign, relating to bankruptcy, insolvency, reorganization, relief, examinership of debtors or the like, seeking to have an order for relief entered with respect to it, or seeking to adjudicate it bankrupt or insolvent, or seeking reorganization, arrangement, adjustment, winding-up, liquidation, dissolution, examinership, composition or other relief with respect to it or its debts, or (ii) seeking appointment of a receiver, examiner, trustee, custodian or other similar official for it or for all or any portion of its assets, or Seller will make a general assignment for the benefit of its creditors;

(b) there will be commenced against either Amarin Party any case, proceeding or other action of a nature referred to in clause (a) above that remains undismissed or undischarged for a period of [***] from the commencement thereof; or

(c) there will be commenced against either Amarin Party any case, proceeding or other action seeking issuance of a warrant of attachment, execution, distraint or similar process against all or any substantial portion of its assets, which results in the entry of an order or decree for any such relief that will not have been vacated, discharged, stayed or satisfied pending appeal for [***] from the entry thereof.

"Bankruptcy Laws" means, collectively, bankruptcy, insolvency, reorganization, examinership, moratorium, fraudulent conveyance, fraudulent transfer or other similar laws affecting the enforcement of creditors' rights generally.

"Bill of Sale" means the Bill of Sale attached hereto as **Exhibit A**.

"Breach" of a representation, warranty, covenant, agreement, obligation or other provision will be deemed to have occurred if there is or has been any inaccuracy in or breach of, or any failure to comply with or perform, such representation, warranty, covenant, agreement, obligation or other provision, and ***"Breach"*** will be deemed to refer to any such inaccuracy, breach or failure.

"Business Day" means any day that is not a Saturday, Sunday or other day on which commercial banks in New York City and Dublin are authorized or required by Applicable Law to remain closed.

"Calendar Quarter" means the 3-month period ended March 31, June 30, September 30 or December 31, as applicable.

"Calendar Year" means the 12-month period from January 1 through December 31.

"***Change in Law***" means any change in, or repeal, withdrawal, adoption or issuance of, any statute, law, rule, regulation, ordinance, order, decision, decree, judgment, ruling, policy, notice, interpretation, position or published guidance of any Governmental Authority that Seller or its advisors reasonably believe could affect the actual or potential applicability of, or Seller's actual or potential liability for, any withholding Tax with respect to payments to Purchaser hereunder.

"Change of Control" means:

(a) the acquisition at any time by a "person" or "group" (as such terms are used in Sections 13(d) and 14(d)(2) of the Securities Exchange Act of 1934, as in effect on the Effective Date (the ***"Exchange Act"***)) who or which are the beneficial owners (as defined in Rule 13(d)-3 under the Exchange Act), directly or indirectly, of securities representing more than 50% of the combined voting power in the election of directors of the then outstanding securities of Seller or Parent or any successor of Seller or Parent;

(b) consummation of any assignment, sale or disposition of all or substantially all of the assets of Seller or Parent (other than any such assignment, sale or disposition by Parent to any of its subsidiaries) or all or substantially all of the Product that is not a license agreement pursuant to subsection (e) below;

(c) consummation of any merger, consolidation, or statutory share exchange to which Seller or Parent is a party, as a result of which the Persons who were stockholders immediately prior to the effective date of the merger, consolidation or share exchange shall have beneficial ownership of less than 50% of the combined voting power in the election of directors of the surviving corporation;

(d) consummation by Seller or Parent of any sale or disposition, directly or indirectly, of any of the Collateral or any interest therein to any Third Person, including by operation of law or otherwise, except as permitted under this Agreement; or

(e) the grant by Seller or Parent or any of its Affiliates at any time during the Payment Period to a Third Person of a license to market, offer for sale and sell Product in the U.S. if, and only if, at the time entry into such license Purchaser has not been paid [***].

Notwithstanding anything to the foregoing, a "Change of Control" shall not include (and nothing herein shall prohibit) a merger or other transaction solely involving Parent and its Affiliates for the purposes of changing the jurisdiction of organization or taxation of the Parent.

"***Clinical Indications***" means collectively, the ANCHOR Clinical Indication and the MARINE Clinical Indication

"***Clinical Trials***" means collectively, the ANCHOR Clinical Trials and the MARINE Clinical Trials. For clarity, the REDUCE-IT clinical studies and any other clinical trial or investigation of the Product conducted by or on behalf of Seller during the Payment Period shall not be deemed "Clinical Trials".

"***Clinical Updates***" means material information and developments with respect to each Clinical Trial, including, without limitation, any regulatory submissions made to, and correspondence received from, the FDA, or corresponding Governmental Entity in a foreign country, with respect to the number of patient deaths that have occurred in such Clinical Trial, including any patient deaths attributed to a Product, and requests to the FDA, or corresponding Governmental Authority in a foreign country, for any Regulatory Approval.

"Closing" has the meaning set forth in Section 1.4.

"Closing Date" has the meaning set forth in Section 1.4.

"Collateral" means the Additional Collateral and, in the event of a Recharacterization, the Additional Collateral plus the Purchased Receivables.

"***Combination Product***" means any Product that includes at least one additional active ingredient other than icosapent ethyl or another omega-3 fatty acid. Drug delivery vehicles, adjuvants, and excipients shall not be deemed to be "active ingredients", except in the case where such delivery vehicle, adjuvant, or excipient is recognized as an active ingredient in accordance with applicable FDA regulations.

"***Commercial Updates***" means material information and developments with respect to the Seller's Commercialization plans and prospects for the Product, including, without limitation, a summary of significant marketing activities with respect to the Product; a summary of any material supply chain and manufacturing matters; and information with respect to any Marketing Approvals obtained for such Product.

"***Commercialization***" means any and all activities directed to the manufacture, distribution, marketing, detailing, promotion, selling and securing of reimbursement of any product after Marketing Approval has been obtained (including without limitation making, using, importing, selling and offering for sale any product), and shall include post-Marketing Approval studies, post-launch marketing, promoting, detailing, marketing research, distributing, customer service, selling a product, importing, exporting or transporting a product for sale, and regulatory compliance with respect to the foregoing. When used as a verb, "Commercialize" shall mean to engage in Commercialization.

"Confidential Information" has the meaning set forth in Section 5.1.

"CRO" means the Irish Companies Registration Office.

"Damages" means any loss, damage, Liability, claim, demand, settlement amount, judgment, award, fine, penalty, Tax, fee (including any reasonable legal fee, expert fee, accounting fee or advisory fee), charge, cost (including any reasonable cost of investigation and court cost) or expense of any nature.

"EBITDA" means, for such period determined on a consolidated basis in accordance with GAAP, net profit or loss plus (without duplication and to the extent deducted in determining net profit or loss) (a) interest expense net of interest income, (b) provision for income taxes and (c) depreciation, amortization and stock-based compensation and other similar non-cash expenses; provided that, to the extent included in EBITDA and without duplication, the following shall be excluded: (i) extraordinary gains and losses and unusual or non-recurring income or charges, (ii) currency translation gains and losses related to currency remeasurements of Indebtedness and (iii) fair value non-cash gains or losses of swaps, derivatives or similar arrangements.

"Effective Date" has the meaning set forth in the Preamble.

"EMEA" means the European Medicines Agency or any successor agency thereto.

"Encumbrance" means any lien, charge, security interest, mortgage, option, pledge, assignment or any other encumbrance of any Person of any kind whatsoever.

"Enforcement Action" means any Proceeding brought, or assertion made, by Seller (whether as plaintiff or by means of counterclaim) against any Third Person relating to arising out of any infringement, misuse or misappropriation by such Third Person of any Vascepa Patent Rights.

"EPO" means the European Patent Office.

"European Patents" means those Patents with a description of "Europe" under the heading "Jurisdiction" on Schedule 3.1(m).

"Event of Default" means each of the following events or occurrences:

(a) failure of Seller to deliver or cause to be delivered to Purchaser any Scheduled Quarterly Amount or Quarterly Cap, as applicable, when and as such payment is due and payable in accordance with the terms of this Agreement and such failure is not cured within 30 days after written notice thereof is given to Seller by Purchaser;

(b) failure of Seller to deliver any of the deliverables to Purchaser in accordance with Section 2.2 and such failure is not cured within [***] after written notice thereof is given to Seller by Purchaser;

(c) Breach of the covenants in Section 4.4(a) (or, solely as it relates thereto, Section 4.4(e)) and such Breach is not cured within [***] of the occurrence of such Breach;

(d) An Amarin Party becomes subject to a Bankruptcy Event; and

(e) Purchaser shall fail to have a first-priority perfected security interest (subject to Permitted Encumbrances) under the UCC (or any comparable law) of all applicable jurisdictions in the United States and Ireland in any of the Additional Collateral to the extent required under the Transaction Documents and such first-priority perfected security interest is not restored within [***] after written notice thereof is given to Seller by Purchaser.

"Existing In-License" has the meaning set forth in Section 3.1(i).

"FDA" means the United States Food and Drug Administration and any successor entity thereto.

"***FFDCA***" means the Federal Food, Drug, and Cosmetic Act.

"Funded Activities" means any and all activities, efforts and services performed in furtherance of the research, discovery, development, commercialization and exploitation of Product, including the purchase of materials, general and administrative expenses, corporate infrastructure and corporate overhead.

"GAAP" means United States generally accepted accounting principles, consistently applied throughout Seller's organization.

"Governmental Authority" means the government of the United States, any other nation or any political subdivision thereof, whether state or local, and any agency, authority (including supranational authority), instrumentality, regulatory body, court, central bank or other Person exercising executive, legislative, judicial, taxing, regulatory or administrative powers or functions of or pertaining to government.

"Guaranty" of any Person means any obligation, contingent or otherwise, of such Person (a) to pay any Indebtedness of any other Person or to otherwise protect, or having the practical effect of protecting, the holder of any such Indebtedness against loss (whether such obligation arises by virtue of such Person being a partner of a partnership or participant in a joint venture or by agreement to pay, to keep well, to purchase assets, goods, securities or services or to take or pay, or otherwise) or (b) incurred in connection with the issuance by a Third Person of a Guaranty of any Indebtedness of any other Person (whether such obligation arises by agreement to reimburse or indemnify such Third Person or otherwise). The word ***"Guarantee"*** when used as a verb has the correlative meaning.

"Guaranteed Obligations" has the meaning set forth in Article 8.

"***Improvements***" means any improvement, invention or discovery relating to the composition, manufacture, use or sale of a Product, an active ingredient therein, the formulation of such Product, or a derivative of any of the foregoing

"Indebtedness" of any Person means (a) any obligation of such Person for borrowed money, (b) any obligation of such Person evidenced by a bond, debenture, note or other similar instrument, (c) any obligation of such Person to pay the deferred purchase price of property or services (except (i) trade account payable that arise in the ordinary course of business, (ii) payroll liabilities and deferred compensation, and (iii) any purchase price adjustment,

royalty, earnout, milestone, contingent or deferred payment obligations, in each case pursuant to this subsection (iii) incurred in connection with an acquisition or In-License), (d) any obligation of such Person as lessee under a capital lease (under GAAP as in effect on the date hereof), (e) any Mandatorily Redeemable Stock of such Person, (f) any obligation of such Person to purchase securities or other property that arises out of or in connection with the sale of the same or substantially similar securities or property, (g) any non-contingent obligation of such Person to reimburse any other Person in respect of amounts paid under a letter of credit or other Guaranty issued by such other Person, (h) any Indebtedness of others secured by an Encumbrance on any asset of such Person and (i) any Indebtedness of others Guaranteed by such Person; provided that intercompany loans among the Amarin Parties and their Affiliates shall not constitute Indebtedness.

"In-License" means any license or other agreement between Seller or any of its Affiliates and any Third Person pursuant to which Seller or any of its Affiliates obtains a license, a right, a covenant not to sue or similar grant of rights, or an option to obtain any such grants of rights, to any Vascepa Product Right that is or was necessary or useful for the research, development, use or Commercialization of the Product. For clarity, Manufacturing Agreements shall not be deemed "In-Licenses".

"Intellectual Property Charge Agreements" means the Irish Intellectual Property Charge Agreement and the US Patent Security Agreement.

"***Intellectual Property Updates***" means any new Patents issued or patent applications filed, amended or supplemented, relating to the Product in a Major Country, any final rejections or abandonments with respect to any of the Vascepa Patent Rights, any third party submissions, requests for reexamination, or oppositions filed, and any other material information or developments with respect to the Vascepa Product Rights.

"Irish Intellectual Property Charge Agreement" means the Irish law Intellectual Property Charge Agreement to be agreed by the Parties.

"***Judgment***" means any judgment, order, writ, injunction, citation, award or decree of any nature.

"Knowledge" means [***].

"Liability" of any Person means (in each case, whether with full or limited recourse) any indebtedness, liability, obligation, covenant or duty of or binding upon, or any term or condition to be observed by or binding upon, such Person or any of its assets, of any kind, nature or description, direct or indirect, absolute or contingent, due or not due, contractual or tortious, liquidated or unliquidated, whether arising under contract, Applicable Law, or otherwise, whether now existing or hereafter arising, and whether for the payment of money or the performance or non-performance of any act.

"***Major Country***" means any of [***]

"Mandatorily Redeemable Stock" means, with respect to any Person, any share of such Person's capital stock to the extent that it is (a) redeemable, payable or required to be purchased or otherwise retired or extinguished, or convertible into any Indebtedness or other Liability of such Person, (i) at a fixed or determinable date, whether by operation of a sinking fund or otherwise, (ii) at the option of any Person other than such Person or (iii) upon the occurrence of a condition not solely within the control of such Person, such as a redemption required to be made out of future earnings or (b) convertible into shares of such Person's capital stock described in subsection (a) above.

"*Manufacturing Agreements*" has the meaning set forth in Section 3.1(k).

"***Marketing Approval***" means the approval of an NDA by the FDA necessary for the Commercialization of a pharmaceutical product in the United States (or, in a country other than the United States, the equivalent necessary approval(s) by applicable Governmental Entities for Commercialization of a pharmaceutical product in such country).

"*Material Adverse Effect*" means a material adverse effect on: (a) the validity or enforceability of any of the Transaction Documents; (b) the back-up security interest granted pursuant to Section 4.8; (c) the security interest granted pursuant to Section 4.9; (d) the right or ability of each Amarin Party to grant any of the rights or perform any of its material obligations under any of the Transaction Documents or to consummate any of the transactions

contemplated thereby; (e) the rights and remedies of Purchaser under any of the Transaction Documents; (f) the right of Purchaser to receive a Scheduled Quarterly Amount payment or the timing, amount or duration of such payment of Scheduled Quarterly Amount; (g) the Purchased Receivables or any of Purchaser's right, title and interest therein, thereto and thereunder pursuant to this Agreement; or (h) Seller's title to or control of, or the validity or enforceability of, any of the Vascepa Product Rights.

"***NDA***" means a new drug application (as such term is used under the FFDCA), or other applicable pharmaceutical approval submission to the FDA for Marketing Approval (or, in a country other than the U.S., the equivalent necessary submissions to the applicable Governmental Entity for Marketing Approval).

"***Net Sales***" means [***]

"Outstanding Threshold Amount" means an amount equal to, when taken together with the cumulative amount of cash paid by Seller (or its Affiliates, as applicable) and actually received by Purchaser under this Agreement prior to such occurrence, the Threshold Amount.

"Party" or ***"Parties"*** has the meaning set forth in the Preamble

"Patents" means all patents and patent applications existing as of the Effective Date and all patent applications filed or patents issued hereafter, including any continuation, continuation-in-part, division, provisional or any substitute applications, any patent issued with respect to any of the foregoing patent applications, any reissue, reexamination, renewal or patent term extension or adjustment (including any supplementary protection certificate) of any such patent, and any confirmation patent or registration patent or patent of addition based on any such patent, and all foreign counterparts of any of the foregoing.

"Payment Period" means the period of time commencing on October 1, 2013 and ending on the Threshold Date.

"Permitted Encumbrances" means:

(a) Encumbrances created in favor of Purchaser pursuant to this Agreement;

(b) inchoate Encumbrances for Taxes not yet delinquent or Encumbrances for Taxes which are being contested in good faith and by appropriate proceedings and for which adequate reserves have been established in accordance with GAAP;

(c) Encumbrances in respect of property of Seller imposed by Applicable Law which were incurred in the ordinary course of business and do not secure Indebtedness for borrowed money, such as carriers', warehousemen's, distributors', wholesalers', materialmen's and mechanics' liens and other similar Encumbrances arising in the ordinary course of business and which do not in the aggregate materially detract from the value of the property of Seller and do not materially impair the use thereof in the operation of the business of Seller;

(d) Encumbrances (i) imposed by Applicable Law or deposits made in connection therewith in the ordinary course of business in connection with workers' compensation, unemployment insurance and other types of social security legislation, (ii) incurred in the ordinary course of business to secure the performance of tenders, statutory obligations (other than excise Taxes), surety, stay, customs and appeal bonds, statutory bonds, bids, leases, government contracts, trade contracts, performance and return of money bonds and other similar obligations (exclusive of obligations for the payment of borrowed money) or (iii) arising by virtue of deposits made in the ordinary course of business to secure liability for premiums to insurance carriers imposed by Applicable Law or deposits made in connection therewith in the ordinary course of business in connection with workers' compensation, unemployment insurance and other types of social security legislation; provided, however, that, in the case of each of subclauses (i), (ii) and (iii) of this clause (d), (A) such Encumbrances are for amounts not yet due and payable or delinquent or, to the extent such amounts are so due and payable, such amounts are being contested in good faith and by appropriate proceedings and such contest is effective under Applicable Law to stay any attempt by the holder of such Encumbrance to realize thereon and for which adequate reserves have been established in accordance with GAAP; and (ii) to the extent such Encumbrances are not imposed by Applicable Law, such Liens shall in no event encumber any property other than cash and cash equivalents; and

(e) Encumbrances, consisting of the rights of licensors or licensees, existing on the date of this Agreement or granted or created in the ordinary course of business after the date of this Agreement, in each such case pursuant to an In-License or a Permitted License.

(f) banker's liens, rights of set-off or similar rights and remedies as to deposit accounts or other funds maintained with depository institutions; provided that such deposit accounts or funds are not established or deposited for the purpose of providing collateral for any Indebtedness and are not subject to restrictions on access by Seller in excess of those required by applicable banking regulations;

(g) Encumbrances arising by virtue of UCC financing statement filings (or similar filings under applicable law) regarding operating leases entered into by the Borrower and the Subsidiaries in the ordinary course of business;

(h) Encumbrances solely on any cash earnest money deposits, escrow arrangements or similar arrangements made by any Amarin Party in connection with any letter of intent or purchase agreement for any merger, consolidation, acquisition or other transaction permitted hereunder; and

(i) Deposits or other cash used to collateralize any Permitted Indebtedness or Permitted Encumbrance under clauses (a) – (g) of this definition of Permitted Encumbrance, and any other cash deposits in the ordinary course of business.

"***Permitted Indebtedness***" means:

(a) Indebtedness in respect of capital leases or otherwise incurred to acquire equipment and capital assets;

(b) Indebtedness with respect to surety and performance bonds and similar obligations arising in the ordinary course of business;

(c) Indebtedness consisting of the endorsement of negotiable instruments for deposit or collection or similar transactions in the ordinary course of business consistent with past practice;

(d) Indebtedness consisting of intercompany journal entries made in connection with cost sharing or transfer pricing transactions, provided that all such transactions are cashless;

(e) Indebtedness incurred in connection with Seller's corporate credit cards issued by companies or financial institutions in the ordinary course of business;

(f) Indebtedness in respect of letters of credit, bank guarantees and similar instruments issued for the account of any Amarin Party in the ordinary course of business supporting obligations under (A) workers' compensation, unemployment insurance and other social security laws and (B) bids, trade contracts, leases, statutory obligations, surety and appeal bonds, performance bonds and obligations of a like nature;

(g) Indebtedness consisting of the financing of insurance premiums in the ordinary course of business;

(h) customer advances or deposits received in the ordinary course of business;

(i) Indebtedness in respect of netting services, overdraft protections, payment processing, automatic clearinghouse arrangements, arrangements in respect of pooled deposit or sweep accounts, check endorsement guarantees, and otherwise in connection with deposit accounts or cash management services;

(j) the Senior Notes;

(k) inventory or receivable financing in a principal amount not to exceed [***];

(l) (i) up to [***], including the Senior Notes, in unsecured Indebtedness with a maturity date after [***] and not redeemable at the option of the holder before [***] (other than customary offers to repurchase such Indebtedness upon a change of control or "fundamental change" and other than settlement upon conversion of convertible Indebtedness), which shall not be issued or guaranteed by Seller (the ***"Initial Unsecured Debt"***); and

(ii) additional unsecured Indebtedness with a maturity date after [***] and not redeemable at the option of the holder before [***] (other than customary offers to repurchase such Indebtedness upon a change of control or "fundamental change" and other than settlement upon conversion of convertible Indebtedness), which shall not be issued or guaranteed by Seller (the ***"Incremental Unsecured Debt"***); provided that the Incremental Unsecured Debt shall not exceed [***];

(m) Royalty financings, provided that (i) the royalties sold or so financed shall not exceed [***], (ii) no scheduled interest or principal payments shall be made pursuant to such financings unless the Company has, at the time of such payments, paid all then due and payable Scheduled Quarterly Amounts and (iii) the Amarin Parties shall have provided Purchaser at least [***] prior written notice of the consummation of any such financing;

(n) Indebtedness incurred to finance acquisitions (including Indebtedness acquired in connection with any acquisition) or to finance the purchase, construction or other acquisition of manufacturing capacity provided that Purchaser shall have consent to the incurrence (or acquisition) of such Indebtedness, which consent is not to be reasonably withheld or delayed (it being agreed that Purchaser may take into account its economic interest in receiving Scheduled Quarterly Amounts in providing or refusing to provide any such consent); and

(o) Extensions, refinancings and renewals of any items of Permitted Indebtedness, provided that the principal amount is not increased or the terms modified to impose more burdensome terms upon such Amarin Party, as the case may be.

"Permitted License" has the meaning set forth in Section 4.12(a).

"Permitted Licensee" has the meaning set forth in Section 4.12(a).

"Person" means any natural person, firm, corporation, limited liability company, partnership, joint venture, association, joint-stock company, trust, unincorporated organization, Governmental Authority or any other legal entity, including public bodies, whether acting in an individual, fiduciary or other capacity.

"Pharmakon" has the meaning set forth in Section 1.6.

"Proceeding" means any action, suit, claim, litigation, arbitration, mediation, proceeding (including any civil, criminal, administrative, investigative or appellate proceeding and any informal proceeding), prosecution, contest, hearing, inquiry, inquest, audit, examination or investigation commenced, brought, conducted or heard by or before, or otherwise involving, any Governmental Authority, any arbitrator or arbitration panel or any mediator.

"Product" means icosapent ethyl (including icosapent ethyl currently marketed as VASCEPA®) and any derivative or Improvement thereof and any formulation comprising icosapent ethyl as the primary active ingredient. [***]

"PTO" means the United States Patent and Trademark Office.

"Purchase Price" has the meaning set forth in Section 1.2(a).

"Purchased Receivables" means (a) each payment of Scheduled Quarterly Amounts and (b) any Scheduled Quarterly Amount underpayments or other monetary recoveries resulting from an audit of Seller pursuant to Section 2.3 and (c) any interest on any amounts referred to in clauses (a) and (b) above payable by Seller to Purchaser pursuant to Section 2.4; in the case of clauses (a), and (b) above, irrespective of any amounts which may be payable by Seller or any of its Affiliates to Third Persons.

"Purchaser" has the meaning set forth in the Preamble.

"Quarterly Cap" has the meaning set forth in Section 2.1(b).

"Quarterly Cap Event Quarter" has the meaning set forth in Section 2.1(b).

"Quarterly Reports" has the meaning set forth in Section 2.2(a).

"Recharacterization" has the meaning set forth in Section 4.8.

"Regulatory Approvals" means the New Drug Application, Abbreviated New Drug Application, Biologics License Application, or similar application which is required to be filed by Seller with the appropriate Governmental Authority (e.g., the FDA in the United States; the EMEA in Europe) to obtain approval to market a Product in the relevant jurisdiction and issued (or to be issued) in the name of Seller (or its Affiliates), and any amendments or supplements thereto.

"Resource Allocation Statement" has the meaning set forth in Section 2.2(c).

"SEC" means the U.S. Securities and Exchange Commission and any successor entity thereto.

"Seller" has the meaning set forth in the Preamble.

"***Senior Notes***" means $150,000,000 principal amount 3.50% exchangeable senior notes due in 2032 issued by Corsicanto Limited, an Affiliate of Seller.

"***SNDA***" means a Supplemental New Drug Application filed with the FDA or the equivalent application filed with any equivalent agency or governmental authority outside the United States (including any supra-national agency such as in the European Union) requiring such filing.

"Tax" means any present or future tax, levy, impost, duty, assessment, charge, fee, deduction or withholding of any nature and whatever called (including interest and penalties thereon and any additions thereto) by any Governmental Authority, on whomsoever and wherever imposed, levied, collected, withheld or assessed.

The ***"Term"*** of this Agreement will be as set forth in Section 6.1.

"Termination Date" has the meaning set forth in Section 2.1(e).

"Territory" means worldwide.

"Third Person" means any Person other than the Parties or their respective Affiliates.

"Threshold Amount" equals $150,000,000.

"***Threshold Date***" means the date on which Purchaser has actually received an aggregate amount of payments on account of the Scheduled Quarterly Payments equal to the Threshold Amount.

"Transaction Documents" means, collectively, this Agreement, the Intellectual Property Charge Agreements, the Bill of Sale, and any document, certificate or other instrument delivered in connection therewith.

"UCC" means the Uniform Commercial Code as in effect from time to time in the State of New York; provided, however, that, if, with respect to any financing statement or by reason of any provisions of law, the perfection or the effect of perfection or non-perfection of Purchaser's ownership interest in the Purchased Receivables, the back-up security interest granted pursuant to Section 4.8, or the security interest granted pursuant to Section 4.9 is governed by the Uniform Commercial Code as in effect in a jurisdiction of the United States other than the State of New York, then ***"UCC"*** shall mean the Uniform Commercial Code as in effect from time to time in such other jurisdiction for purposes of the provisions of this Agreement and any financing statement relating to such perfection or effect of perfection or non-perfection.

"U.S." or ***"United States"*** means the United States of America, its 50 states, each territory thereof and the District of Columbia.

"U.S. Patent Security Agreement" means the U.S. law Patent Security Agreement attached hereto as **Exhibit C.**

"Unaudited Financial Statements" has the meaning set forth in Section 2.2(b).

"Vascepa Patent Rights" means (i) the Patents and patent applications listed in Schedule 3.1(m) (including any PCT and/or U.S. utility application claiming priority to such provisional application(s) that are filed on or before the one year conversion date of such application(s)); (ii) any patent or patent application that claims priority to, and is a divisional, continuation, reissue, renewal, reexamination, substitution or extension of, any patent application

identified in (i); (iii) any patents issuing on any patent application identified in (i) or (ii), including any reissues, renewals, reexaminations, substitutions or extensions thereof; (iv) any claim of a divisional, continuation or continuation-in-part application or patent (including any reissues, renewals, reexaminations, substitutions or extensions thereof) that is entitled to the priority date of, and is directed specifically to subject matter specifically described in, at least one of the patents or patent applications identified in (i), (ii) or (iii); (v) any foreign counterpart (including PCTs) of any patent or patent application identified in (i), (ii) or (iii) or of the claims identified in (iv); and (vi) any supplementary protection certificates or similar patent term extensions of any patents and patent applications identified in (i) through (v).

"Vascepa Product Rights" means any and all of the following, as they exist throughout the world: (A) Vascepa Patent Rights; (B) rights in registered and unregistered trademarks, service marks, trade names, trade dress, logos, packaging design, slogans and Internet domain names, and registrations and applications for registration of any of the foregoing, in each case, as related to a Product; (C) copyrights in both published and unpublished works, including without limitation all compilations, databases and computer programs, manuals and other documentation and all copyright registrations and applications, and all derivatives, translations, adaptations and combinations of the above, in each case, as related to a Product; (D) rights in know-how, trade secrets, confidential or proprietary information, research in progress, algorithms, data, databases, data collections, designs, processes, procedures, methods, protocols, materials, formulae, drawings, schematics, blueprints, flow charts, models, strategies, prototypes, techniques, and the results of experimentation and testing, including samples, in each case, as specifically related to a Product; (E) any and all other intellectual property rights and/or proprietary rights specifically relating to any of the foregoing; (F) claims of infringement and misappropriation against Third Parties relating to a Product; and (G) regulatory filings, submissions and approvals related to a Product, including, but not limited to, Vascepa New Drug Application No. N202057 and any supplemental New Drug Application relating thereto, and all data provided in any of the foregoing.

EXHIBIT A

BILL OF SALE

THIS BILL OF SALE (this ***"Purchaser Bill of Sale"***) is made, entered into and effective this day of , 2012, by and between **AMARIN PHARMACEUTICALS IRELAND LIMITED**, a company incorporated under the laws of Ireland (registered number 408912) having its registered office at 88 Harcourt Street, Dublin 2, and its permitted successors and assigns (***"Seller"***) and **BIOPHARMA SECURED DEBT FUND II HOLDINGS CAYMAN LP**, a Cayman Islands exempted limited partnership, and its permitted successors and assigns (***"Purchaser"***). Capitalized terms used but not defined herein will have the meanings ascribed to such terms in that certain Purchase and Sale Agreement, dated as of December [__], 2012, by and between Seller, Purchaser and Amarin Corporation PLC, a public limited company incorporated under the laws of England and Wales (the ***"Purchase Agreement"***).

RECITALS

WHEREAS, Seller desires to sell, transfer, convey and assign to Purchaser, and Purchaser desires to purchase and accept from Seller, all of Seller's right, title and interest in, to and under the Purchased Receivables, on the terms and conditions set forth in the Purchase Agreement.

NOW, THEREFORE, in consideration of the premises and the mutual agreements contained herein and other good and valuable considerations, the receipt and adequacy of which are hereby acknowledged, the Parties hereto agree as follows:

1. Seller, by this Purchaser Bill of Sale, does hereby sell, transfer, convey, assign and deliver to Purchaser, and Purchaser does hereby purchase and accept, all of Seller's right, title and interest in, to and under the Purchased Receivables.

2. Seller hereby covenants that, at any time or from time to time after the date hereof, at Purchaser's reasonable request and without further consideration but at Purchaser's expense, Seller will execute and deliver to Purchaser such other instruments of sale, transfer, conveyance and assignment as Purchaser may reasonably deem necessary to sell, transfer, convey, assign and deliver to Purchaser, and to confirm Purchaser's title to, all of Seller's right, title and interest in, to and under the Purchased Receivables.

3. Seller represents, warrants and covenants that (a) it has absolute title to the Purchased Receivables free and clear of all Encumbrances (other than Permitted Encumbrances), (b) it has not made any prior sale, transfer, conveyance, assignment, grant or delivery of any Purchased Receivables, (c) it has the present lawful right, power and authority to sell, transfer, convey, assign and deliver the Purchased Receivables to Purchaser free and clear of all Encumbrances (other than Permitted Encumbrances), and (d) all action has been taken which is required for Seller to make this Purchaser Bill of Sale, and this Purchaser Bill of Sale is, a legal, valid and binding obligation of Seller.

4. This Purchaser Bill of Sale will be binding upon and inure to the benefit of Seller, Purchaser and their respective permitted successors and assigns under the Purchase Agreement, for the uses and purposes set forth and referred to above, effective immediately upon its delivery to Purchaser.

5. (a) THIS PURCHASER BILL OF SALE AND ANY PROCEEDING ARISING OUT OF OR RELATING TO THIS PURCHASER BILL OF SALE OR THE TRANSACTIONS CONTEMPLATED HEREBY (WHETHER IN CONTRACT, TORT OR OTHERWISE) WILL BE GOVERNED BY, AND CONSTRUED, INTERPRETED AND ENFORCED IN ACCORDANCE WITH THE INTERNAL SUBSTANTIVE LAWS OF THE STATE OF NEW YORK, WITHOUT GIVING EFFECT TO THE PRINCIPLES OF CONFLICTS OF LAW THEREOF OTHER THAN SECTION 5-1401 OF THE GENERAL OBLIGATIONS LAW OF THE STATE OF NEW YORK, AND THE OBLIGATIONS, RIGHTS AND REMEDIES OF THE PARTIES HEREUNDER WILL BE DETERMINED IN ACCORDANCE WITH SUCH LAWS.

(b) ANY PROCEEDING WITH RESPECT TO THIS PURCHASER BILL OF SALE WILL BE BROUGHT IN THE COURTS OF THE STATE OF NEW YORK LOCATED IN THE BOROUGH OF MANHATTAN, THE CITY OF NEW YORK OR OF THE UNITED STATES OF AMERICA FOR THE SOUTHERN DISTRICT OF NEW YORK, AND EACH PARTY HEREBY ACCEPTS FOR ITSELF AND IN RESPECT OF ITS

RESPECTIVE PROPERTY, GENERALLY AND UNCONDITIONALLY, THE EXCLUSIVE JURISDICTION OF THE AFORESAID COURTS.

(c) EACH PARTY HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, TRIAL BY JURY IN ANY ACTION OR DISPUTE ARISING OUT OF OR RELATING TO THIS PURCHASER BILL OF SALE OR THE TRANSACTIONS CONTEMPLATED HEREBY (WHETHER IN CONTRACT, TORT OR OTHERWISE).

(d) EACH PARTY HEREBY IRREVOCABLY WAIVES ANY OBJECTION, INCLUDING ANY OBJECTION TO THE LAYING OF VENUE OR BASED ON THE GROUNDS OF FORUM NON CONVENIENS, WHICH IT MAY NOW OR HEREAFTER HAVE TO THE BRINGING OF ANY SUCH ACTION OR PROCEEDING IN SUCH RESPECTIVE JURISDICTIONS.

(e) EACH PARTY IRREVOCABLY CONSENTS TO THE SERVICE OF PROCESS OF ANY OF THE AFOREMENTIONED COURTS IN ANY SUCH ACTION OR PROCEEDING BY THE SENDING OF COPIES THEREOF BY FEDERAL EXPRESS OR OTHER OVERNIGHT COURIER COMPANY, TO SUCH PARTY AT ITS ADDRESS SPECIFIED BY SECTION 9.9 OF THE PURCHASE AGREEMENT, SUCH SERVICE TO BECOME EFFECTIVE FOUR DAYS AFTER DELIVERY TO SUCH COURIER COMPANY.

(f) NOTHING HEREIN WILL AFFECT THE RIGHT OF ANY PARTY TO SERVE PROCESS IN ANY OTHER MANNER PERMITTED BY LAW.

6. This Purchaser Bill of Sale may be executed in any number of counterparts, each of which so executed will be deemed to be an original, but all of such counterparts will together constitute but one and the same instrument.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, the Parties hereto have executed this Purchaser Bill of Sale as of the day and year first written above.

SELLER:

AMARIN PHARMACEUTICALS IRELAND LIMITED

By: _____

Name:

Title:

PURCHASER:

BIOPHARMA SECURED DEBT FUND II HOLDINGS CAYMAN LP

By: Pharmakon Advisors, LP, its investment manager

By: Pharmakon Management I, LLC its general partner

By: _____

Name: _____

Title: _____

Signature Page to Purchaser Bill of Sale

EXHIBIT B

US LAW PATENT SECURITY AGREEMENT

Schedules

3.1(i) Existing In-Licenses
3.1(k) Manufacturing Agreements
3.1(m) Vascepa Patent Rights

Schedule 3.1(i)
Existing In-Licenses

None

Schedule 3.1(k)

Manufacturing Agreements

1. Supply Agreement between Nisshin Pharma Inc. and Amarin Pharmaceuticals Ireland Limited, dated November 1, 2010.

2. API Commercial Supply Agreement by and between Chemport Inc. and Amarin Pharmaceuticals Ireland Limited, dated May 25, 2011 (as amended as of April 4, 2012 and July 19, 2012).

3. API Supply Agreement by and between Equateq Limited and Amarin Pharmaceuticals Ireland Limited, dated May 25, 2011 (as amended October 19, 2011, January 9, 2012 and May 2012).

4. Second Amended and Restated API Supply Agreement by and between Slanmhor Pharmaceutical Inc. and Amarin Pharmaceuticals Ireland Limited, dated July 26, 2012.

5. Softgel Commercial Manufacturing Agreement by and between Catalent Pharma Solutions, LLC and Amarin Pharmaceuticals Ireland Limited, dated August 16, 2011.

6. Commercial Product Supply Agreement by and between Banner Pharmacaps Europe B.V. and Amarin Pharmaceuticals Ireland Limited, dated July 2, 2012.

SCHEDULE 3.1(m)

LIST OF PATENTS

[***]

Schedule 3.1(m) (cont.)

INFRINGEMENT OF VASCEPA PATENT RIGHTS

None

Exhibit 10.54

English Summary of German Language Commercial Lease Agreement between Zug Estates AG and Amarin Switzerland GmbH

Section	Provision	Terms and Conditions/Explanation
Preamble	Landlord	Zug Estates AG, Industriestrasse 12, 6300 Zug
Preamble	Tenant	Amarin Switzerland GmbH
Preamble	Building	Überbauung Metalli, Gotthardstrasse 2, 6300 Zug
1.1	Premises	1st floor, 419.10 sqm
1.1	Purpose	Office
2.1	Lease commencement date	February 1, 2022
2.3	Term	Fixed term of five years until January 31, 2027 (the “Initial Term”). Automatic termination without prior notice as of January 31, 2027, unless extended.
2.4	Renewal option	At the end of the Initial Term, Tenant has the option to extend the lease for an additional term of five years (i.e. until January 31, 2032). Such option must be exercised no later than 18 months prior to the end of the Initial Term (i.e. no later than July 31, 2025). In case of extension, Landlord may increase the rent by a maximum of 5%, if such increase corresponds to customary local conditions. Tenant must be informed of such increase no later than October 31, 2025, and Tenant has the right to revoke exercise of the renewal option within two months of receipt of the adjustment notice.
2.5	Right of First Refusal	Right of first refusal to rent office space at the property Gotthardstrasse 2 and Baarerstrasse 14. If a third party is willing to rent this space, Landlord must inform Tenant. Tenant must inform Landlord within 15 calendar days whether it will rent this additional space at the conditions offered by the third party. If the space is not rented to a third party or there is no offer to rent from a third party, Tenant shall be entitled at any time to rent this space in addition pursuant to the conditions of the lease agreement.

3; 1.1	Rent	Total of CHF 192,786.10 per year (CHF 460/sqm/year, plus VAT of CHF 14,844.53 and payment on account for ancillary costs of 18,054.82), in total CHF 225,685.45 per year, payable quarterly in advance.
3.2	Indexation	Yes, pursuant to the development of the Swiss Consumer Price Index, for the first time as of January 1, 2023.
3.2	Rent adjustment during the fixed period	In case of value-enhancing investments of Landlord.
3.4.1	VAT	The lease agreement is subject to VAT (currently 7.7%).
4.1	Ancillary costs	Tenant shall bear effective ancillary costs of the exhaustive list of items set out in the lease agreement. Due to eco-friendly energy contracting, Tenant shall also bear the costs of amortization, capital costs, repair, insurance of the heating facility.
5	Default Interest	In the event of late payment of rent, Landlord will charge Tenant default interest of 6% of the amount owed from the due date.
6.1	Alterations by Tenant	Permissible, subject to Landlord's prior approval.
8; 2.1	Building Condition	Core and shell lease. All existing fixtures and fit-outs are deemed to be Tenant's fixtures and fit-outs.

8.5	Repairs	Tenant shall bear the costs of: minor repairs up to CHF 1,000 per repair and case; and all repairs of its own fixtures and fit-outs.
8.7	Reinstatement	Landlord is entitled to require Tenant to reinstate the Premises to original condition at the end of the lease. If Landlord waives this right, the fit-outs shall be left at the Premises. Tenant waives its right to a reimbursement of any added value of fixtures and fit-outs remaining at the Premises at the end of the lease.
10	Sublease and transfer of lease	Sublease and transfer of lease require the approval of Landlord, which under mandatory Swiss law can only be refused for specific reasons. Group internal sublease or transfer only requires information of Landlord, not approval.
13	Security	Cash deposit of CHF 112,000 at bank escrow account.
14	Insurance	Tenant shall take out a third-party liability insurance with a coverage of at least CHF 5.0 million and an insurance against fire and damages by natural forces.
15.5	Access of Landlord	Upon advance notice of 72 hours.
15.6	Registration of the lease agreement in the land register	Yes.
15.7	Development	Landlord is considering to further develop the site. Landlord can offer temporary replacement offices if appropriate because of the construction in such case. The cost of moving will be borne by Landlord. If the construction causes material disturbances to Tenant, Tenant may ask for a rent reduction.
N/A	Language of contractual agreements	German.
16.4	Applicable law	Swiss law.
16.4	Exclusive place of jurisdiction	Zug.

Exhibit 10.55

Office Service Agreement

Agreement Date (dd/mm/yy):	21 / 10 / 2021	**Reference No.:**	12678344

Business Centre Address:
Regus Solna Frösunda Port
Gustav III:s Boulevard 34
Solna 169 73
Sweden

Client Address (Not a Business Centre Address):	
Company Name:	Amarin Switzerland GmbH Sweden filial
Contact Name:	Tom Maher
Address:	c/o TMF Sweden AB, Sergels Torg 12
Address:	111 57 Stockholm
Phone & Email:	tom.maher@amarincorp.eu

Office Payment Details (excluding tax/GST and excluding services)

Office Number	No. of People	Monthly Office Fee	Currency
415	2	9,205.50	KR
416	2	9,205.50	KR
417	3	15,190.50	KR
Total per Month			-

Initial Payment	First Month's Fee		33,601.50kr
	Service Retainer		67,203KR
	Total Initial Payment		100,804.00kr -
Monthly Payment	Total Monthly Payment Thereafter		33,601KR

Service Provision	Start Date	1st November 2021	End Date*	30th November 2022

**** All agreements end on the last calendar day of the month.***

Comments:

An Activation fee of [350KR] per occupant will be payable, (a one time, per occupant fee for Office and Coworking (dedicated desk) customers that covers all aspects of customer onboarding, administration and set-up.)

We are IWG Management Sweden AB, referred to in the terms and conditions as “We”, “Us”, “Our”. The Company Name listed above will be referred to in the terms and conditions as “You”, “Your”. This Agreement incorporates Our terms of business set out on attached Terms and Conditions, attached House Rules and Service Price Guide (where available), which You confirm You have read and understood. We both agree to comply with those terms and our obligations as set out in them. This agreement is binding from the agreement date and may not be terminated once it is made, except in accordance with its terms. Note that the Agreement does not come to an end automatically. See “Automatic Renewal” section of Your terms and conditions for the notice terms if You wish to end your agreement.

Name (printed): Tom Maher

Title (printed): Director

Date: October 27, 2021

SIGNED on your behalf

These General Terms and Conditions apply to Office/Co-Working, Virtual Office and Membership agreements for services We supply to You.

1. General Agreement

1.1. Nature of an agreement: At all times, each Center remains in Our possession and control. YOU ACCEPT THAT AN AGREEMENT CREATES NO TENANCY INTEREST, LEASEHOLD ESTATE OR OTHER REAL PROPERTY INTEREST IN YOUR FAVOR WITH RESPECT TO THE ACCOMMODATION.

1.2. House Rules: The House Rules, which are incorporated into these terms and conditions, are primarily in place and enforced to ensure that all clients have a professional environment to work in.

1.3. Availability at the start of an agreement: If for any unfortunate reason We cannot provide the services or accommodation in the Center stated in an agreement by the start date, We will have no liability to You for any loss or damage but You may either move to one of Our other Centers (subject to availability), delay the start of the agreement or cancel it.

1.4. **AUTOMATIC RENEWAL:** SO THAT WE CAN MANAGE YOUR SERVICES EFFECTIVELY AND TO ENSURE SEAMLESS CONTINUITY OF THOSE SERVICES, ALL AGREEMENTS WILL RENEW AUTOMATICALLY FOR SUCCESSIVE PERIODS EQUAL TO THE CURRENT TERM UNTIL BROUGHT TO AN END BY YOU OR US. ALL PERIODS SHALL RUN TO THE LAST DAY OF THE MONTH IN WHICH THEY WOULD OTHERWISE EXPIRE. THE FEES ON ANY RENEWAL WILL BE AT THE THEN PREVAILING MARKET RATE (PRICES ARE SET ANNUALLY SO DEPENDING ON WHEN YOUR AGREEMENT IS DUE TO RENEW, THERE MAY BE A CHANGE IN PRICE). IF YOU DO NOT WISH FOR AN AGREEMENT TO RENEW THEN YOU CAN CANCEL IT EASILY WITH EFFECT FROM THE END DATE STATED IN THE AGREEMENT, OR AT THE END OF ANY EXTENSION OR RENEWAL PERIOD, BY GIVING US PRIOR NOTICE. NOTICE MUST BE GIVEN THROUGH YOUR ONLINE ACCOUNT OR THROUGH THE APP. THE NOTICE PERIODS REQUIRED ARE AS FOLLOWS:

Term	Notice Period
Month-to-Month	no less than 1 month's notice from the 1st day of any calendar month
3 months	no less than 2 months' notice prior to the end of the term
More than 3 months	no less than 3 months' notice prior to the end of the term

1.5. We may elect not to renew an agreement. If so, We will inform You by email, through the App or Your online account, according to the same notice periods specified above.

1.6. If the Center is no longer available: In the event that We are permanently unable to provide the services and accommodation at the Center stated in an agreement, We will offer You accommodation in one of Our other centers. In the unlikely event We are unable to find a nearby alternative accommodation, Your agreement will end and You will only have to pay monthly fees up to that date and for any additional services You have used.

1.7. Ending an agreement immediately: We may put an end to an agreement immediately by giving You notice if (a) You become insolvent or bankrupt; or (b) You breach one of your obligations which cannot be remedied, or which We have given You notice to remedy and which You have failed to remedy within 14 days of that notice; or (c) Your conduct, or that of someone at the Center with Your permission or invitation, is incompatible with ordinary office use and, (i) that conduct continues despite You having been given notice, or (ii) that conduct is material enough (in Our reasonable opinion) to warrant immediate termination; or (d) You are in breach of the "Compliance With Law" clause below. If We put an end to an agreement for any of the reasons referred to in this clause, it does not put an end to any of Your financial obligations, including, without limitation, for the remainder of the period for which Your agreement would have lasted if We had not terminated it.

1.8. When an Office agreement ends: When an agreement ends You must vacate Your accommodation immediately, leaving it in the same state and condition as it was when You took it. If You leave any property in the Center, We may dispose of it at Your cost in any way We choose without owing You any responsibility for it or any proceeds of sale. If You continue to use the accommodation when an agreement has ended, You are responsible for any loss, claim or liability We may incur as a result of Your failure to vacate on time.

1.9. Transferability: Subject to availability (which shall be determined in Our sole discretion) You may transfer Your agreement to alternative accommodation in the IWG network of Centers provided that Your financial commitment remains the same (or increases) and such transfer is not used to extend or renew an existing agreement. Such a transfer may require entry into a new agreement.

2. Use of the Centers:

2.1. Business Operations: You may not carry on a business that competes with Our business of providing serviced offices and flexible working. You may not use Our name (or that of Our affiliates) in any way in connection with Your business. You are only permitted to use the address of a Center as Your registered office address if it is permitted by both law and if We have given You prior written consent (given the administration there is an additional fee chargeable for this service). You must only use the accommodation for office business purposes. If We decide that a request for any particular service is excessive, We reserve the right to charge an additional fee. In order to ensure that the Center provides a great working environment for all, We kindly ask you to limit any excessive visits by members of the public.

2.2. Accommodation

2.2.1. Alterations or Damage: You are liable for any damage caused by You or those in the Center with Your permission, whether express or implied, including but not limited to all employees, contractors and/or agents.

2.2.2. IT Installations: We take great pride in Our IT infrastructure and its upkeep and, therefore, You must not install any cabling, IT or telecom connections without Our consent, which We may refuse at our absolute discretion. As a condition to Our consent, You must permit Us to oversee any installations (for example, IT or electrical systems) and to verify that such installations do not interfere with the use of the accommodation by other clients or Us or any landlord of the building. Fees for installation and de-installation will be at Your cost.

2.2.3. Use of the Accommodation: An agreement will list the accommodation We initially allocate for Your use. You will have a non-exclusive right to the rooms allocated to You. Where the accommodation is a Coworking desk, this can only be used by one individual, it cannot be shared amongst multiple individuals. Occasionally to ensure the efficient running of the Center, We may need to allocate different accommodation to You, but it will be of reasonably equivalent size and We will notify You with respect to such different accommodation in advance.

2.2.4. Access to the Accommodation: To maintain a high level of service, We may need to enter Your accommodation and may do so at any time, including and without limitation, in an emergency, for cleaning and inspection or in order to resell the space if You have given notice to terminate. We will always endeavor to respect any of Your reasonable security procedures to protect the confidentiality of Your business.

2.3. Membership:

2.3.1. If You have subscribed to a Membership Agreement, You will have access to all participating centers worldwide during standard business working hours and subject to availability.

2.3.2. Membership Usage: Usage is measured in whole days and unused days cannot be carried over to the following month. A membership is not intended to be a replacement for a full-time workspace and all workspaces must be cleared at the end of each day. You are solely responsible for Your belongings at the center at all times. We are not responsible for any property that is left unattended. Should You use more than Your membership entitlement, We will charge You an additional usage fee. You may bring in 1 guest free of charge (subject to fair usage). Any additional guests will be required to purchase a day pass.

2.3.3. As a Member, You may not use any Center as Your business address without an accompanying office or virtual office agreement in place. Any use of the Center address in such a way will result in an automatic enrollment in the Virtual Office product for the same term as Your membership and You will be invoiced accordingly.

2.4. Compliance with Law: You must comply with all relevant laws and regulations in the conduct of Your business. You must not do anything that may interfere with the use of the Center by Us or by others (including but not limited to political campaigning or immoral activity), cause any nuisance or annoyance, or cause loss or damage to Us (including damage to reputation) or to the owner of any interest in the building. If We have been advised by any government authority or other legislative body that it has reasonable suspicion that You are conducting criminal activities from the Center, or You are or will become subject to any government sanctions, then We shall be entitled to terminate any and all of Your agreements with immediate effect. You acknowledge that any breach by You of this clause shall constitute a material default, entitling Us to terminate Your agreement without further notice.

2.5. Ethical Trading: Both We and You shall comply at all times with all relevant anti-slavery, anti-bribery and anti- corruption laws.

2.6. Data Protection:

2.6.1. Each party shall comply with all applicable data protection legislation. The basis on which we will process Your personal data is set out in our privacy policies (available on our website at www.iwgplc.com/clientprivacypolicy.)

2.6.2. You acknowledge and accept that we may collect and process personal data concerning You and/or your personnel in the course of our agreement for services with you. Such personal data will be processed in accordance with our privacy policy. Where you provide this data to us, you will ensure that you have the necessary consents and notices in place to allow for this.

2.7. Employees: We will both have invested a great deal in training Our staff, therefore, neither of us may knowingly solicit or offer employment to the other's staff employed in the Center (or for 3 months after they have left their employment). To recompense the other for staff training and investment costs, if either of us breaches this clause the breaching party will pay upon demand to the other the equivalent of 6 months' salary of any employee concerned.

2.8. Confidentiality: The terms of an agreement are confidential. Neither of us may disclose them without the other's consent unless required to do so by law or an official authority. This obligation continues for a period of 3 years after an agreement ends.

2.9. Assignment: An agreement is personal to You and cannot be transferred to anyone else without prior consent from Us unless such transfer is required by law. However, We will not unreasonably withhold our consent to assignment to an affiliate provided that You execute our standard form of assignment. We may transfer any agreement and any and all amounts payable by You under an agreement to any other member of Our group.

2.10. Applicable law: An agreement is interpreted and enforced in accordance with the law of the place where the Center is located other than in a few specific jurisdictions which are detailed in the House Rules. We and You both accept the exclusive jurisdiction of the courts of that jurisdiction. If any provision of these terms and conditions is held void or unenforceable under the applicable law, the other provisions shall remain in force.

3. Our liability to You and Insurance

3.1. The extent of Our liability: To the maximum extent permitted by applicable law, We are not liable to You in respect of any loss or damage You suffer in connection with an agreement, including without limitation any loss or damage arising as a result of our failure to provide a service as a result of mechanical breakdown, strike or other event outside of Our reasonable control otherwise unless We have acted deliberately or have been negligent. In no event shall We be liable for any loss or damage until You provide written notice and give Us a reasonable time to remedy it. If We are liable for failing to provide You with any service under an agreement then, subject to the exclusions and limits set out immediately below, We will pay any actual and the reasonable additional expense You have incurred in obtaining the same or similar service from elsewhere.

3.2. Your Insurance: It is Your responsibility to arrange insurance for property which You bring in to the Center, for any mail You send or receive and for Your own liability to your employees and to third parties. We strongly recommend that You put such insurance in place.

3.3. IT Services and Obligations: Whilst We have security internet protocols in place and strive to provide seamless internet connectivity, WE DO NOT MAKE ANY REPRESENTATION AND CANNOT GUARANTEE ANY MAINTAINED LEVEL OF CONNECTIVITY TO OUR NETWORK OR TO THE INTERNET, NOR THE LEVEL OF SECURITY OF IT INFORMATION AND DATA THAT YOU PLACE ON IT. You should adopt whatever security measures (such as encryption) You believe are appropriate to Your business. Your sole and exclusive remedy in relation to issues of reduced connectivity which are within Our reasonable control shall be for Us to rectify the issue within a reasonable time following notice from You to Us.

3.4. EXCLUSION OF CONSEQUENTIAL LOSSES: WE WILL NOT IN ANY CIRCUMSTANCES HAVE ANY LIABILITY TO YOU FOR LOSS OF BUSINESS, LOSS OF PROFITS, LOSS OF ANTICIPATED SAVINGS, LOSS OF OR DAMAGE TO DATA, THIRD PARTY CLAIMS OR ANY CONSEQUENTIAL LOSS. WE STRONGLY RECOMMEND THAT YOU INSURE AGAINST ALL SUCH POTENTIAL LOSS, DAMAGE, EXPENSE OR LIABILITY.

3.5. Financial limits to our liability: In all cases, our liability to You is subject to the following limits:

3.5.1. without limit for personal injury or death;

3.5.2. up to a maximum of GBP 1 million (or USD 1.5 million or EUR 1 million or other local equivalent) for any one event or series of connected events for damage to Your personal property; and

3.5.3. in respect of any other loss or damage, up to a maximum equal to 125% of the total fees paid between the date services under an agreement commenced and the date on which the claim in question arises; or if higher, for office agreements only, GBP 50,000 / USD 100,000 / EUR 66,000 (or local equivalent).

4. Fees

4.1. Service Retainer/Deposit: Your service retainer / deposit will be held by Us without generating interest as security for performance of all Your obligations under an agreement. All requests for the return must be made through Your online account or App after which the service retainer/deposit or any balance will be returned within 30 days to You once your agreement has ended and when You have settled Your account. We will deduct any outstanding fees and other costs due to Us before returning the balance to You. We will require You to pay an increased retainer if the monthly office or virtual office fee increases upon renewal, outstanding fees exceed the service retainer/deposit held, and/or You frequently fail to pay invoices when due.

4.2. Taxes and duty charges: You agree to pay promptly (i) all sales, use, excise, consumption and any other taxes and license fees which You are required to pay to any governmental authority (and, at Our request, You will provide to Us evidence of such payment) and (ii) any taxes paid by Us to any governmental authority that are attributable to Your accommodation, where applicable, including, without limitation, any gross receipts, rent and occupancy taxes, tangible personal property taxes, duties or other documentary taxes and fees.

4.3. Payment: We are continually striving to reduce our environmental impact and support You in doing the same. Therefore, We will send all invoices electronically and You will make payments via an automated method such as Direct Debit or Credit Card, wherever local banking systems permit.

4.4. Late payment: If You do not pay fees when due, a fee will be charged on all overdue balances. This fee will differ by country and is listed in the House Rules. If You dispute any part of an invoice, You must pay the amount not in dispute by the due date or be subject to late fees. We also reserve the right to withhold services (including for the avoidance of doubt, denying You access to the Center where applicable) while there are any outstanding fees and/or interest, or You are in breach of an agreement.

4.5. Insufficient Funds: Due to the additional administration We incur, You will pay a fee for any returned or declined payments due to insufficient funds. This fee will differ by country and is listed in the House Rules.

4.6. Activation: An activation fee is payable in respect of each agreement You have with Us (including any new agreements entered into under clause 1.9 above). This fee covers the administrative cost of the client onboarding process and account setup. This fee is set out in each Local Services Agreement and is charged on a per occupant basis for Serviced Office and Coworking (dedicated desk), on a per location basis for Virtual Office and on a per person basis for Membership. Further information is set out in the House Rules.

4.7. Indexation: If an agreement is for a term of more than 12 months, or a month to month agreement is not terminated within 12 months, We will increase the monthly fee on each anniversary of the start date in line with the relevant inflation index detailed in the House Rules.

4.8. Office Restoration: Upon Your departure or if You choose to relocate to a different room within a Center, We will charge a fixed office restoration service fee to cover normal cleaning and any costs incurred to return the accommodation to its original condition and state. This fee will differ by country and is listed in the House Rules. We reserve the right to charge additional reasonable fees for any repairs needed above and beyond normal wear and tear.

4.9. Standard services: Monthly fees, plus applicable taxes, and any recurring services requested by You are payable monthly in advance. Where a daily rate applies, the charge for any such month will be 30 times the daily fee. For a period of less than one month, the fee will be applied on a daily basis.

4.10. Pay-as-you-use and Additional Variable Services: Fees for pay-as-you-use services, plus applicable taxes, are payable monthly in arrears at our standard rates which may change from time to time and are available on request.

4.11. Discounts, Promotions and Offers: If You benefited from a special discount, promotion or offer, We will discontinue that discount, promotion or offer without notice if You materially breach Your agreement.

Exhibit 10.56

Office Service Agreement

Agreement Date (dd/mm/yy):	21 / 10 / 2021	**Reference No.:**	12561629

Business Centre Address:
Regus Solna Frösunda Port
Gustav III:s Boulevard 34
Solna 169 73
Sweden

Client Address (Not a Business Centre Address):	
Company Name:	Amarin Switzerland GmbH Sweden filial
Contact Name:	Tom Maher
Address:	c/o TMF Sweden AB, Sergels Torg 12
Address:	111 57 Stockholm
Phone & Email:	tom.maher@amarincorp.eu

Office Payment Details (excluding tax/GST and excluding services)

Office Number	No. of People	Monthly Office Fee	Currency
419	2	9,205.50	KR
Total per Month			-

Initial Payment	First Month's Fee		9,205.50kr
	Service Retainer		18,411KR
	Total Initial Payment		27,616.50kr -
Monthly Payment	Total Monthly Payment Thereafter		9,205.50KR

Service Provision	Start Date	1st December 2021	End Date*	30th November 2022

**** All agreements end on the last calendar day of the month.***

Comments:

An Activation fee of [350KR] per occupant will be payable, (a one time, per occupant fee for Office and Coworking (dedicated desk) customers that covers all aspects of customer onboarding, administration and set-up.)

We are IWG Management Sweden AB, referred to in the terms and conditions as "We", "Us", "Our". The Company Name listed above will be referred to in the terms and conditions as "You", "Your". This Agreement incorporates Our terms of business set out on attached Terms and Conditions, attached House Rules and Service Price Guide (where available), which You confirm You have read and understood. We both agree to comply with those terms and our obligations as set out in them. This agreement is binding from the agreement date and may not be terminated once it is made, except in accordance with its terms. Note that the Agreement does not come to an end automatically. See "Automatic Renewal" section of Your terms and conditions for the notice terms if You wish to end your agreement.

Name (printed): Tom Maher

Title (printed): Director

Date: October 27, 2021

SIGNED on your behalf

These General Terms and Conditions apply to Office/Co-Working, Virtual Office and Membership agreements for services We supply to You.

1. General Agreement

1.1. Nature of an agreement: At all times, each Center remains in Our possession and control. YOU ACCEPT THAT AN AGREEMENT CREATES NO TENANCY INTEREST, LEASEHOLD ESTATE OR OTHER REAL PROPERTY INTEREST IN YOUR FAVOR WITH RESPECT TO THE ACCOMMODATION.

1.2. House Rules: The House Rules, which are incorporated into these terms and conditions, are primarily in place and enforced to ensure that all clients have a professional environment to work in.

1.3. Availability at the start of an agreement: If for any unfortunate reason We cannot provide the services or accommodation in the Center stated in an agreement by the start date, We will have no liability to You for any loss or damage but You may either move to one of Our other Centers (subject to availability), delay the start of the agreement or cancel it.

1.4. **AUTOMATIC RENEWAL:** SO THAT WE CAN MANAGE YOUR SERVICES EFFECTIVELY AND TO ENSURE SEAMLESS CONTINUITY OF THOSE SERVICES, ALL AGREEMENTS WILL RENEW AUTOMATICALLY FOR SUCCESSIVE PERIODS EQUAL TO THE CURRENT TERM UNTIL BROUGHT TO AN END BY YOU OR US. ALL PERIODS SHALL RUN TO THE LAST DAY OF THE MONTH IN WHICH THEY WOULD OTHERWISE EXPIRE. THE FEES ON ANY RENEWAL WILL BE AT THE THEN PREVAILING MARKET RATE (PRICES ARE SET ANNUALLY SO DEPENDING ON WHEN YOUR AGREEMENT IS DUE TO RENEW, THERE MAY BE A CHANGE IN PRICE). IF YOU DO NOT WISH FOR AN AGREEMENT TO RENEW THEN YOU CAN CANCEL IT EASILY WITH EFFECT FROM THE END DATE STATED IN THE AGREEMENT, OR AT THE END OF ANY EXTENSION OR RENEWAL PERIOD, BY GIVING US PRIOR NOTICE. NOTICE MUST BE GIVEN THROUGH YOUR ONLINE ACCOUNT OR THROUGH THE APP. THE NOTICE PERIODS REQUIRED ARE AS FOLLOWS:

Term	Notice Period
Month-to-Month	no less than 1 month's notice from the 1st day of any calendar month
3 months	no less than 2 months' notice prior to the end of the term
More than 3 months	no less than 3 months' notice prior to the end of the term

1.5. We may elect not to renew an agreement. If so, We will inform You by email, through the App or Your online account, according to the same notice periods specified above.

1.6. If the Center is no longer available: In the event that We are permanently unable to provide the services and accommodation at the Center stated in an agreement, We will offer You accommodation in one of Our other centers. In the unlikely event We are unable to find a nearby alternative accommodation, Your agreement will end and You will only have to pay monthly fees up to that date and for any additional services You have used.

1.7. Ending an agreement immediately: We may put an end to an agreement immediately by giving You notice if (a) You become insolvent or bankrupt; or (b) You breach one of your obligations which cannot be remedied, or which We have given You notice to remedy and which You have failed to remedy within 14 days of that notice; or (c) Your conduct, or that of someone at the Center with Your permission or invitation, is incompatible with ordinary office use and, (i) that conduct continues despite You having been given notice, or (ii) that conduct is material enough (in Our reasonable opinion) to warrant immediate termination; or (d) You are in breach of the "Compliance With Law" clause below. If We put an end to an agreement for any of the reasons referred to in this clause, it does not put an end to any of Your financial obligations, including, without limitation, for the remainder of the period for which Your agreement would have lasted if We had not terminated it.

1.8. When an Office agreement ends: When an agreement ends You must vacate Your accommodation immediately, leaving it in the same state and condition as it was when You took it. If You leave any property in the Center, We may dispose of it at Your cost in any way We choose without owing You any responsibility for it or any proceeds of sale. If You continue to use the accommodation when an agreement has ended, You are responsible for any loss, claim or liability We may incur as a result of Your failure to vacate on time.

1.9. Transferability: Subject to availability (which shall be determined in Our sole discretion) You may transfer Your agreement to alternative accommodation in the IWG network of Centers provided that Your financial commitment remains the same (or increases) and such transfer is not used to extend or renew an existing agreement. Such a transfer may require entry into a new agreement.

2. Use of the Centers:

2.1. Business Operations: You may not carry on a business that competes with Our business of providing serviced offices and flexible working. You may not use Our name (or that of Our affiliates) in any way in connection with Your business. You are only permitted to use the address of a Center as Your registered office address if it is permitted by both law and if We have given You prior written consent (given the administration there is an additional fee chargeable for this service). You must only use the accommodation for office business purposes. If We decide that a request for any particular service is excessive, We reserve the right to charge an additional fee. In order to ensure that the Center provides a great working environment for all, We kindly ask you to limit any excessive visits by members of the public.

2.2. Accommodation

2.2.1. Alterations or Damage: You are liable for any damage caused by You or those in the Center with Your permission, whether express or implied, including but not limited to all employees, contractors and/or agents.

2.2.2. IT Installations: We take great pride in Our IT infrastructure and its upkeep and, therefore, You must not install any cabling, IT or telecom connections without Our consent, which We may refuse at our absolute discretion. As a condition to Our consent, You must permit Us to oversee any installations (for example, IT or electrical systems) and to verify that such installations do not interfere with the use of the accommodation by other clients or Us or any landlord of the building. Fees for installation and de-installation will be at Your cost.

2.2.3. Use of the Accommodation: An agreement will list the accommodation We initially allocate for Your use. You will have a non-exclusive right to the rooms allocated to You. Where the accommodation is a Coworking desk, this can only be used by one individual, it cannot be shared amongst multiple individuals. Occasionally to ensure the efficient running of the Center, We may need to allocate different accommodation to You, but it will be of reasonably equivalent size and We will notify You with respect to such different accommodation in advance.

2.2.4. Access to the Accommodation: To maintain a high level of service, We may need to enter Your accommodation and may do so at any time, including and without limitation, in an emergency, for cleaning and inspection or in order to resell the space if You have given notice to terminate. We will always endeavor to respect any of Your reasonable security procedures to protect the confidentiality of Your business.

2.3. Membership:

2.3.1. If You have subscribed to a Membership Agreement, You will have access to all participating centers worldwide during standard business working hours and subject to availability.

2.3.2. Membership Usage: Usage is measured in whole days and unused days cannot be carried over to the following month. A membership is not intended to be a replacement for a full-time workspace and all workspaces must be cleared at the end of each day. You are solely responsible for Your belongings at the center at all times. We are not responsible for any property that is left unattended. Should You use more than Your membership entitlement, We will charge You an additional usage fee. You may bring in 1 guest free of charge (subject to fair usage). Any additional guests will be required to purchase a day pass.

2.3.3. As a Member, You may not use any Center as Your business address without an accompanying office or virtual office agreement in place. Any use of the Center address in such a way will result in an automatic enrollment in the Virtual Office product for the same term as Your membership and You will be invoiced accordingly.

2.4. Compliance with Law: You must comply with all relevant laws and regulations in the conduct of Your business. You must not do anything that may interfere with the use of the Center by Us or by others (including but not limited to political campaigning or immoral activity), cause any nuisance or annoyance, or cause loss or damage to Us (including damage to reputation) or to the owner of any interest in the building. If We have been advised by any government authority or other legislative body that it has reasonable suspicion that You are conducting criminal activities from the Center, or You are or will become subject to any government sanctions, then We shall be entitled to terminate any and all of Your agreements with immediate effect. You acknowledge that any breach by You of this clause shall constitute a material default, entitling Us to terminate Your agreement without further notice.

2.5. Ethical Trading: Both We and You shall comply at all times with all relevant anti-slavery, anti-bribery and anti- corruption laws.

2.6. Data Protection:

2.6.1. Each party shall comply with all applicable data protection legislation. The basis on which we will process Your personal data is set out in our privacy policies (available on our website at www.iwgplc.com/clientprivacypolicy.)

2.6.2. You acknowledge and accept that we may collect and process personal data concerning You and/or your personnel in the course of our agreement for services with you. Such personal data will be processed in accordance with our privacy policy. Where you provide this data to us, you will ensure that you have the necessary consents and notices in place to allow for this.

2.7. Employees: We will both have invested a great deal in training Our staff, therefore, neither of us may knowingly solicit or offer employment to the other's staff employed in the Center (or for 3 months after they have left their employment). To recompense the other for staff training and investment costs, if either of us breaches this clause the breaching party will pay upon demand to the other the equivalent of 6 months' salary of any employee concerned.

2.8. Confidentiality: The terms of an agreement are confidential. Neither of us may disclose them without the other's consent unless required to do so by law or an official authority. This obligation continues for a period of 3 years after an agreement ends.

2.9. Assignment: An agreement is personal to You and cannot be transferred to anyone else without prior consent from Us unless such transfer is required by law. However, We will not unreasonably withhold our consent to assignment to an affiliate provided that You execute our standard form of assignment. We may transfer any agreement and any and all amounts payable by You under an agreement to any other member of Our group.

2.10. Applicable law: An agreement is interpreted and enforced in accordance with the law of the place where the Center is located other than in a few specific jurisdictions which are detailed in the House Rules. We and You both accept the exclusive jurisdiction of the courts of that jurisdiction. If any provision of these terms and conditions is held void or unenforceable under the applicable law, the other provisions shall remain in force.

3. Our liability to You and Insurance

3.1. The extent of Our liability: To the maximum extent permitted by applicable law, We are not liable to You in respect of any loss or damage You suffer in connection with an agreement, including without limitation any loss or damage arising as a result of our failure to provide a service as a result of mechanical breakdown, strike or other event outside of Our reasonable control otherwise unless We have acted deliberately or have been negligent. In no event shall We be liable for any loss or damage until You provide written notice and give Us a reasonable time to remedy it. If We are liable for failing to provide You with any service under an agreement then, subject to the exclusions and limits set out immediately below, We will pay any actual and the reasonable additional expense You have incurred in obtaining the same or similar service from elsewhere.

3.2. Your Insurance: It is Your responsibility to arrange insurance for property which You bring in to the Center, for any mail You send or receive and for Your own liability to your employees and to third parties. We strongly recommend that You put such insurance in place.

3.3. IT Services and Obligations: Whilst We have security internet protocols in place and strive to provide seamless internet connectivity, WE DO NOT MAKE ANY REPRESENTATION AND CANNOT GUARANTEE ANY MAINTAINED LEVEL OF CONNECTIVITY TO OUR NETWORK OR TO THE INTERNET, NOR THE LEVEL OF SECURITY OF IT INFORMATION AND DATA THAT YOU PLACE ON IT. You should adopt whatever security measures (such as encryption) You believe are appropriate to Your business. Your sole and exclusive remedy in relation to issues of reduced connectivity which are within Our reasonable control shall be for Us to rectify the issue within a reasonable time following notice from You to Us.

3.4. EXCLUSION OF CONSEQUENTIAL LOSSES: WE WILL NOT IN ANY CIRCUMSTANCES HAVE ANY LIABILITY TO YOU FOR LOSS OF BUSINESS, LOSS OF PROFITS, LOSS OF ANTICIPATED SAVINGS, LOSS OF OR DAMAGE TO DATA, THIRD PARTY CLAIMS OR ANY CONSEQUENTIAL LOSS. WE STRONGLY RECOMMEND THAT YOU INSURE AGAINST ALL SUCH POTENTIAL LOSS, DAMAGE, EXPENSE OR LIABILITY.

3.5. Financial limits to our liability: In all cases, our liability to You is subject to the following limits:

3.5.1. without limit for personal injury or death;

3.5.2. up to a maximum of GBP 1 million (or USD 1.5 million or EUR 1 million or other local equivalent) for any one event or series of connected events for damage to Your personal property; and

3.5.3. in respect of any other loss or damage, up to a maximum equal to 125% of the total fees paid between the date services under an agreement commenced and the date on which the claim in question arises; or if higher, for office agreements only, GBP 50,000 / USD 100,000 / EUR 66,000 (or local equivalent).

4. Fees

4.1. Service Retainer/Deposit: Your service retainer / deposit will be held by Us without generating interest as security for performance of all Your obligations under an agreement. All requests for the return must be made through Your online account or App after which the service retainer/deposit or any balance will be returned within 30 days to You once your agreement has ended and when You have settled Your account. We will deduct any outstanding fees and other costs due to Us before returning the balance to You. We will require You to pay an increased retainer if the monthly office or virtual office fee increases upon renewal, outstanding fees exceed the service retainer/deposit held, and/or You frequently fail to pay invoices when due.

4.2. Taxes and duty charges: You agree to pay promptly (i) all sales, use, excise, consumption and any other taxes and license fees which You are required to pay to any governmental authority (and, at Our request, You will provide to Us evidence of such payment) and (ii) any taxes paid by Us to any governmental authority that are attributable to Your accommodation, where applicable, including, without limitation, any gross receipts, rent and occupancy taxes, tangible personal property taxes, duties or other documentary taxes and fees.

4.3. Payment: We are continually striving to reduce our environmental impact and support You in doing the same. Therefore, We will send all invoices electronically and You will make payments via an automated method such as Direct Debit or Credit Card, wherever local banking systems permit.

4.4. Late payment: If You do not pay fees when due, a fee will be charged on all overdue balances. This fee will differ by country and is listed in the House Rules. If You dispute any part of an invoice, You must pay the amount not in dispute by the due date or be subject to late fees. We also reserve the right to withhold services (including for the avoidance of doubt, denying You access to the Center where applicable) while there are any outstanding fees and/or interest, or You are in breach of an agreement.

4.5. Insufficient Funds: Due to the additional administration We incur, You will pay a fee for any returned or declined payments due to insufficient funds. This fee will differ by country and is listed in the House Rules.

4.6. Activation: An activation fee is payable in respect of each agreement You have with Us (including any new agreements entered into under clause 1.9 above). This fee covers the administrative cost of the client onboarding process and account setup. This fee is set out in each Local Services Agreement and is charged on a per occupant basis for Serviced Office and Coworking (dedicated desk), on a per location basis for Virtual Office and on a per person basis for Membership. Further information is set out in the House Rules.

4.7. Indexation: If an agreement is for a term of more than 12 months, or a month to month agreement is not terminated within 12 months, We will increase the monthly fee on each anniversary of the start date in line with the relevant inflation index detailed in the House Rules.

4.8. Office Restoration: Upon Your departure or if You choose to relocate to a different room within a Center, We will charge a fixed office restoration service fee to cover normal cleaning and any costs incurred to return the accommodation to its original condition and state. This fee will differ by country and is listed in the House Rules. We reserve the right to charge additional reasonable fees for any repairs needed above and beyond normal wear and tear.

4.9. Standard services: Monthly fees, plus applicable taxes, and any recurring services requested by You are payable monthly in advance. Where a daily rate applies, the charge for any such month will be 30 times the daily fee. For a period of less than one month, the fee will be applied on a daily basis.

4.10. Pay-as-you-use and Additional Variable Services: Fees for pay-as-you-use services, plus applicable taxes, are payable monthly in arrears at our standard rates which may change from time to time and are available on request.

4.11. Discounts, Promotions and Offers: If You benefited from a special discount, promotion or offer, We will discontinue that discount, promotion or offer without notice if You materially breach Your agreement.

EXHIBIT 21.1

Subsidiaries of the Registrant as of December 31, 2021

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 and 333-240321 of Amarin Corporation plc; and
(3) Registration Statements on Form S-3 No. 333-236670 of Amarin Corporation plc;

of our reports dated March 1, 2022, 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, 2021.

/s/ Ernst & Young LLP

Iselin, New Jersey
March 1, 2022

EXHIBIT 31.1

CERTIFICATION

I, Karim Mikhail, 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: March 1, 2022

/s/ Karim Mikhail

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

EXHIBIT 31.2

CERTIFICATION

I, Michael W. Kalb, certify that:

1. I have reviewed this 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: March 1, 2022

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

EXHIBIT 32.1

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

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

(1) The Company's Annual Report on Form 10-K for the period ended December 31, 2021, 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/ Karim Mikhail

Date: March 1, 2022

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

/s/ Michael W. Kalb

Date: March 1, 2022

Michael W. Kalb
Senior 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.