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, 2019

OR

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

For the transition period from to

Commission File No. 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

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 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, 2019 was approximately $6,371.7 million, based upon the closing price on the NASDAQ Capital Market reported for such date.

361,201,553 shares were outstanding as of February 21, 2020, including 360,999,820 shares held as American Depositary Shares (ADSs), each representing one Ordinary Share, 50 pence par value per share and 201,733 Ordinary Shares. In addition, 28,931,746 ordinary share equivalents were issuable in exchange for outstanding preferred shares as of February 21, 2020, for a total of 390,133,299 ordinary shares and ordinary share equivalents outstanding as of February 21, 2020.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information required to be disclosed in Part III of this report 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 report.

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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 Vascepa and factors that can affect such success; plans to expand promotion of Vascepa; interpretation of court decisions; expectation on determinations and policy positions of the United States Food and Drug Administration, or 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 report 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 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 with expertise in omega-3 fatty acids and lipid science focused on the commercialization and development of therapeutics to improve cardiovascular, or CV, health and reduce CV risk. Our lead product, Vascepa® (icosapent ethyl) was first approved by the U.S. Food and Drug Administration, or 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. On December 13, 2019, the FDA approved a new indication and label expansion for Vascepa based on the landmark results of our cardiovascular outcomes trial of Vascepa, REDUCE-IT® (Reduction of Cardiovascular Events with EPA – Intervention Trial). Vascepa is the first and only drug approved by the FDA as an adjunct to maximally tolerated statin therapy for reducing persistent cardiovascular risk in select high risk patients.

Since our inception, we have devoted substantial resources to our research and development efforts, most significantly, the development and conduct of our long-term cardiovascular outcomes study of Vascepa, REDUCE-IT. We announced topline results from REDUCE-IT on September 24, 2018. On November 10, 2018, we presented primary results of REDUCE-IT 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.

Based on REDUCE-IT results, several clinical treatment guidelines and position statements have been updated as follows:

- In March 2019, the American Diabetes Association, or ADA, issued important updates to the Standard of Medical Care in Diabetes for 2019, including a recommendation for the use of icosapent ethyl in treating at-risk patients based on the results of the REDUCE-IT cardiovascular outcomes study.
- In August 2019, the AHA recognized the results of REDUCE-IT and recommended directing medical care away from unproven fish oil dietary supplements and to prescription drug therapy in patients with elevated TG levels.
- In September 2019, the National Lipid Association issued a position statement recognizing the cardiovascular risk-lowering effects of icosapent ethyl based on the REDUCE-IT results.
- In September 2019, the European Society of Cardiology and the European Atherosclerosis Society updated their Clinical Practice Guidelines for the Management of Dyslipidemias to incorporate findings from the REDUCE-IT study.
- In February 2020, the American Association of Clinical Endocrinologists and the American College of Endocrinology released a consensus statement on the comprehensive management of type 2 diabetes. The statement included new guidance for managing patients with established or high risk for cardiovascular disease who have triglyceride levels between 135 – 499 mg/dL with icosapent ethyl which has proven benefits to prevent the next adverse cardiovascular event.

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. ICER's report indicated that Vascepa was cost effective across all of the non-profit organization's analyses, including its quality-adjusted life year metrics of <$50,000. The conclusion from the report is that Vascepa easily meets "commonly cited thresholds for cost-effectiveness and therefore represents a high long-term value for money" based on the organization's value assessment framework. In addition, an independent academic, patient-level, cost-effectiveness analysis of icosapent ethyl led by Dr. William S. Weintraub, M.D., director of Outcomes Research with MedStar Cardiovascular Research Network, indicated that Vascepa was projected to not only be cost-effective but also to reduce long-term health care costs in a majority of the scenarios analyzed.

The 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 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, 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 FDA approved a new indication and related label expansion based on REDUCE-IT. Vascepa is the first and only drug approved by the 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 triglyceride, or 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 over 50 million adults in the United States have elevated triglyceride levels ≥150 mg/dL. 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 initial drug approval from 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 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 low-density lipoprotein, or 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. Worldwide, cardiovascular disease, or CVD, remains the number one killer of men and women. In the United States, CVD leads to one in every three deaths —one death approximately every 38 seconds—with annual treatment cost in excess of $500.0 billion.

Commercialization

We commenced the commercial launch of Vascepa in the United States in January 2013. We sell 1-gram and 0.5-gram capsule sizes of Vascepa principally to a limited number of major wholesalers, as well as selected regional wholesalers and specialty pharmacy providers, or collectively, our distributors or our customers, that in turn resell Vascepa to retail pharmacies for subsequent resale to patients and healthcare providers.

Prior to results of the REDUCE-IT study, we did not have cardiovascular outcomes data regarding the clinical effect of Vascepa and a substantial portion of our resources were being spent on the REDUCE-IT study. As a result, our commercialization of Vascepa was somewhat limited. Subsequent to learning the positive cardiovascular outcomes results of the REDUCE-IT study, we have increased our promotional efforts.

Prior to the REDUCE-IT results topline announcement in September 2018, our direct sales force consisted of approximately 170 sales professionals, including sales representatives and their managers. Based on the positive REDUCE-IT results, in early 2019, we increased the size of our sales team to approximately 440 sales professionals, including approximately 400 sales representatives. As a result of the FDA's newly approved indication and label expansion, we are close to completing the expansion of our direct sales force to approximately 900 sales professionals, including approximately 800 sales representatives. Hiring, training and deploying approximately 400 new sales representatives is a multi-stage process which commenced in July 2019 and is expected to be completed in early 2020. Most of the expanded sales management team needed to support this sales force expansion was hired, or internally promoted, and trained prior to December 31, 2019.

We also employ various medical affairs and marketing personnel to support our commercialization of Vascepa. We expanded certain medical education and market awareness initiatives following the reporting of positive REDUCE-IT results in 2018. We intend to further expand promotion of Vascepa, including direct to consumer advertising, as a result of the new indication and label expansion of Vascepa approved by the FDA on December 13, 2019. Our field sales efforts are further complemented by investments in digital and non-personal channels as well as peer-to-peer (e.g., promotional medical education programs and product theaters) initiatives to further increase Vascepa brand awareness and clarify Vascepa's unique clinical profile. In January 2020, we launched an educational campaign, *True To Your Heart*, to help people learn more about cardiovascular disease and how to better protect against persistent cardiovascular risk.

In addition to promotion of Vascepa in the United States, based on REDUCE-IT, we have increased focus on expansion of our development efforts for Vascepa to major markets outside the United States. We currently have strategic collaborations to develop and commercialize Vascepa in select territories outside the United States. In February 2015, we announced an exclusive agreement with Eddingpharm (Asia) Macao Commercial Offshore Limited, or Eddingpharm, to develop and commercialize Vascepa capsules in what we refer to as the China Territory, consisting of the territories of Mainland China, Hong Kong, Macau and Taiwan, for uses that are currently commercialized and under development by us in the United States. In March 2016, we entered into an agreement with Biologix FZCo, or Biologix, to register and commercialize Vascepa in several Middle Eastern and North African countries. In September 2017, we entered into an agreement with HLS 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 granted priority review status for the New Drug Submission, which was filed in April 2019, for Vascepa. In December 2019, HLS received formal confirmation from Health Canada that the Canadian regulatory authority granted approval for Vascepa to reduce the risk of cardiovascular events (cardiovascular death, non-fatal myocardial infarction, non-fatal stroke, coronary revascularization or hospitalization for unstable angina) in statin-treated patients with elevated triglycerides, who are at high risk of cardiovascular events

due to: established cardiovascular disease, or diabetes, and at least one other cardiovascular risk factor. In January 2020, HLS obtained a regulatory exclusivity designation. In 2020, we intend to explore potential development and commercial paths for Vascepa in other markets such as the European Union. In December 2019, the European Medicines Agency, or EMA, validated our marketing authorization application, or MAA, seeking approval for Vascepa in the European Union. This validation confirms the submission is sufficiently complete for the EMA to begin its review, which review is currently expected to be completed before the end of 2020.

We plan to assess other potential partnership opportunities for licensing Vascepa to partners outside of the United States as we seek to maximize the value of the Vascepa franchise globally.

Research and Development

Since our inception, we have devoted substantial resources to the research and development of Vascepa capsules. Vascepa is a single-molecule prescription product consisting of the omega-3 acid commonly known as EPA in ethyl-ester form. Vascepa is derived from fish through a stringent and complex FDA-regulated manufacturing process designed to effectively eliminate impurities and isolate and protect the single molecule active ingredient from degradation. Vascepa was designated as a new chemical entity by the FDA. Vascepa is known in scientific literature as AMR101.

Our most important clinical trials of Vascepa are summarized here and discussed in further detail below:

- The REDUCE-IT trial, a Phase 3 global study of 8,179 statin-treated adults with elevated cardiovascular risk with a primary endpoint being the first occurrence of MACE in the intent-to-treat patient population, patients with LDL-C between 41-100 mg/dL (median baseline LDL-C 75 mg/dL) controlled by statin therapy and various cardiovascular risk factors including persistent elevated TG between 135-499 mg/dL 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);
- The MARINE trial, a Phase 3, multi-center, placebo-controlled, randomized, double-blind, 12-week study in patients with very high (≥500 mg/dL) TGs with the primary endpoint being the lowering of TG levels; and
- The ANCHOR trial, a Phase 3 multi-center, placebo-controlled, randomized, double-blind, 12-week pivotal study in patients with high (≥200 and <500 mg/dL) TGs who were also receiving optimized statin therapy with the primary endpoint being the lowering of TG levels.

The REDUCE-IT cardiovascular outcomes study of Vascepa has been the centerpiece of our research and development efforts. Prior research on Vascepa, such as the MARINE and ANCHOR trials, had been focused on the effects of the drug on biomarkers associated with increased risk of pancreatitis and increased risk of cardiovascular events. Other prior and ongoing research and development efforts include the study of potential mechanisms of action of Vascepa.

The REDUCE-IT study was conducted based on a special protocol assessment, or SPA, agreement with the FDA. Based on the final positive results of REDUCE-IT, we sought additional indicated uses for Vascepa in the United States. Based on REDUCE-IT, we are also pursuing additional approvals for Vascepa around the world. We 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*. Potential additional research and development opportunities beyond REDUCE-IT will be prioritized after giving priority to securing regulatory approval for Vascepa based on the REDUCE-IT results in various geographies internationally, including pursuit of approval for Vascepa in Europe and in countries where we have commercialization partners for Vascepa.

We are also developing other products based on the active pharmaceutical ingredient in Vascepa, the ethyl ester form of the omega-3 acid, eicosapentaenoic acid, or EPA. 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. In January 2020, we achieved certain milestones under the agreement, resulting in payment of $1.0 million to Mochida.

Additional research and development opportunities beyond REDUCE-IT will continue to be assessed.

Commercial and Clinical Supply

We manage the manufacturing and supply of Vascepa internally and have done so since we began clinical development of Vascepa prior to the drug's marketing approval by FDA in 2012. We rely on contract manufacturers in each step of our commercial and clinical product supply chain. These steps include active pharmaceutical ingredient, or API, manufacturing, encapsulation of the API, product packaging and supply-related logistics. Our approach to product supply procurement is designed to mitigate risk of supply interruption and maintain an environment of cost competition through diversification of contract manufacturers at each stage of the supply chain and lack of reliance on any single supplier. We have multiple FDA-approved international API suppliers, encapsulators and packagers to support the Vascepa commercial franchise. The amount of supply we seek to purchase in future periods will depend on the level of growth of Vascepa revenues and minimum purchase commitments with certain suppliers. While our current supply chain is scalable, we continue efforts to expand, diversify and further enhance it.

Lipid Disorders and Cardiovascular Disease

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—2019 Update* from the American Heart Association, CVD is the underlying cause of death in approximately 1 out of every 3 deaths. Approximately 121 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 occur each year. An estimated 29 million adults ≥20 years of age have high total serum cholesterol levels (≥240 mg/dL), and an estimated 71 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 2020 Heart and Stroke Statistics from the AHA, 45.1% 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 $748.7 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 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 FDA as an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, 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 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 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.

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.

Limitations of Current Therapies

Hypertriglyceridema, or 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 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 FDA-approved TG-lowering therapies.

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.

Potential Benefits and Market Opportunity for Vascepa

Vascepa is 1-gram of icosapent ethyl, or ethyl-EPA, and contains no DHA. 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. More study is needed to 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.

Clinical Trials

The REDUCE-IT Study (basis for new FDA approved indication and label expansion)

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 FDA on a SPA for the design of the REDUCE-IT cardiovascular outcomes study. A SPA is an evaluation by the 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 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. A SPA is generally binding upon the 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 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. Amarin 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 triglycerides, or 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 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 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 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 FDA approved a new indication and label expansion for Vascepa capsules. Vascepa is the first and only drug approved by the 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.

The MARINE Trial (first FDA-approved label for Vascepa)

The MARINE trial, the 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 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 g/day and 2 g/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 (promoted in the United States under court declaration)

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 FDA-approved label for Vascepa.

In April 2015, we received a Complete Response Letter, or CRL, from the FDA in response to our supplemental new drug application, or 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 FDA of a SPA agreement and three failed attempts by us to appeal that rescission at FDA. The FDA has acknowledged the success of the ANCHOR study, which met all primary and secondary endpoints. However, FDA determined that there were insufficient data to conclude that drug-induced changes in serum triglycerides could be recognized by the 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 FDA has acknowledged that the standard of proof required by the 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 FDA did not determine that the drug-induced effects of Vascepa, which go beyond triglyceride-lowering, would not actually reduce cardiovascular risk in this population.

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, FDA-approved labeling for the drug. Historically, FDA has considered promotion of drug uses not covered by 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 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 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 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.

Observed Efficacy of Ethyl-EPA

In Japan, ethyl-EPA is marketed under the product name of Epadel by 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.

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 have been 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 eight million estimated normalized total prescriptions of Vascepa have been reported by Symphony Health.

New Lipid Compounds and Other Preclinical Programs

We are also considering development of other next generation compounds based on our internal lipid science expertise, including potential combination and derivative therapies.

In August 2013, we completed dosing of AMR102, a fixed dose combination of Vascepa and a leading statin product. The study is a randomized, open-label, single-dose, 4-way cross-over study to continue testing of the relative bioavailability of AMR102 capsules, Vascepa capsules with the selected statin taken concomitantly, Vascepa taken alone and the selected statin taken alone. The results of this study support the feasibility of AMR102. We have suspended additional development of AMR102 while we focus on commercializing the expanded indication of Vascepa; however, we will continue to evaluate these types of opportunities over time.

We believe that Vascepa and other lipid-based compositions may have an impact on a number of biological factors in the body such as anti-inflammatory mechanisms, cell membrane composition and plasticity, triglyceride levels and regulation of glucose metabolism. Currently all other development activities are at formulation or pre-clinical stages.

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 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 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 FDA has approved several international large-scale API manufacturers, global encapsulation leaders and two U.S.-based packagers for use in the manufacturing of Vascepa. All of our manufacturing facilities were approved by the FDA following successful preapproval inspections and they remain active manufacturers of Vascepa under FDA authority.

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. Among the conditions for 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 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.

Some of our agreements with our API suppliers are exclusive and include minimum purchase commitments. During 2019, 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.

Our Commercialization Plans

We commenced the commercial launch of Vascepa in the United States in January 2013. In October 2016, in addition to the original 1-gram capsule size for Vascepa, we introduced a smaller 0.5-gram capsule size, the first and only 0.5-gram prescription omega-3 alternative available on the market, for the subset of patients who prefer a smaller capsule. The FDA-approved dosing for Vascepa is 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. We sell the 1-gram and 0.5-gram capsule sizes of Vascepa principally to a limited number of major wholesalers, as well as selected regional wholesalers and specialty pharmacy providers, or collectively, our distributors or our customers, that in turn resell Vascepa to retail pharmacies for subsequent resale to patients and healthcare providers.

We currently market Vascepa in the United States through our direct sales force. We currently target clinicians who are top prescribers of lipid-regulating therapies, including statins. Prior to the REDUCE-IT results topline announcement in September 2018, our direct sales force consisted of approximately 170 sales professionals, including sales representatives and their managers. Based on the positive REDUCE-IT results, in early 2019, we increased the size of our sales team to approximately 440 sales professionals, including approximately 400 sales representatives. As a result of the FDA's newly approved indication and label expansion, we are close to completing the expansion of our direct sales force to approximately 900 sales professionals, including approximately 800 sales representatives. Hiring, training and deploying approximately 400 new sales representatives is a multi-stage process which commenced in July 2019 and is expected to be completed in early 2020. Most of the expanded sales management team needed to support this sales force expansion was hired, or internally promoted, and trained prior to December 31, 2019.

From May 2014 through December 2018, in addition to Vascepa promotion by our sales representatives, Kowa Pharmaceuticals America, Inc. co-promoted Vascepa in the United States in conjunction with its promotion of its primary product, a branded statin for patients with high cholesterol. This co-promotion reached its mutually agreed upon termination date in December 2018. During 2018, as a result of not renewing the agreement, we incurred expense for the accrual of co-promotion tail payments, which were calculated as a percentage of the 2018 co-promotion fee. Kowa Pharmaceuticals America, Inc. will receive $17.8 million in co-promotion tail payments, the present value of which, $16.6 million, was fully accrued as of December 31, 2018 and will be paid over three years with declining amounts each year. We made $7.3 million in tail payments as of December 31, 2019.

We also employ various medical affairs and marketing personnel to support our commercialization of Vascepa. We expanded certain medical education and market awareness initiatives, including, pilot testing of new promotional initiatives following the reporting of positive REDUCE-IT results in 2018 and we intend to further expand such initiatives based on the newly approved indication and label expansion of Vascepa. Our field sales efforts are further complemented by investments in digital and non-personal channels as well as peer-to-peer (e.g., promotional medical education programs and product theaters) initiatives to further increase Vascepa brand awareness and clarify Vascepa's unique clinical profile. In January 2020, we launched an educational campaign, *True To Your Heart*, to help people learn more about cardiovascular disease and how to better protect against persistent cardiovascular risk.

Since commercial launch of Vascepa in January 2013, we have promoted Vascepa based on the MARINE clinical trial data as reflected in the first 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 FDA-reviewed and agreed effects of Vascepa demonstrated in the ANCHOR clinical trial. 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 new indication and label expansion.

The datasets from the clinical development of Vascepa are large, representing greater than 35,000 patient years of study. Additionally, the list of prespecified endpoints evaluated in support of the REDUCE-IT sNDA was extensive. We submitted an sNDA to the FDA in the United States in March 2019 seeking approval to expand the label for Vascepa based on the effects of Vascepa demonstrated in the REDUCE-IT study. On December 13, 2019, the FDA approved a new indication and label expansion for Vascepa capsules. Vascepa is the first and only drug approved by the FDA as an adjunct to maximally tolerated statins 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.

Throughout 2019, we continued an efficient expansion of our commercial activities and capabilities directed primarily toward targeted providers and payor decision-makers. We brought the results of REDUCE-IT to healthcare providers and payors, in a manner we believed was both truthful and non-misleading and consistent with an August 2015 federal district court declaration and related March 2016 settlement with the FDA. Thus, we directly connected Vascepa with the REDUCE-IT data for these target audiences, in advance of having a new label. Further, now that a new FDA- approved cardiovascular risk reduction indication has been granted in the United States, we expect to deploy a direct to consumer campaign in 2020 consistent with the expanded U.S. label.

Based on monthly compilations of data provided by a third party, Symphony Health, the estimated number of normalized total Vascepa prescriptions for the three months ended December 31, 2019 was approximately 992,000 compared to 865,000, 756,000, 618,000, and 539,000 in the three months ended September 30, 2019, June 30, 2019, March 31, 2019, and December 31, 2018, respectively. According to data from another third party, IQVIA, the estimated number of normalized total Vascepa prescriptions for the three months ended December 31, 2019 was approximately 909,000 compared to 787,000, 683,000, 553,000, and 492,000 in the three months ended September 30, 2019, June 30, 2019, March 31, 2019, and December 31, 2018, respectively. Normalized total prescriptions represent the estimated total number of Vascepa prescriptions dispensed to patients, calculated on a normalized basis (i.e., one month's supply, or total capsules dispensed multiplied by the number of grams per capsule divided by 120 grams). Inventory levels at wholesalers tend to fluctuate based on seasonal factors, prescription trends and other factors.

Companies such as Symphony Health and IQVIA collect and report estimates of weekly, monthly, quarterly and annual prescription information. There is a limited amount of information available to such companies to determine the actual number of total prescriptions for prescription products like Vascepa during such periods. Each vendor's estimates utilize a proprietary projection methodology and are based on a combination of data received from pharmacies and other distributors, and historical data when actual data is unavailable. Their calculations of changes in prescription levels between periods can be significantly affected by lags in data reporting from various sources or by changes in pharmacies and other distributors providing data. Such methods can from time to time result in significant inaccuracies in information when ultimately compared with actual results. These inaccuracies have historically been most prevalent and pronounced during periods of time of inflections upward or downward in rates of use. Further, data for a single and limited period may not be representative of a trend or otherwise predictive of future results. Data reported by Symphony Health and IQVIA is rarely identical. As such, the resulting conclusions from such sources should be viewed with caution. We are not responsible for the accuracy of these companies' information and we do not receive prescription data directly from retail pharmacies.

We sell Vascepa principally to a limited number of major wholesalers, as well as selected regional wholesalers and specialty pharmacy providers in the United States, that in turn resell Vascepa to retail pharmacies for subsequent resale to patients and healthcare providers. We recognize revenue from product sales when the distributor obtains control of our product, which occurs at a point in time, typically upon delivery to the distributor. Timing of shipments to wholesalers, as used for revenue recognition purposes, and timing of prescriptions as estimated by these third parties may differ from period to period. Although we believe these data are prepared on a period-to-period basis in a manner that is generally consistent and that such results can be generally indicative of current prescription trends, these data are based on estimates and should not be relied upon as definitive. While we expect to be able to grow Vascepa revenues over time, no guidance should be inferred from the operating metrics described above. We also anticipate that such sales growth will be inconsistent from period to period. We believe that investors should view the above-referenced operating metrics with caution, as data for this limited period may not be representative of a trend consistent with the results presented or otherwise predictive of future results. Seasonal fluctuations in pharmaceutical sales, for example, may affect future prescription trends of Vascepa, as could changes in prescriber sentiment, quarterly changes in distributor purchases, and other factors. We believe investors should consider our results over several quarters, or longer, before making an assessment about potential future performance.

The commercialization of pharmaceutical products is a complex undertaking, and our ability to effectively and profitably commercialize Vascepa will depend in part on our ability to generate market demand for Vascepa through education, marketing and sales activities, our ability to achieve market acceptance of Vascepa, our ability to generate product revenue and our ability to receive adequate levels of reimbursement from third-party payers. See "*Risk Factors—Risks Related to the Commercialization and Development of Vascepa*."

Outside of the United States, we have expanded our commercialization activities through partnering arrangements in certain territories. In February 2015, we entered into a Development, Commercialization and Supply Agreement, or the DCS Agreement, with Eddingpharm related to the development and commercialization of Vascepa in the China Territory. Under the DCS Agreement, Eddingpharm will be solely responsible for development and commercialization activities in the China Territory and associated expenses. Additionally, Eddingpharm is required to conduct clinical trials in the China Territory to secure regulatory approval in certain territories. For example, in December 2017, Eddingpharm commenced a pivotal clinical trial aimed to support the regulatory approval of the first indication of Vascepa in a patient population with severe hypertriglyceridemia in Mainland China. Additional clinical development efforts are necessary in certain segments of this market. If Eddingpharm is not able to effectively develop and commercialize Vascepa in the China Territory, we may not be able to generate revenue from the DCS Agreement resulting from the sale of Vascepa in the China Territory.

In March 2016, we entered into an agreement with Biologix 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 in Lebanon in March 2018, in United Arab Emirates in July 2018 and in Qatar in January 2020. 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 MENA region. Commercialization across the Middle East and North Africa is subject to similar risks as in the China Territory.

In September 2017, we entered into an agreement with 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. Commercial launch in Canada began in February 2020 on a limited scale with subsequent expansion intended. If HLS Therapeutics 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.

In December 2019, the EMA validated the marketing authorization application seeking approval for Vascepa. The validation confirms the submission is sufficiently complete for the EMA to begin its review, which is currently expected to be completed before the end of 2020. Commercialization across Europe is several years away, if at all.

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

Competition

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

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

In addition, in May 2014, Epanova® (omega-3-carboxylic acids) capsules, a free fatty acid form of omega-3 (comprised of 55% EPA and 20% DHA), was approved by the FDA for patients with severe hypertriglyceridemia. Epanova was developed by Omthera Pharmaceuticals, Inc., and is now owned by AstraZeneca Pharmaceuticals LP (AstraZeneca). Also, in April 2014, Omtryg, another omega-3-acid fatty acid composition developed by Trygg Pharma AS, received FDA approval for severe hypertriglyceridemia. Neither Epanova nor Omtryg have been commercially launched, but could launch at any time. AstraZeneca has greater resources than we do, including financial, product development, marketing, personnel and other resources.

AstraZeneca had been conducting a long-term outcomes study to assess Statin Residual Risk Reduction With EpaNova in HiGh Cardiovascular Risk PatienTs With Hypertriglyceridemia (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 end the STRENGTH trial due to its low likelihood of demonstrating benefit to studied patients, i.e., patients with mixed dyslipidemia who were at increased risk of cardiovascular disease. AstraZeneca also stated that full data from the STRENGTH trial will be presented at a future medical meeting. 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 (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 UK cohort of over 15,000 individuals with diabetes who do not have atherosclerotic cardiovascular disease.

In a meta-analysis, presented in 2018 by the Cochran Foundation and separately as published in JAMA, additional omega-3 studies were evaluated. Similar to the VITAL and ASCEND studies, most of the studies in these omega-3 meta-analyses were of omega-3 mixtures, including DHA, and most were studies of relatively low doses of omega-3 as is associated with dietary supplementation and/or they studied relatively low risk patient populations. The exception was the JELIS study, conducted in Japan, of highly pure EPA which 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.

We are also aware of other pharmaceutical companies that are developing products that, if successfully developed, approved and marketed, would compete with Vascepa. Acasti Pharma, or Acasti, a subsidiary of Neptune Technologies & Bioresources Inc., announced in December 2015 that it intends to pursue a regulatory pathway under section 505(b)(2) of the FDCA for its omega-3 prescription drug candidate, CaPre® (omega-3 phospholipid), derived from krill oil, for the treatment of hypertriglyceridemia. In September 2016, Acasti announced positive results from its pivotal bioavailability bridging study comparing CaPre to Lovaza, establishing a scientific bridge between the two that is expected to support the feasibility of a 505(b)(2) regulatory pathway. In the first quarter of 2018, Acasti initiated a Phase 3 clinical program (TRILOGY 1 & 2) to assess the safety and efficacy of CaPre in patients with very high (≥500 mg/dL) triglycerides. In January 2020, Acasti announced topline results of the TRILOGY 1 trial of CaPre. The study did not reach statistical significance and further analysis is underway. In February 2020, Acasti announced their intention to request a meeting with the FDA to discuss the TRILOGY 1 data and will seek guidance about how to conduct the analysis of the TRILOGY 2 data. As a result, Acasti also stated that they expect to announce topline results of TRILOGY 2 in the third quarter of 2020. NDA submission (if any) and resultant review/approval timelines will be announced following completion of TRILOGY 1 and 2 data analysis. We believe Micelle BioPharma Inc., or Micelle, is also developing potential treatments for hypertriglyceridemia based on omega-3 fatty acids. To our knowledge, Micelle, after acquiring SC401 from Sancilio & Company, or Sancilio, is pursuing a regulatory pathway under section 505(b)(2) of the FDCA for its product and submitted an Investigational New Drug Application, or IND, in July 2015. Micelle (Sancilio) completed two pharmacokinetic studies and Phase 2 bioavailability studies (FASTR I&II), with one comparing SC401 to Lovaza. We expect the company or a potential partner to initiate a pivotal clinical Phase 3 study as the next step in development.

Matinas BioPharma, Inc., or Matinas, is developing an omega-3-based therapeutic, or MAT9001, for the treatment of severe hypertriglyceridemia and mixed dyslipidemia. In the fourth quarter of 2014, Matinas filed an IND with the FDA to conduct a human study in the treatment of severe hypertriglyceridemia and, in June 2015, the company announced topline results for its head-to-head comparative short duration pharmacokinetic and pharmacodynamic study of MAT9001 versus Vascepa in patients under conditions inconsistent with the FDA-approved label for Vascepa and presented results based on biomarker modification without outcomes data. In September 2017, Matinas announced that it will be seeking a partner company to develop and commercialize MAT9001. In March 2019, Matinas announced that net proceeds from a public offering of common stock would be used for development activities for MAT9001. In September 2019, Matinas announced that it will begin a comparative clinical bridging bioavailability study in the fourth calendar quarter of 2019, with expected completion in the first half of 2020, and has planned an additional Phase 2 head-to-head pharmacokinetic and pharmacodynamic study, or ENHANCE-IT, against Vascepa in patients with elevated triglycerides (150-499 mg/dL). Patient enrollment is expected to commence in early 2020, with topline data expected in the fourth quarter of 2020. Matinas anticipates initiating a Phase 3 placebo-controlled study of MAT9001 in statin-treated patients with high risk hypertriglyceridemia by the end of 2020. We are not aware if or when Matinas intends to conduct a cardiovascular outcomes study of MAT9001.

In June 2018, Gemphire Therapeutics (renamed NeuroBo Pharmaceuticals, Inc. following completion of a merger on December 31, 2019) 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 FDA requested that Gemphire conduct an additional long-term toxicity study before commencing any further clinical testing, thereby effectively placing gemcabene on clinical hold. Gemphire expects to submit a request to the FDA to lift the clinical hold in the first quarter of 2020. 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.

Afimmune Ltd. has an oral, small molecule drug candidate, epeleuton, or DS-102, in development for a number of conditions of the liver and lung, including severe hypertriglyceridemia, Phase 2 clinical trials are currently ongoing for non-alcoholic fatty liver disease, or NAFLD, and chronic obstructive pulmonary disease, or COPD, 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.

Based on prior communications from the FDA, including communications in connection with its review of the ANCHOR indication for Vascepa, it is our understanding that the FDA is not prepared to approve any therapy for treatment of cardiovascular risk based on biomarker modification without outcomes study data, with the potential exception of therapies which lower LDL-cholesterol. In particular, it is our understanding that the FDA is not prepared to approve any therapy based primarily on data demonstrating lowering of triglyceride levels. In our view, this position from the 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 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 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 FDA-approved, prescription-only status, and EPA-only purity and stability of Vascepa or FDA's stringent regulatory oversight, as significant advantages versus omega-3 dietary supplements regardless of clinical study results and other scientific data.

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 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 the FDA through the NDA process before they are first marketed in the United States. 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

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 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 FDA's Good Laboratory Practices regulations, or GLP, and an investigational new drug application, or IND, is filed with the 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 FDA prior to commencement of a clinical trial. If the 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.

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 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 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 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 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 FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

After the 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 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 FDA may ultimately decide that the NDA does not satisfy the criteria for approval.

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

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

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

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

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.

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 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 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 regulatory body and 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.

Post-Marketing Requirements

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 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 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 FDA regulates prescription drug promotion, including direct-to-consumer advertising. Prescription drug promotional materials must be submitted to the 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 FDA. The 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 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 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.

Federal and State Fraud and Abuse Laws and Data Regulation

In addition to 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.

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 FCA 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 CMS information related to direct or indirect payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held in the company by physicians and their immediate family members. Beginning on January 1, 2022, applicable manufacturers also will be required to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives.

Many foreign countries and the majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers. 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 will commence enforcement actions against violators beginning 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 European Economic Area, or 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, 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, the United Kingdom's exit of the EU, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. Pursuant to Article 50 of the Lisbon Treaty, the United Kingdom ceased being a Member State of the EU on January 31, 2020. However, the terms of the withdrawal have yet to be fully negotiated. The implementation period began February 1, 2020 and will continue until December 31, 2020. In particular, it is unclear how data transfers to and from the United Kingdom will be regulated following the completion of the withdrawal.

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, disorgnment, 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.

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. For example, since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the Affordable Care Act. On January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. On October 13, 2017, President Trump signed an Executive Order terminating the cost-sharing subsidies that reimburse insurers under the ACA. The Trump administration has 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. The effects of this gap in reimbursement on third-party payors, the viability of the ACA marketplace, providers, and potentially our business, are not yet known. In December 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. CMS also published a final rule that would give states greater flexibility, starting in 2020, in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.

Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the Affordable Care Act 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. Pending review, the ACA remains in effect, but it is unclear at this time what effect the latest ruling will have on the status of the ACA.

Further, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act 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 January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices; however, on December 20, 2019, President Trump signed into law the Further Consolidated Appropriations Act (H.R. 1865), which repeals the Cadillac tax, the health insurance provider tax, and the medical device excise tax. 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 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 the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services. 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 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, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals for spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction, which triggered the legislation's automatic reductions. In concert with subsequent legislation, this has resulted in aggregate reductions to Medicare payments to providers of, on average, 2% per fiscal year through 2029 unless Congress takes additional action. 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.

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. For example, at the federal level, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. The Trump administration's budget for fiscal years 2020 and 2021 contain further drug price control measures that could be enacted during the budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low income patients.

While some proposed measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. For example, on September 25, 2019, the Senate Finance Committee introduced the Prescription Drug Pricing Reduction Action of 2019, a bill intended to reduce Medicare and Medicaid prescription drug prices. The proposed legislation would restructure the Part D benefit, modify payment methodologies for certain drugs, and impose an inflation cap on drug price increases. An even more restrictive bill, the Lower Drug Costs Now Act of 2019, was introduced in the House of Representatives on September 19, 2019, and would require the Department of Health and Human Services, or HHS, to directly negotiate drug prices with manufacturers. The Lower Drugs Costs Now Act of 2019 has passed out of the House and was delivered to the Senate on December 16, 2019. However, it is unclear whether either of these bills will make it through both chambers and be signed into law, and if either is enacted, what effect it would have on our business. 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.

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. NCE marketing exclusivity precludes approval during the five-year exclusivity period of certain 505(b)(2) applications and abbreviated new drug applications, or 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 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, 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 from 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 FDA from approving a marketing application for an ANDA, a product candidate that the FDA views as having the same conditions of approval as Vascepa (for example, the same indication and/or other conditions of use), or a 505(b)(2) NDA submitted to the FDA with Vascepa as the reference product, for a period of three years from the date of FDA approval. The FDA may accept and commence review of such applications during the three-year exclusivity period. Such three-year exclusivity grant does not prevent a company from challenging the validity of patents at any time, subject to any prior four-year period pending from a grant of five-year exclusivity. This three-year form of exclusivity may also not prevent the FDA from approving an NDA that relies only on its own data to support the change or innovation.

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

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 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 FDA and other requirements, new information regarding the safety or effectiveness of a product could lead the FDA to modify or withdraw a product approval. 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 report, we had 92 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 92 allowed and issued applications include the following:

- 2 issued U.S. patents directed to a pharmaceutical composition of Vascepa in a capsule that have terms that expire in 2020 and 2030, respectively;
- 1 issued U.S. patent covering a composition containing highly pure EPA that expires in 2021;
- 49 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;
- 14 U.S. patents covering or related to the use of Vascepa in the REDUCE-IT population with terms expiring in 2033 or later;
- 1 additional US patent directed to a pharmaceutical composition comprised of free fatty acids with a term that expires in 2030;
- 4 additional patents related to the use of a pharmaceutical composition comprised of free fatty acids to treat the ANCHOR patient population with a term that expires in 2030 or later;
- 2 additional patents related to the use of a pharmaceutical composition comprised of free fatty acids to treat the MARINE patient population with a term that expires in 2030;
- 3 additional patents related to the use of a pharmaceutical composition comprised of free fatty acids to treat the REDUCE-IT population expiring 2033;
- 3 additional patent related to a pharmaceutical composition comprised of free fatty acids and uses thereof to treat both the MARINE and ANCHOR patient populations with a term that expires in 2030;
- 1 additional patent related to the use of a pharmaceutical composition comprised of re-esterified EPA triglyceride to treat the REDUCE-IT population expiring 2033;
- 3 additional patents related to a formulation of EPA/DHA and uses thereof with a term that expires in 2030;
- 2 additional patents related to the use of Vascepa to treat obesity with a term that expires in 2034;
- 3 additional patents covering a pharmaceutical composition comprised of EPA and a hydroxyl compound with a term that expires in 2034; and
- 4 additional patents covering a new combination therapy comprised of EPA and another drug.

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

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

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

Although we intend to make reasonable efforts to protect our current and future intellectual property rights and to ensure that any proprietary technology we acquire or develop does not infringe 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.

Employees

At February 21, 2020, we had 965 full-time employees employed in sales, marketing, general and administrative and research and development functions. We believe our relations with our employees are good.

Organizational Structure

At February 21, 2020, 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%
Amarin Neuroscience Limited	Scotland	100%
Corsicanto II DAC	Ireland	100%
Ester Neurosciences Limited	Israel	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., with little to no operating activity being conducted by Amarin Neuroscience Limited or Ester Neurosciences Limited. Corsicanto DAC (formerly Corsicanto Limited) was liquidated in January 2019 pursuant to a resolution of Amarin Corporation plc as a sole shareholder. Corsicanto II DAC was placed into liquidation in September 2019 pursuant to a resolution of Amarin Corporation plc as a sole shareholder.

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, 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, 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.

Risks Related to the Commercialization and Development of Vascepa

We are substantially dependent upon Vascepa, its commercialization in the United States and its development and commercialization in major markets.

The success of our company depends on our ability to successfully commercialize our single product, Vascepa® (icosapent ethyl) capsules, in major markets. Our primary focus has been on the U.S. market as much of our near-term results and value as a company has depended on our ability to execute our development commercial strategy for Vascepa in the United States. Recently, with substantial achievements in the United States such as the FDA approval of an indication for Vascepa for the reduction of cardiovascular risk in certain patients (our second indication approval for Vascepa in the United States), we have increased focus on expansion of our development efforts for Vascepa to major markets outside the United States. We currently have multiple partners for the development and commercialization of Vascepa in select geographies and intend to consider potential additional 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 and are currently developing Vascepa on our own and exploring possible strategic collaborations in major markets such as Europe. If commercialization efforts 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, only after years of preceding product development, in December 2019, the EMA validated our MAA seeking approval for icosapent ethyl (brand name Vascepa in the United States) as a treatment to reduce the risk of cardiovascular events in select high-risk patients.

Likewise, if we seek to diversify our development programs or product offerings through licensing or acquisitions, such transactions are also time-consuming, dilutive to existing shareholdings, and can be disruptive to operations. These dynamics can restrict our ability to respond rapidly to adverse business conditions for Vascepa. If 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.

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.

In January 2013, we launched Vascepa based on the U.S. Food and Drug Administration, or FDA, approval of our MARINE indication, for use as an adjunct to diet to reduce triglyceride levels in adult patients with severe (TG ≥500 mg/dL) hypertriglyceridemia. Guidelines for the management of very high triglyceride levels suggest that the primary goal of reducing triglyceride levels in this patient population is reduction in the risk of acute pancreatitis. A secondary goal for this patient population is to reduce cardiovascular risk. The effect of Vascepa on cardiovascular mortality and morbidity, or the risk for pancreatitis, in patients with severe hypertriglyceridemia has not been determined and our FDA-approved labeling and promotional efforts state these facts. In September 2018, we announced topline results from the REDUCE-IT® (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 FDA-approved labeling.

In December 2019, the FDA approved a new 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 we have recently received approval for a new 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 new approved use. 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 perceived efficacy and safety of Vascepa by prescribing healthcare professionals, as compared to no treatment and as compared to alternative treatments in various at-risk patient populations;
- 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;
- publicity concerning Vascepa or competing products;
- our ability to continually promote Vascepa in the United States consistent with and outside of FDA-approved labeling and the related perception thereof;
- sufficient third-party coverage or reimbursement for Vascepa and its prescribe uses, on-label and off-label;
- natural disasters, including pandemics such as the recent outbreak of coronavirus, and political unrest that could inhibit our ability to promote Vascepa regionally and can negatively affect product demand by creating obstacles for patients to seek treatment and fill prescriptions;
- new policies or laws affecting Vascepa sales, such as state and federal efforts to affect drug pricing and provide or remove healthcare coverage that includes reimbursement for prescription drugs; and
- the actual 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 their breadth of their use among different patient populations, 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 "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 FDA-approved labeling. By contrast, 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 FDA labeling, FDA-approved labeling that is more closely tied to the patient population studied in a clinical trial could limit use generally and by making reimbursement more difficult.

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 FDA approved a new 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 FDA has approved Vascepa for an expanded label and new 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 it could exceed, match or may not meet investor expectations. This type of updates and any future presentation and additional data may exceed, match or may not meet investors' expectations.

In addition, the same set of data can sometimes be interpreted to reach different conclusions, as was the case when Health Canada approved an indication based on REDUCE-IT data that was different in certain respects than that approved by FDA in the United States. It is possible the scope of subsequent regulatory approvals, if any, could likewise differ based on the same data, such as in the case of our pending European Union application. Conflicting interpretations of data, or new data, could impact public and medical community perception of the totality of the efficacy and safety data from REDUCE-IT.

Aspects that from time to time in the future could be considered by regulatory authorities and medical guideline committees internationally and change and impact the final evaluation of the totality of the efficacy and safety data from REDUCE-IT, in addition to those noted above, may include some or all of the following:

- 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 related to adverse events such as bleeding and trial 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 analyses regarding the placebo used in REDUCE-IT and other studies of Vascepa).

If additional data or analyses released from time to time does not meet expectations, the perception of REDUCE-IT results and the perceived and actual value of Vascepa may suffer. If this occurs, our revenue and business could suffer and our stock price could significantly decline.

Ongoing clinical trials 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, could provide further information on the effects of Vascepa and its commercial and regulatory prospects. The Effect of Vascepa on Improving Coronary Atherosclerosis in People with High Triglycerides Taking Statin Therapy (EVAPORATE; ClinicalTrials.gov number, NCT02926027), is examining changes in patients' coronary plaque over 9 to 18 months. The goal of this study is to evaluate whether treatment with Vascepa (4 grams/day) results in a greater change from baseline in low attenuation plaque than placebo in subjects with elevated triglycerides (200-499 mg/dL). Entry criteria for EVAPORATE include: elevated triglycerides (fasting value between 200-499 mg/dL) at qualifying or baseline visit; LDL-C >40 mg/dL and LDL-C ≤115 mg/dL on appropriate statin therapy; stable diet and exercise, as defined as the same pattern for the previous 4 weeks; and stable treatment with a statin with or without ezetimibe for at least 4 weeks. In November 2019, interim data from the EVAPORATE study were presented showing a reduction in total plaque volume when compared with placebo, with no shown reduction of low attenuation plaque volume compared with placebo. This study is continuing as designed and final results are expected to be announced in the second half of 2020. In addition, 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 2021, but could be announced sooner. If the outcomes of one or both of these studies does not meet expectations, the perception of REDUCE-IT results and the perceived 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 and developing sales internationally.

It is estimated that over 25 million adults in the United States have elevated triglyceride levels ≥200 mg/dL and that more than 50 million adults in the United States have elevated triglyceride levels ≥150 mg/dL. Approximately 2 to 3 million adults in the United States have very high triglyceride levels (≥500 mg/dL), the MARINE patient population. There are approximately 5 to 15 million people in the United States that meet the specific REDUCE-IT inclusion criteria. Since 1976, mean triglyceride levels have increase in concert with the growing epidemic of obesity, insulin resistance, and type 2 diabetes mellitus. In contrast, mean LDL-C levels have decreased.

Prior to the REDUCE-IT results topline announcement in September 2018, our direct sales force consisted of approximately 170 sales professionals, including sales representatives and their managers. Based on the positive REDUCE-IT results, in early 2019, we increased the size of our sales team to approximately 440 sales professionals, including approximately 400 sales representatives. As a result of the FDA's newly approved indication and label expansion, we are close to completing the expansion of our direct sales force to approximately 900 sales professionals, including approximately 800 sales representatives. Hiring, training and deploying approximately 400 new sales representatives is a multi-stage process which commenced in July 2019 and is expected to be completed in early 2020. Most of the expanded sales management team needed to support this sales force expansion was hired, or internally promoted, and trained prior to December 31, 2019. This sales team promotes Vascepa to a limited group of physicians and other healthcare professionals in select geographies in the United States. Even after planned expansion, this sales team is not large enough to call upon all physicians.

In addition to the sales force expansion in the United States, we plan to work ourselves and with partners to support regulatory efforts toward approvals outside the United States based primarily on REDUCE-IT results. We will again need to overcome challenges associated with rapidly hiring and training personnel and managing larger teams of people, directly or through our partners.

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

- our inability to attract and retain adequate numbers of effective sales and marketing personnel;
- our inability to adequately train our sales and marketing personnel 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;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- an inability by us or our partners to obtain regulatory and marketing approval or establish marketing channels in foreign jurisdictions; and
- unforeseen costs and expenses associated with operating a new independent sales and marketing organization.

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

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

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

In May 2015, we and a group of independent physicians filed a lawsuit against the FDA seeking a federal court declaration that would permit us and our agents to promote to healthcare professionals the use of Vascepa in the ANCHOR population and promote on the potential of Vascepa to reduce the risk of cardiovascular disease so long as the promotion is truthful and non-misleading. This use of Vascepa at issue reflected recognized medical practice but was not approved by the FDA and is thus not covered by current FDA-approved labeling for the drug. Promotion of an off-label use has generally been considered by the FDA to be illegal under the FDCA.

The lawsuit, captioned *Amarin Pharma, Inc., et al. v. Food & Drug Administration, et al.*, 119 F. Supp. 3d 196 (S.D.N.Y. 2015), was filed in the United States District Court for the Southern District of New York. In the lawsuit, we contended principally that FDA regulations limiting off-label promotion of truthful and non-misleading information are unconstitutional under the freedom of speech clause of the First Amendment to the U.S. Constitution as applied in the case of our proposed promotion of Vascepa. The physicians in the suit regularly treated patients at risk of cardiovascular disease and, as the complaint contended, have First Amendment rights to receive truthful and non-misleading information from Amarin. The suit was based on the principle that better informed physicians make better treatment decisions for their patients. The FDA opposed this lawsuit but did not dispute the veracity of the subject ANCHOR clinical trial data (the safety data from which was already and currently is in FDA-approved labeling of Vascepa) or the peer-reviewed research related to Vascepa and the potential for cardiovascular risk reduction.

In August 2015, we were granted preliminary relief in this lawsuit through the court's declaratory judgment that confirmed we may engage in truthful and non-misleading speech promoting the off-label use of Vascepa to healthcare professionals, i.e., to treat patients with persistently high triglycerides, and that such speech may not form the basis of a misbranding action under the FDCA. In August 2015, we began to communicate promotional information beyond the MARINE indication to healthcare professionals in the United States as permitted by this court declaration. The FDA did not appeal the court's ruling.

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

While we believe we are now permitted under applicable law to more broadly promote Vascepa, the FDA-approved labeling for Vascepa did not change as a result of this litigation and settlement, and neither government nor other third-party coverage or reimbursement to pay for the off-label use of Vascepa promoted under the court declaration was required. 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 and from the REDUCE-IT trial 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.

Even though we have the benefit of a final settlement in this litigation, our promotion is still subject to a high, perhaps abnormally high, degree of scrutiny to ensure that our promotion remains within the scope covered by the settlement. For example, under the settlement, we remain responsible for ensuring our speech is truthful and non-misleading. We, the FDA, the U.S. government, our competitors and other interested parties may not agree on the truthfulness and non-misleading nature of our promotional materials Federal and state governments or agencies may also seek to find other means to prevent our promotion of unapproved truthful and non-misleading information about Vascepa. If our promotional activities or other operations are found to be in violation of any law or governmental regulation through existing or new interpretations, we may be subject to prolonged litigation, penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Also, if governmental parties or our competitors view our claims as misleading or false, we could also be subject to liability based on fair competition-based statutes, such as the Lanham Act. Any of such negative circumstances could adversely affect our ability to operate our business and our results of operations.

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

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

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

In addition, in May 2014, Epanova® (omega-3-carboxylic acids) capsules, a free fatty acid form of omega-3 (comprised of 55% EPA and 20% DHA), was approved by the FDA for patients with severe hypertriglyceridemia. Epanova was developed by Omthera Pharmaceuticals, Inc., and is now owned by AstraZeneca Pharmaceuticals LP, or AstraZeneca. Also, in April 2014, Omtryg, another omega-3-acid fatty acid composition developed by Trygg Pharma AS, received FDA approval for severe hypertriglyceridemia. Neither Epanova nor Omtryg have been commercially launched, but could launch at any time. AstraZeneca has greater resources than we do, including financial, product development, marketing, personnel and other resources.

AstraZeneca had been conducting a long-term outcomes study to assess Statin Residual Risk Reduction With EpaNova in HiGh Cardiovascular Risk PatienTs With Hypertriglyceridemia (STRENGTH). The study is a randomized, double-blind, placebo-controlled (corn oil), parallel group design that is believed to have enrolled approximately 13,000 patients with hypertriglyceridemia and low HDL and high risk for cardiovascular disease randomized 1:1 to either corn oil plus statin or Epanova plus statin, once daily. 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. AstraZeneca also stated that full data from the STRENGTH trial will be presented at a future medical meeting. In addition, in March 2017, Kowa Research Institute (a subsidiary of the Japanese company Kowa Co., Ltd) initiated a phase III cardiovascular outcomes trial titled PROMINENT examining the effect of pemafibrate (experimental name K-877) in reducing cardiovascular events in Type II diabetic patients with hypertriglyceridemia. Kowa Research Institute has publicly estimated study completion in May 2022, and if successful, U.S. regulatory approval is estimated in mid-2023.

During 2018, two outcomes studies were completed of omega-3 mixtures which both failed to achieve their primary endpoints of cardiovascular risk reduction and two meta-analyses were published showing that omega-3 mixtures are not effective in lowering cardiovascular risk. Results of these failed outcomes studies and analysis, while not done with Vascepa, may negatively affect sales of Vascepa. For example, results of VITamin D and OmegA-3 TriaL (VITAL), as announced immediately before the presentation of REDUCE-IT results at the 2018 Scientific Sessions of the 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 UK cohort of over 15,000 individuals with diabetes who do not have atherosclerotic cardiovascular disease.

In a meta-analysis, presented in 2018 by the Cochran Foundation and separately as published in JAMA, additional omega-3 studies were evaluated. Similar to the VITAL and ASCEND studies, most of the studies in these omega-3 meta-analyses were of omega-3 mixtures, including DHA, and most were studies of relatively low doses of omega-3 as is associated with dietary supplementation and/or they studied relatively low risk patient populations. The exception was the JELIS study, conducted in Japan, of highly pure EPA which 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.

We are also aware of other pharmaceutical companies that are developing products that, if successfully developed, approved and marketed, would compete with Vascepa. Acasti Pharma, or Acasti, a subsidiary of Neptune Technologies & Bioresources Inc., announced in December 2015 that it intends to pursue a regulatory pathway under section 505(b)(2) of the FDCA for its omega-3 prescription drug candidate, CaPre® (omega-3 phospholipid), derived from krill oil, for the treatment of hypertriglyceridemia. In September 2016, Acasti announced positive results from its pivotal bioavailability bridging study comparing CaPre to Lovaza, establishing a scientific bridge between the two that is expected to support the feasibility of a 505(b)(2) regulatory pathway. In the first quarter of 2018, Acasti initiated a Phase 3 clinical program (TRILOGY 1 & 2) to assess the safety and efficacy of CaPre in patients with very high (≥500 mg/dL) triglycerides. In January 2020, Acasti announced topline results of the Trilogy 1 trial of CaPre. The study did not reach statistical significance and further analysis in underway. In February 2020, Acasti announced their intention to request a meeting with the FDA to discuss the TRILOGY 1 data and will seek guidance about how to conduct the analysis of the TRILOGY 2 data. As a result, Acasti also stated that they expect to announce topline results of TRILOGY 2 in the third quarter of 2020. NDA submission (if any) and resultant review/approval timelines will be announced following completion of Trilogy 1 and 2 data analysis. We believe Micelle BioPharma Inc., or Micelle, is also developing potential treatments for hypertriglyceridemia based on omega-3 fatty acids. To our knowledge, Micelle, after acquiring SC401 from Sancilio & Company, or Sancilio, is pursuing a regulatory pathway under section 505(b)(2) of the FDCA for its product and submitted an Investigational New Drug Application, or IND, in July 2015. Micelle (Sancilio) completed two pharmacokinetic studies and Phase 2 bioavailability studies (FASTR I&II), with one comparing SC401 to Lovaza. We expect the company or a potential partner to initiate a pivotal clinical Phase 3 study as the next step in development.

Matinas BioPharma, Inc., 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 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 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 September 2019, Matinas announced that it will begin a comparative clinical bridging bioavailability study in the fourth calendar quarter of 2019, with expected completion in the first half of 2020, and has planned an additional Phase 2 head-to-head pharmacokinetic and pharmacodynamic study (ENHANCE-IT) against Vascepa in patients with elevated triglycerides (150-499 mg/dL). Patient enrollment is expected to commence in early 2020, with topline data expected in the fourth quarter of 2020. Matinas anticipates initiating a Phase 3 placebo-controlled study of MAT9001 in statin-treated patients with high risk hypertriglyceridemia by the end of 2020.

In June 2018, Gemphire Therapeutics (renamed NeuroBo Pharmaceuticals, Inc. following completion of a merger on December 31, 2019) announced positive topline results from a Phase 2b trial (INDIGO-1) of its drug candidate, gemcabene, in patients with severe hypertriglyceridemia. Gemcabene is an oral, once-daily pill for a number of hypercholesterolemic populations and severe hypertriglyceridemia. In August 2018, the FDA requested that Gemphire conduct an additional long-term toxicity study before commencing any further clinical testing, thereby effectively placing gemcabene on clinical hold. Gemphire expects to submit a request to the FDA to lift the clinical hold in the fourth quarter of 2019. In June 2019, Gemphire announced top-line clinical results from a Phase II trial in Familial Partial Lipodystrophy (FPL)/NASH in which Gemcabene safely met the primary endpoint in a sub-set of patients. Phase III studies for homozygous familial hypercholesterolemia (HoFH), heterozygous familial hypercholesterolemia (HeFH) and non-familial hypercholesterolemia in ASCVD patients are planned. Afimmune Ltd. has an oral, small molecule drug candidate, epeleuton (DS-102), in development for a number of conditions of the liver and lung, including severe hypertriglyceridemia, Phase 2 clinical trials are currently ongoing for non-alcoholic fatty liver disease, or NAFLD, and chronic obstructive pulmonary disease, or COPD, 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.

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

Generic company competitors are seeking FDA approval of generic versions of Vascepa in the United States. We are now engaged in related patent litigation based on our MARINE trial-based indication, expect appeals of any judgment, and expect additional patent litigation given FDA approval of a REDUCE-IT-based indication.

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

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

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

(I) there is no patent information listed for the reference drug;

(II) the listed patent has expired for the reference drug;

(III) the listed patent for the reference drug has not expired, but will expire on a particular date and approval is sought after patent expiration; or

(IV) the listed patent for the reference drug is invalid, unenforceable, or will not be infringed by the manufacture, use or sale of the product for which the ANDA or 505(b)(2) NDA is submitted.

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

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

In the first half of 2014, we received six paragraph IV notices notifying us of accepted ANDAs to the Vascepa 1-gram dose strength under the Hatch-Waxman Amendments. These ANDAs were submitted and accepted by FDA under the regulatory scheme adopted under the Hatch-Waxman Amendments based on the FDA's determination that we were entitled to three, and not five-year exclusivity. As a result, from the first half of 2014 until June 2015, we were engaged in costly litigation with the ANDA applicants to protect our patent rights.

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

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

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

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

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

We filed patent infringement lawsuits against three of these four ANDA applicants. In October 2016, Amarin filed a lawsuit against Roxane Laboratories, Inc. and related parties, collectively, Roxane, in the U.S. District Court for the District of Nevada. The case against Roxane is captioned *Amarin Pharma, Inc. et al. v. Roxane Laboratories, Inc. et al.*, Civ. A. No. 2:16-cv-02525 (D. Nev.). According to a stipulation filed with the Nevada court, in December 2016, Roxane transferred its ANDA to West-Ward Pharmaceuticals International Limited, which then designated West-Ward Pharmaceuticals Corp. (or together with West-Ward Pharmaceuticals International Limited, West-Ward) as its agent for FDA communications. In view of the ANDA transfer, in February 2017, West-Ward replaced Roxane and related parties as Defendants in the above-referenced case. The case against West-Ward is now captioned *Amarin Pharma, Inc. et al. v. West-Ward Pharmaceuticals Corp. et al.*, Civ. A. No. 2:16-cv-02525 (D. Nev.). In November 2016, Amarin filed a lawsuit against Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd., collectively, DRL, in the U.S. District Court for the District of Nevada. The case against DRL is captioned *Amarin Pharma, Inc. et al. v. Dr. Reddy's Laboratories, Inc. et al.*, Civ. A. No. 2:16-cv-02562 (D. Nev.). In November 2016, Amarin filed a lawsuit against Teva Pharmaceuticals USA, Inc. and Teva Pharmaceuticals Industries Limited, or collectively, Teva, in the U.S. District Court for the District of Nevada. The case against Teva was captioned *Amarin Pharma, Inc. et al. v. Teva Pharmaceuticals USA, Inc. et al.*, Civ. A. No. 2:16-cv-02658. In all three lawsuits, we are seeking, among other remedies, an order enjoining each defendant from marketing generic versions of the 1-gram dose strength of Vascepa before the last to expire of the asserted patents in 2030. The three lawsuits have been consolidated for pretrial proceedings.

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

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

On May 24, 2018, we entered into a settlement agreement with Teva that resolves our ANDA patent litigation as it relates to Teva's as amended ANDA for both the 1-gram and 0.5-gram dose strengths of Vascepa. As part of this settlement agreement, Teva may first begin selling its generic version of Vascepa in the United States on August 9, 2029, or earlier under certain customary circumstances, including commercial launch by another generic manufacturer under certain circumstances, in which event Teva would pay us certain royalties on its generic Vascepa products. The ANDA patent litigation continued in the United States District Court for the District of Nevada with parties West-Ward and DRL. The trial for this litigation took place from mid to late January 2020 and a decision, based on statements by the Court, is expected by the end of March 2020.

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

We expect to face similar patent litigation related to the patents filed in the Orange Book related to the REDUCE-IT study. In addition, 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 the approval of our sNDA for REDUCE-IT study results. Such three-year exclusivity protection precludes the FDA from approving a marketing application for an ANDA, a product candidate that the FDA views as having the same conditions of approval as Vascepa (for example, the same indication and/or other conditions of use), or a 505(b)(2) NDA submitted to the FDA with Vascepa as the reference product until December 13, 2022, three years from the date of FDA approval of the REDUCE-IT sNDA. While this three-year exclusivity would 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 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 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, or PTAB, of the U.S. Patent and Trademark Office. Such a proceeding could be introduced against us within the statutory one-year window triggered by service of a complaint for infringement 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 or any subsequently filed lawsuits or *inter partes* review.

If an ANDA filer meets the approval requirements for a generic version of Vascepa to the satisfaction of the FDA under its ANDA, FDA may grant tentative approval to the ANDA during a Hatch-Waxman 30-month stay period 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.

The statutory NCE-related 30-month stay triggered by the 1-gram dose patent litigation following generic application submissions permitted on July 26, 2016 expired on January 26, 2020, seven-and-a-half years from our initial FDA approval of Vascepa. However, based on court proceedings, we do not expect an at-risk launch from either generic filer before the court issues a decision on the merits in the pending MARINE-related patent litigation, which decision, based on statements by the Court, is expected by the end of March 2020. Based on historical practice in the field, we expect the final decision by the Court on the merits of this MARINE-related patent litigation to be appealed by the losing parties. The timing of such appeal proceedings and an outcome on the merits is difficult to predict. It is not uncommon for such an appeal to take from several months to approximately one year until judgment. Based on our current understanding of the strength of our position in the litigation, if the Court were to rule against us, we expect we would file an expedited motion for an injunction to prevent any generic launch while the appeal is pending. We believe we would be favorably situated to obtain an injunction against generic launch pending appeal, subject to our posting a bond to secure generics' lost profits in the event that generics prevail on appeal. There can be no guarantee we would be successful in any of such efforts.

If final approval of a generic ANDA is granted, an ANDA filer is able to supply the product in significant commercial quantities and circumstances described in the preceding paragraph do not maintain the status quo as it existed prior to any adverse Court ruling, generic companies could introduce generic versions of Vascepa in the market. Any such introduction of a generic version of Vascepa would also be subject to current patent infringement claims that may then be subject to an appeal.

Any generic market entry would limit our U.S. sales, which would have a significant adverse impact on our business and results of operations. In addition, even if a competitor's effort to introduce a generic product is ultimately unsuccessful, the perception that such development is in progress and/or news related to such progress could materially affect the perceived value of our company and our stock price.

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

Our only product, Vascepa, is a prescription-only form of EPA, an omega-3 fatty acid in ethyl ester form. Mixtures of omega-3 fatty acids in triglyceride form are naturally occurring substances contained in various foods, including fatty fish. Omega-3 fatty acids are marketed by others in a number of chemical forms as non-prescription dietary supplements. We cannot be sure physicians will

view the pharmaceutical grade purity and proven efficacy and safety of Vascepa as having a superior therapeutic profile to unproven and loosely regulated omega-3 fatty acid dietary supplements. In addition, the FDA has not yet enforced to the full extent of its regulatory authority what we view as illegal claims made by certain omega-3 fatty acid product manufacturers to the extent we believe appropriate under applicable law and regulations, for example, claims that certain of such chemically altered products are dietary supplements and that certain of such products reduce triglyceride levels or could reduce cardiovascular risk.

Also, for more than a decade now, subject to certain limitations, the FDA has expressly permitted dietary supplement manufacturers that sell supplements containing the omega-3 fatty acids EPA and/or DHA to make the following qualified health claim directly to consumers: Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease. Such companies are not, however, permitted, based on 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, Amarin 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 Amarin's 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, Amarin 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. We have also engaged with 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 commercial alternatives instead of writing or filling prescriptions for Vascepa or patients may elect on their own to take commercially available omega-3 fatty acids. Also, insurance plans may increasingly impose policies that favor supplement use over Vascepa. While Vascepa is highly price-competitive for patients generally, and in particular when covered by insurance—cheaper in many cases—any of these outcomes may adversely impact our results of operations by limiting how we price our product and limiting the revenue we receive from the sale of Vascepa due to reduced market acceptance.

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

There can be no assurance as to the adequacy for commercial success of Vascepa outside the United States. For example, even if we obtain approval to commercialize Vascepa in Europe or we and Eddingpharm obtain marketing approval in Mainland China, Hong Kong, Macau and Taiwan, or the China Territory, applicable regulatory agencies may impose restrictions on the product's conditions for use, distribution or marketing and in some cases may impose ongoing requirements for post-market surveillance, post-approval studies or clinical trials.

Also, there is a degree of unpredictability with regard to the eventual pricing and reimbursement levels of medications in markets outside the United States. In some foreign countries, including Canada and major markets in the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take 6 to 12 months or longer after the receipt of regulatory marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a pharmacoeconomic study that compares the cost-effectiveness of Vascepa to other available therapies. Such pharmacoeconomic studies can be costly and the results uncertain. Our business could be harmed if reimbursement of our products is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels. If 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. Furthermore, with regard to any indications for which we may gain approval in territories outside the United States, the number of actual patients with the condition included in such approved indication may be smaller than we anticipate. If any 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 FDA marketing approval, numerous post-approval requirements apply. Among other things, the holder of an approved NDA is subject to periodic and other monitoring and reporting obligations enforced by the FDA and other regulatory bodies, including obligations to monitor and report adverse events and instances of the failure of a product to meet the specifications in the approved application. Application holders must also submit advertising and other promotional material to regulatory authorities and report on ongoing clinical trials.

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

We also are subject to the federal transparency requirements under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, enacted in March 2010, which require manufacturers of certain drugs, devices, biologics, and medical supplies to report to the Centers for Medicare & Medicaid Services, or CMS, information related to payments and other transfers of value to physicians and teaching hospitals and physician ownership and investment interests. We may also be subject, directly or indirectly through our customers and partners, to various fraud and abuse laws, including, without limitation, the U.S. Anti-Kickback Statute, U.S. False Claims Act, and similar state laws, which impact, among other things, our proposed sales, marketing, and scientific/educational grant programs. We participate in the U.S. Medicaid Drug Rebate Program, the Federal Supply Schedule of the U.S. Department of Veterans Affairs, or other government drug programs, 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 Pharmaceuticals America, Inc. In addition, even if we comply with FDA and other requirements, new information regarding the safety or effectiveness of a product could lead the FDA to modify or withdraw a product approval. Newly discovered or developed safety or effectiveness data may require changes to a drug's approved labeling 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. 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.

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

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

Specifically, in both the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes to the healthcare system in ways that could affect our ability to sell our products profitably. For example, on August 2, 2011, the Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals for spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction, which triggered the legislation's automatic reductions. In concert with subsequent legislation, this has resulted in aggregate reductions to Medicare payments to providers of, on average, 2% per fiscal year through 2029 unless Congress takes additional action. These cuts reduce reimbursement payments related to our products, which could potentially negatively impact our revenue. Also for example, the ACA has substantially changed the way healthcare is financed by both governmental and private insurers and has significantly impacted the U.S. pharmaceutical industry. Among other cost-containment measures, the ACA establishes:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents;
- a new Medicare Part D coverage gap discount program, in which pharmaceutical manufacturers who wish to have their drugs covered under Part D must offer discounts to eligible beneficiaries during their coverage gap period; and
- a new formula that increases the rebates a manufacturer must pay under the Medicaid Drug Rebate Program and extends the Medicaid Drug Rebate Program to individuals enrolled in Medicaid managed care organizations.

There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. The Trump administration is currently assessing additional proposals that are designed to affect drug pricing, such as tying U.S. drug prices to prices outside the United States. Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. For example, the State of California enacted legislation that requires notice for exceeding specified limits on annual drug price increases and other legislation that seeks to limit the use of co-pay cards in certain situations.

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

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

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

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

The Health Resources and Services Administration, or HRSA, which administers the 340B program, issued a final regulation regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities, which became effective on January 1, 2019. It is currently unclear how HRSA will apply its enforcement authority under the new regulation. 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, we participate in the U.S. Department of Veterans Affairs, or VA, Federal Supply Schedule, or FSS, pricing program. As part of this program, we are obligated to make our products available for procurement on an FSS contract under which we must comply with standard government terms and conditions and charge a price that is no higher than the statutory Federal Ceiling Price, or FCP, to four federal agencies (VA, U.S. Department of Defense, or DOD, Public Health Service, and U.S. Coast Guard). The FCP is based on the Non-Federal Average Manufacturer Price, or Non-FAMP, which we calculate and report to the VA on a quarterly and annual basis. Pursuant to applicable law, knowing provision of false information in connection with a Non-FAMP filing can subject a manufacturer to significant penalties for each item of false information. These obligations also contain extensive disclosure and certification requirements.

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

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

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

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

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

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

Certain provisions of the ACA have been subject to judicial challenges, as well as efforts to repeal or replace them or to alter their interpretation or implementation. Since January 2017, the Trump administration has signed Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. One Executive Order directs federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. The second Executive Order terminated the cost-sharing subsidies under the ACA. Nineteen state Attorneys General filed suit to stop the administration from terminating the subsidies, but on July 18, 2018, the U.S. District Court for the Northern District of California dismissed the case without prejudice. Further, on June 14, 2018, U.S. Court of Appeals for the Federal Circuit ruled that, due to Congressional appropriations riders that prohibited the Department of Health and Human Services, or HHS, from paying out more in risk corridor payments than it collected, HHS was not required to pay more than $12 billion in ACA risk corridor payments owed to insurers under the risk corridor formula. On November 6, 2018, the Federal Circuit declined to rehear the case *en banc*. The case is currently pending a ruling by the Supreme Court.

Moreover, the Tax Act included a provision that eliminated the tax-based shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code of 1986, commonly referred to as the “individual mandate,” effective January 1, 2019. The Bipartisan Budget Act of 2018, or the BBA, among other things, amends the ACA to create a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% (effective as of January 1, 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D.

Under the Trump Administration, CMS has issued regulations that give states greater flexibility, starting in 2020, in the identification of the essential health benefits benchmarks for non-grandfathered individual and small group market health insurance coverage, including plans sold through the health insurance exchanges established under the ACA. On December 14, 2018, the U.S. District Court for the Northern District of Texas ruled (i) that the “individual mandate” was unconstitutional as a result of the associated tax penalty being repealed by Congress as part of the Tax Act; and (ii) the individual mandate is not severable from the rest of the ACA, as a result the entire ACA is invalid. On December 18, 2019, the U.S. Court of Appeals for the Fifth Circuit affirmed the district court’s decision that the individual mandate is unconstitutional, but remanded the case to the district court to reconsider the severability question. It is unclear how the ultimate decision in this case, or other efforts to repeal, replace, or invalidate the ACA or its implementing regulations, or portions thereof, will impact our business.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. In August 2011, the Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals for spending reductions. The Joint Select Committee on Deficit Reduction did not reach required goals, thereby triggering the legislation’s automatic reductions. This has resulted in aggregate reductions to Medicare payments to providers of, on average, 2% per fiscal year through 2027 unless Congress takes additional action.

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

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

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

We and any potential collaborators may be subject to federal, state, and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under 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 European Union, or EU. 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 General Data Protection Regulation, or 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 European Union to the United States. Failure to comply with the requirements of the GDPR, and the related national data protection laws of the European Union Member States may result in restrictions against regulatory approval in the EU 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 FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products. If we or our partners are found to have improperly promoted uses, efficacy or safety of Vascepa, we may become subject to significant fines and other liability. The government may seek to find means to prevent our promotion of truthful and non-misleading information beyond the current court ruling and litigation settlement.

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products. In particular, in general, the U.S. government's position has been that a product may not be promoted for uses that are not approved by

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

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

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

We may not be successful in developing 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 FDA generally requires preclinical testing and clinical trials of each drug to establish its safety and efficacy and extensive pharmaceutical development to ensure its quality before its introduction into the market. Regulatory authorities in other jurisdictions impose similar requirements. The process of obtaining regulatory approvals is lengthy and expensive and the issuance of such approvals is uncertain. The commencement and rate of completion of clinical trials and the timing of obtaining marketing approval from regulatory authorities may be delayed by many factors, including but not limited to:

- the lack of efficacy during clinical trials;
- the inability to manufacture sufficient quantities of qualified materials under cGMPs for use in clinical trials;
- slower than expected rates of patient recruitment;
- the inability to observe patients adequately after treatment;
- changes in regulatory requirements for clinical trials or preclinical studies;
- the emergence of unforeseen safety issues in clinical trials or preclinical studies;
- delay, suspension, or termination of a trial by the institutional review board responsible for overseeing the study at a particular study site;
- unanticipated changes to the requirements imposed by regulatory authorities on the extent, nature or timing of studies to be conducted on quality, safety and efficacy;
- 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 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 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, no strong evidence for biological activity of mineral oil was identified by the FDA before its approval of Vascepa after review of the MARINE and ANCHOR trials and consideration of other data regarding mineral oil. It was ultimately concluded that the between-group differences likely provided the most appropriate descriptions of the treatment effect of Vascepa and that whatever factor(s) led to the within-group changes over time in the placebo group were likely randomly distributed to all treatment groups. Thus, the FDA approved Vascepa for use in the MARINE indication in July 2012, FDA did not dispute the veracity of the ANCHOR trial data and, in connection with the March 2016 agreement we reached with the FDA allowing us to promote the results of the ANCHOR study, the FDA did not seek to require that we include any qualification related to this earlier question regarding the mineral oil placebo.

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

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

The process of establishing a commercial infrastructure is difficult, expensive and time-consuming. Prior to the REDUCE-IT results topline announcement in September 2018, our direct sales force consisted of approximately 170 sales professionals, including sales representatives and their managers. Based on the positive REDUCE-IT results, in early 2019, we increased the size of our sales team to approximately 440 sales professionals, including approximately 400 sales representatives in the United States. As a result of the FDA's newly approved indication and label expansion, we are close to completing the expansion of our direct sales force to approximately 900 sales professionals, including approximately 800 sales representatives. Hiring, training and deploying approximately 400 new sales representatives is a multi-stage process which commenced in July 2019 and is expected to be completed in early 2020. Most of the expanded sales management team needed to support this sales force expansion was hired, or internally promoted, and trained prior to December 31, 2019. This sales team promotes Vascepa to a limited group of physicians and other healthcare professionals in select geographies in the United States. Even after planned expansion, this sales team is not large enough to call upon all physicians.

In addition to sales force expansion in the United States, Amarin continues to work with its international partners to support regulatory efforts outside the United States based on REDUCE-IT results. As our operations expand with the anticipated growth of our product sales, we expect that we will need to manage additional relationships with various collaborative partners, suppliers and other third parties. Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. Our future financial performance and our ability to commercialize Vascepa and to compete effectively will depend, in part, on our ability to manage our future growth effectively. To that end, we must be able to manage our development efforts effectively, and hire, train, integrate and retain additional management, administrative and sales and

marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

Risks Related to Our Reliance on Third Parties

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

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

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

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

Expanding manufacturing capacity and qualifying such capacity is complex and subject to numerous regulations and other operational challenges. The resources of our suppliers vary and are limited; costs associated with projected expansion and qualification can be significant. There can be no assurance that the expansion plans of any of our suppliers will be successful. Our aggregate capacity to produce API is dependent upon the continued qualification of our API suppliers and, depending on the ability of existing suppliers to meet our supply demands, potentially the qualifications of new suppliers. Each of our API suppliers has outlined plans for potential further capacity expansion. If no additional API supplier is approved by the FDA as part of an sNDA, our API supply will be limited to the API we purchase from previously approved suppliers. If our third-party manufacturing capacity is not expanded and/or compliant with applicable regulatory requirements, we may not be able to supply sufficient quantities of Vascepa to meet anticipated demand. We cannot guarantee that we can contract with any future manufacturer on acceptable terms or that any such alternative supplier will not require capital investment from us in order for them to meet our requirements. Alternatively, our purchase of supply may exceed actual demand for Vascepa.

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

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

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

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 specialty pharmacy providers, or collectively, our distributors or our customers, that in turn resell Vascepa to retail pharmacies for subsequent resale to patients and healthcare providers. These parties exercise a substantial amount of bargaining power over us given their control over large segments of the market for Vascepa. This bargaining power has led us to bear increasingly higher discounts in the sale of Vascepa. In addition, payors have broad latitude to change individual products' formulary position or to implement other barriers that

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

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

The manufacture, packaging and distribution of pharmaceutical products, such as Vascepa, are regulated by the FDA and similar foreign regulatory bodies and must be conducted in accordance with the FDA's current good manufacturing practices, or cGMPs, and comparable requirements of foreign regulatory bodies. There are a limited number of manufacturers that operate under these cGMPs 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 FDA review and pre-approval of the manufacturing process and procedures in accordance with the FDA's cGMPs. Any new facility may be subject to a pre-approval inspection by the FDA and would again require us to demonstrate product comparability to the FDA. There are comparable foreign requirements under ICH guidelines. This review may be costly and time consuming and could delay or prevent the launch of a product.

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

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

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

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

In February 2015, we entered into a Development, Commercialization and Supply Agreement, or the DCS Agreement, with Eddingpharm related to the development and commercialization of Vascepa in the China Territory. Under the DCS Agreement, Eddingpharm is responsible for development and commercialization activities in the China Territory and associated expenses. Additionally, Eddingpharm is required to conduct clinical trials in the China Territory to secure regulatory approval in certain territories. For example, in December 2017, Eddingpharm commenced a pivotal clinical trial aimed to support the regulatory approval of the first indication of Vascepa in a patient population with severe hypertriglyceridemia in Mainland China. Additional clinical development efforts may be necessary in this market. Any efforts in the China Territory may be negatively impacted by the spread of the coronavirus, which outbreak initially surfaced in Wuhan, China in December 2019. Although the effects of the coronavirus are expected to be temporary, and are not limited to the China territory, the concentration of the outbreak in China could cause disruptions or delays in Eddingpharm's development activities, including with the enrollment or monitoring of patients in Eddingpharm's clinical trials, particularly at clinical trial sites located in impacted jurisdictions, or with the ability to obtain sufficient and timely clinical supplies if the production capabilities of suppliers is disrupted. Further, regulatory oversight and actions may be disrupted or delayed in this region if regulators and industry professionals are expending significant and unexpected resources addressing the coronavirus outbreak. If Eddingpharm is not able to effectively develop and commercialize Vascepa in the China Territory, we may not be able to generate revenue from the DCS Agreement resulting from the sale of Vascepa in the China Territory.

In March 2016, we entered into an agreement with Biologix FZCo, or Biologix, to register and commercialize Vascepa in several Middle Eastern and North African countries. Under the terms of the distribution agreement, we granted to Biologix a non-exclusive license to use our trademarks in connection with the importation, distribution, promotion, marketing and sale of Vascepa in the Middle East and North Africa territory. Biologix obtained approval of Vascepa in Lebanon on March 2018, in United Arab Emirates on July 2018 and in Qatar in January 2020. Vascepa was launched in Lebanon and the United Arab Emirates on June 2018 and February 2019, respectively. 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.

In September 2017, we entered into an agreement with HLS Therapeutics Inc., or HLS, to register, commercialize and distribute Vascepa in Canada. Under the agreement, HLS is responsible for regulatory and commercialization activities and associated costs. Amarin is responsible for providing assistance towards local filings, supplying finished product under negotiated supply terms, maintaining intellectual property, and continuing the development and funding of REDUCE-IT-related activities. 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. However, if HLS Therapeutics is not able to effectively commercialize Vascepa in Canada through effective pricing (initially and over time) or otherwise we may not be able to generate revenue from the sale of Vascepa in Canada.

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

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

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

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. Liability may be established without a person or entity having actual knowledge of the federal anti-kickback statute or specific intent to violate it. In addition, the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability. Moreover, there are no safe harbors for many common practices, such as educational and research grants or patient or product support programs;
- the federal Civil False Claims Act, or FCA, which prohibits, among other things, any person from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds, or knowingly making or using, or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly concealing, or knowingly and improperly avoiding, decreasing, or concealing an obligation to pay money to the federal government. The FCA also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the statute and to share in any monetary recovery. Recently, several pharmaceutical and other healthcare companies have been investigated or faced enforcement actions under the FCA for a variety of alleged improper marketing activities, including allegations that they caused false claims to be submitted because of the company’s marketing of the product for unapproved, and thus allegedly non-reimbursable, uses. Federal enforcement agencies also have showed increased interest in pharmaceutical companies’ product and patient assistance programs, including reimbursement and co-pay support services, and a number of investigations into these programs have resulted in significant civil and criminal settlements. Pharmaceutical and other healthcare companies also are subject to other federal

false claims laws, including, among others, federal criminal healthcare fraud and false statement statutes that extend to non-government health benefit programs;

- HIPAA, which, among other things, imposes criminal and civil liability for knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payor and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services;
- HIPAA, and its implementing regulations, which impose, among other things, requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;
- the federal Physician Payment Sunshine Act, being implemented as the Open Payments Program, which requires manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to direct or indirect payments and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held in the company by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; and other state or local laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; restrict the ability of manufacturers to offer co-pay support to patients for certain prescription drugs; require drug manufacturers to report information related to clinical trials, or information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and/or require identification or licensing of sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts

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

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

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

Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct

may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations.

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

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

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

Risks Related to Our Intellectual Property

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

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

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

We have prosecuted, and are currently prosecuting, multiple patent applications to protect the intellectual property developed during the Vascepa development program. As of the date of this report, we had 92 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 92 allowed and issued applications include the following:

- 2 issued U.S. patents directed to a pharmaceutical composition of Vascepa in a capsule that have terms that expire in 2020 and 2030, respectively;
- 1 issued U.S. patent covering a composition containing highly pure EPA that expires in 2021;
- 49 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;
- 14 U.S. patents covering or related to the use of Vascepa in the REDUCE-IT population with terms expiring in 2033 or later;
- 1 additional US patent directed to a pharmaceutical composition comprised of free fatty acids with a term that expires in 2030;
- 4 additional patents related to the use of a pharmaceutical composition comprised of free fatty acids to treat the ANCHOR patient population with a term that expires in 2030 or later;
- 2 additional patents related to the use of a pharmaceutical composition comprised of free fatty acids to treat the MARINE patient population with a term that expires in 2030;
- 3 additional patents related to the use of a pharmaceutical composition comprised of free fatty acids to treat the REDUCE-IT population expiring 2033;
- 3 additional patent related to a pharmaceutical composition comprised of free fatty acids and uses thereof to treat both the MARINE and ANCHOR patient populations with a term that expires in 2030;
- 1 additional patent related to the use of a pharmaceutical composition comprised of re-esterified EPA triglyceride to treat the REDUCE-IT population expiring 2033;

- 3 additional patents related to a formulation of EPA/DHA and uses thereof with a term that expires in 2030;
- 2 additional patents related to the use of Vascepa to treat obesity with a term that expires in 2034;
- 3 additional patents covering a pharmaceutical composition comprised of EPA and a hydroxyl compound with a term that expires in 2034; and
- 4 additional patents covering a new combination therapy comprised of EPA and another drug.

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

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

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

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

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

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

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

We plan to vigorously defend our rights under issued patents. For example, in March 2014, we filed a patent infringement suit against Omthera Pharmaceuticals, Inc., and its parent company, AstraZeneca Pharmaceuticals LP. The suit sought injunctive relief and monetary damages for infringement of our U.S. Patent No. 8,663,662. The complaint alleged infringement of the patent arising from the then expected launch of Epanova, a product that, in 2014, was expected to compete with Vascepa in the United States. In November 2014, based on a representation from AstraZeneca Pharmaceuticals LP in the court proceedings that the commercial launch of Epanova was not imminent, the court dismissed our complaint, without prejudice (i.e., preserving our ability to later re-file the suit). The court required the defendant to notify us before any product launch. While we no longer expect a launch of Epanova due to the clinical failure of the STRENGTH cardiovascular outcomes trial announced in January 2020, we intend to pursue this litigation vigorously and aggressively protect our intellectual property rights should the product be launched. We likewise plan to engage in similar patent litigation should other competitors arise with products that infringe our intellectual property rights.

Patent litigation is a time-consuming and costly process. There can be no assurance that we will be successful in enforcing this patent or that it will not be successfully challenged and invalidated. Even if we are successful in enforcing this patent, the process could take years to reach conclusion.

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

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

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

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

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

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

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

Risks Related to Our Business

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

In January 2020, we issued financial and business guidance, including expected fiscal year 2020 total net revenue and expectations regarding inventory build, and 2020 operating expenses. All such guidance and updates are based on estimates and the judgment of management. Because of the inherent nature of estimates, there could be significant differences between our estimates and the actual amount of product demand. If, for any reason, we are unable to realize our currently projected 2020 revenue, we may not realize our publicly announced financial guidance. If we fail to realize or if we change or update any element of our publicly disclosed financial guidance as we have done in the past or other expectations about our business change, our stock price could decline in value.

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

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

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

Despite the implementation of security measures, our internal computer systems and those of our third-party clinical research organizations and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war, and telecommunication and electrical failures. 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 instance, in June 2019, a report published by security researchers claimed that a database, which we are informed did not include social security numbers or credit card information, belonging to one of our vendors containing information about individuals who use or have expressed interest in Vascepa was accessible to unauthorized users. 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 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.

The rules regarding determination of tax residence outlined above will change effective January 1, 2020, when a modified Ireland-UK DTA comes into effect pursuant to the MLI, which has recently entered into force in Ireland. Under the modified Ireland-UK DTA, from January 1, 2020, we will be tax resident in Ireland only and not tax resident in the UK if we continue to be centrally managed and controlled in Ireland and if it is mutually agreed between the Irish and UK tax authorities under the MLI "tie-breaker rule" that we are tax resident in Ireland only. Both the Irish and UK tax authorities have issued guidance on how companies impacted by this rule change under the MLI should submit to such tax authorities to obtain confirmation of their mutual agreement of a single jurisdiction of tax residence. We have made a submission to the Irish tax authority, or the Irish Revenue Commissioners, requesting that they provide confirmation of the mutual agreement of the two tax authorities that we continue to be tax resident in Ireland only.

Our and our subsidiaries' income tax returns are periodically examined by various tax authorities, including the Internal Revenue Service, or the IRS, and states. We recently completed the audits by the IRS for the years 2013 to 2014, with no material changes to the filed income tax returns. In addition, we were notified by the IRS in January 2020 that it will be auditing our 2018 US income tax return and the examination is expected to begin 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 future audits will have a material adverse effect on our consolidated financial position or results of operations.

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

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

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

We are highly dependent upon the efforts of our senior management. The loss of the services of one or more members of senior management could have a material adverse effect on us. As a small company with a streamlined management structure, the departure of any key person could have a significant impact and would be potentially disruptive to our business until such time as a suitable replacement is hired. Furthermore, because of the specialized nature of our business, as our business plan progresses we will be highly dependent upon our ability to attract and retain qualified scientific, technical and key management personnel. As we evolve from a development stage company to a commercial stage company we may experience turnover among members of our senior management team. We may have difficulty identifying and integrating new executives to replace any such losses. There is intense competition for qualified personnel in the areas of our activities. In this environment, we may not be able to attract and retain the personnel necessary for the development of our business, particularly if we do not achieve profitability. The failure to recruit key scientific, technical and management personnel would be detrimental to our ability to implement our business plan.

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

A significant portion of our sales are to wholesalers in the pharmaceutical industry. Three customers individually accounted for 10% or more of our gross product sales. Customers A, B, and C accounted for 36%, 29%, and 25%, respectively, of gross product sales for the year ended December 31, 2019 and represented 35%, 20%, and 37%, respectively, of the gross accounts receivable balance as of December 31, 2019. Customers A, B, and C accounted for 31%, 30%, and 27%, respectively, of gross product sales for the year ended December 31, 2018 and represented 26%, 24%, 39% and, respectively, of the gross accounts receivable balance as of December 31, 2018. There can be no guarantee that we will be able to sustain our accounts receivable or gross sales levels from our key customers. If, for any reason, we were to lose, or experience a decrease in the amount of business with our largest customers, whether directly or through our distributor relationships, our financial condition and results of operations could be negatively affected.

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.

On June 23, 2016, the UK held a referendum in which a majority of the eligible members of the electorate voted to leave the EU, commonly referred to as Brexit. Pursuant to Article 50 of the Lisbon Treaty, the UK ceased being a Member State of the EU on January 31, 2020. However, the terms of the withdrawal have yet to be fully negotiated. The implementation period began February 1, 2020 and will continue until December 31, 2020. During this 11-month period, the UK will continue to follow all of the EU's rules, the EU's pharmaceutical law remains applicable to the UK and the UK's trading relationship will remain the same. However, regulations (including financial laws and regulations, tax and free trade agreements, intellectual property rights, data protection laws, supply chain logistics, environmental, health and safety laws and regulations medicine licensing and regulations, immigration laws and employment laws), have yet to be addressed. This lack of clarity on future UK laws and regulations and their interaction with the EU laws and regulations may negatively impact foreign direct investment in the UK, increase costs, depress economic activity and restrict access to capital.

The 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) beyond the date of Brexit.

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 negotiate 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 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 and, in particular, any arrangements for the UK to retain access to EU markets either during a transitional period or more permanently.

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 European Economic Area, or EEA, and these operations and clinical activities could be disrupted by Brexit.

We may also face new regulatory costs and challenges that could have an adverse effect on our operations. Depending on the terms of the UK's withdrawal from the EU, the UK could lose the benefits of global trade agreements negotiated by the EU on behalf of its members, which may result in increased trade barriers that could make our doing business in the EU and the EEA more difficult. 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 approval of our product candidates in the UK For instance, in November 2017, EU member states voted to move the EMA, the EU's regulatory body, from London to Amsterdam. Operations in Amsterdam commenced in March 2019, and the move itself may cause significant disruption to the regulatory approval process in Europe. It remains to be seen how, if at all, Brexit will impact regulatory requirements for product candidates and products in the UK Any delay in obtaining, or an inability to obtain, any regulatory approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the UK and/or the EU and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the UK and/or EU for our product candidates, which could significantly and materially harm our business Even prior to any change to the UK's relationship with the EU, the announcement of Brexit has created economic uncertainty surrounding the terms of Brexit and its consequences 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.

Risks Related to Our Financial Position and Capital Requirements

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

We have not yet reached sustained profitability. For the fiscal years ended December 31, 2019, 2018, and 2017, we reported losses of approximately $22.6 million, $116.4 million, and $67.9 million, respectively, and we had an accumulated deficit as of December 31, 2019 of $1.4 billion. Substantially all of our operating losses resulted from costs incurred in connection with our research and development programs, from general and administrative costs associated with our operations, and costs related to the commercialization of Vascepa. Additionally, as a result of our significant expenses relating to research and development and to

commercialization, we expect to continue to incur significant operating losses for an indefinite period. Because of the numerous risks and uncertainties associated with developing and commercializing pharmaceutical products, we are unable to predict the magnitude of these future losses. Our historic losses, combined with expected future losses, have had and will continue to have an adverse effect on our cash resources, shareholders' deficit and working capital.

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

Our ability to become profitable 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 FDA for marketing in the United States for two important indications, it may not gain enough market acceptance to support 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 our expanded commercialization efforts, for example. If we are unable to continue to generate robust product revenues, we will not become profitable on a sustained basis in the near term, if ever, and may be unable to continue operations without continued funding.

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

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

- the continuing evolution of the medical community's and the public's perception of the REDUCE-IT study results;
- the level of demand for Vascepa, due to changes in prescriber sentiment, quarterly changes in Distributor purchases, and other factors;
- the extent to which coverage and reimbursement for Vascepa is available from government and health administration authorities, private health insurers, managed care programs and other third-party payers and the timing and extent to which such coverage and reimbursement changes;
- the timing, cost and level of investment in our sales and marketing efforts to support Vascepa sales and the resulting effectiveness of those efforts;
- 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 recent outbreak of coronavirus;
- the timing and ability of efforts outside the United States, to develop, register and commercialize Vascepa in the EU, 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 $644.6 million as of December 31, 2019, will be sufficient to fund our projected operations for at least twelve months. 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 expansion of Vascepa promotion and potential Vascepa promotion beyond which we are currently executing. If additional capital is required and we are unable to obtain additional capital, we may be forced to delay, limit or eliminate certain promotional activities. We anticipate that quarterly net cash outflows in future periods will be variable.

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

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

- the timing, amount and consistency of revenue generated from the commercial sale of Vascepa;
- the costs associated with commercializing Vascepa in the United States, including expenditures such as potential direct-to-consumer advertising and increased sales force sizing, and for additional 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;
- 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 may suffer materially.

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

Tax law and policies in the United States and Ireland are subject to change based on adjustments in political perspectives. In the United States and internationally, how to tax entities with international operations, like Amarin, has been subject to significant re-evaluation. We 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.

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

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

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

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

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

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

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

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

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

Risks Related to Ownership of our ADSs and Common Shares

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

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

As of February 21, 2020, we had 361,201,553 common shares outstanding including 360,999,820 shares held as ADSs and 201,733 held as ordinary shares (which are not held in the form of ADSs). There is a risk that there may not be sufficient liquidity in the market to accommodate significant increases in selling activity or the sale of a large block of our securities. Our ADSs have historically had limited trading volume, which may also result in volatility. 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 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. Lack of clarity about future UK laws and regulations as the United Kingdom determines which EU rules and regulations to replace or replicate, including regulatory and financial laws and regulations, tax and free trade agreements, IP rights, supply chain logistics, environmental, health and safety laws and regulations, immigration laws and employment laws, 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.

The number of our ordinary shares, or ADSs representing such ordinary shares, outstanding may increase substantially as a result of our March 2015 private placement and the later consolidation and redesignation of the Series A Preference Shares

represented by Preference ADSs issued thereunder, and some of the investors may then beneficially own significant blocks of our ordinary shares; the ordinary shares and Series A Preference Shares resulting from the private placement will be generally available for resale in the public market upon registration under the Securities Act.

In March and July 2015, we completed a private placement of American Depositary Shares in two tranches representing 352,150,790 and 38,867,180 Series A Preference Shares, respectively, each ten (10) of which may be consolidated and redesignated into one (1) ordinary share in our capital. During 2015, 62,833,330 preferred shares were converted, resulting in the issuance of 6,283,333 ordinary shares and during 2018, the entire tranche completed in July 2015 of 38,867,180 preferred shares were converted, resulting in the issuance of 3,886,718 ordinary shares. The consolidation and redesignation of the Series A Preference Shares currently outstanding would result in an additional 28,931,746 ordinary shares outstanding, resulting in substantial dilution to shareholders. Although the Series A Preference Shares do not have voting rights, in general, upon consolidation and redesignation into ordinary shares some of the investors in the private placement could then have significant influence over the outcome of any shareholder vote, including the election of directors and the approval of mergers or other business combination transactions.

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

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

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

For example, under each of these agreements we have agreed to file and maintain the effectiveness of certain resale registration statements for ADSs representing the ordinary shares underlying the Series A Preference shares we issued and sold under these agreements. Specifically, we have agreed to pay liquidated damages to the investors in the respective private placements if (a) the applicable resale registration statements we are required to file are not declared effective within 120 days after the closing of the applicable private placement, or (b) after effectiveness and subject to certain specified exceptions, we suspend the use of the applicable registration statement or the registration statement ceases to remain continuously effective as to all the securities for which it is required to be effective. We refer to each of these events as a registration default. Subject to the specified exceptions, for each 30-day period or portion thereof during which a registration default remains uncured, we are obligated to pay liquidated damages to each investor in cash in an amount equal to 1% of the aggregate subscription price paid by each such investor in the private placement, up to a maximum of 8% of such aggregate subscription price. These amounts could be material, and any liquidated damages we are required to pay could have a material adverse effect on our financial condition.

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

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

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

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, 2019 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.

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

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

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

Upon a transaction resulting in a change of control of Amarin, as defined in the agreement, CPPIB will be automatically entitled to receive any amounts not previously paid, up to our maximum repayment obligation. As defined in the agreement, "change of control" includes, among other things, (i) a greater than 50 percent change in the ownership of Amarin, (ii) a sale or disposition of any collateral securing our debt with CPPIB and (iii), unless CPPIB has been paid a certain amount under the indebtedness, certain licensings of Vascepa to a third party for sale in the United States. The acceleration of the payment obligation in the event of a change of control transaction may make us less attractive to potential acquirers, and the payment of such funds out of our available cash or acquisition proceeds would reduce acquisition proceeds for our shareholders.

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

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

Our indebtedness could adversely affect our financial condition.

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

- increase our vulnerability to general adverse economic and industry conditions;
- limit our ability to raise additional funds by borrowing or engaging in equity sales in order to fund future working capital, capital expenditures, research and development and other general corporate requirements;

- require us to dedicate a substantial portion of our cash to service payments on our debt or to restructure our debt; or
- limit our flexibility to react to changes in our business and the industry in which we operate or to pursue certain strategic opportunities that may present themselves.

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

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

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

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

- Under English law and our Articles of Association, each shareholder present at a meeting has only one vote unless demand is made for a vote on a poll, in which case each holder gets one vote per share owned. Under U.S. law, each shareholder typically is entitled to one vote per share at all meetings.
- Under English law, it is only on a poll that the number of shares determines the number of votes a holder may cast. You should be aware, however, that the voting rights of ADSs are also governed by the provisions of a deposit agreement with our depositary bank.
- Under English law, subject to certain exceptions and disapplications, each shareholder generally has preemptive rights to subscribe on a proportionate basis to any issuance of ordinary shares or rights to subscribe for, or to convert securities into, ordinary shares for cash. Under U.S. law, shareholders generally do not have preemptive rights unless specifically granted in the certificate of incorporation or otherwise.
- Under English law and our Articles of Association, certain matters require the approval of 75% of the shareholders who vote (in person or by proxy) on the relevant resolution (or on a poll of shareholders representing 75% of the ordinary shares voting (in person or by proxy)), including amendments to the Articles of Association. This may make it more difficult for us to complete corporate transactions deemed advisable by our board of directors. Under U.S. law, generally only majority shareholder approval is required to amend the certificate of incorporation or to approve other significant transactions.
- In the United Kingdom, takeovers may be structured as takeover offers or as schemes of arrangement. Under English law, a bidder seeking to acquire us by means of a takeover offer would need to make an offer for all of our outstanding ordinary shares/ADSs. If acceptances are not received for 90% or more of the ordinary shares/ADSs under the offer, under English law, the bidder cannot complete a "squeeze out" to obtain 100% control of us. Accordingly, acceptances of 90% of our outstanding ordinary shares/ADSs will likely be a condition in any takeover offer to acquire us, not 50% as is more common in tender offers for corporations organized under Delaware law. By contrast, a scheme of arrangement, the successful completion of which would result in a bidder obtaining 100% control of us, requires the approval of a majority of shareholders voting at the meeting and representing 75% of the ordinary shares voting for approval.
- Under English law and our Articles of Association, shareholders and other persons whom we know or have reasonable cause to believe are, or have been, interested in our shares may be required to disclose information regarding their interests in our shares upon our request, and the failure to provide the required information could result in the loss or restriction of rights attaching to the shares, including prohibitions on certain transfers of the shares, withholding of dividends and loss of voting rights. Comparable provisions generally do not exist under U.S. law.
- The quorum requirement for a shareholders' meeting is a minimum of two shareholders entitled to vote at the meeting and present in person or by proxy or, in the case of a shareholder which is a corporation, represented by a duly authorized officer. Under U.S. law, a majority of the shares eligible to vote must generally be present (in person or by proxy) at a shareholders' meeting in order to constitute a quorum. The minimum number of shares required for a quorum can be reduced pursuant to a provision in a company's certificate of incorporation or bylaws, but typically not below one-third of the shares entitled to vote at the meeting.

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

The Takeover Code provides a framework within which takeovers of certain companies organized in the United Kingdom are regulated and conducted. However, because our place of central management and control is currently outside of the United Kingdom,

we are not subject to the Takeover Code. As a result, our shareholders are not entitled to the benefit of certain takeover offer protections provided under the Takeover Code. The following is a brief summary of some of the most important rules of the Takeover Code which, as noted, does not apply to us:

- In connection with a potential offer, if following an approach by or on behalf of a potential bidder, the company is "the subject of rumor or speculation" or there is an "untoward movement" in the company's share price, there is a requirement for the potential bidder to make a public announcement about a potential offer for the company, or for the company to make a public announcement about its review of a potential offer.
- When a person or group (a) acquires interests in shares carrying 30% or more of the voting rights of a company (which percentage is treated by the Takeover Code as the level at which effective control is obtained) or (b) increases the aggregate percentage interest they have when they are already interested in not less than 30% and not more than 50%, they must make a cash offer to all other shareholders at the highest price paid by them in the 12 months before the offer was announced.
- When interests in shares carrying 10% or more of the voting rights of a class have been acquired by an offeror (i.e., a bidder) in the offer period (i.e., before the shares subject to the offer have been acquired) and the previous 12 months, the offer must be in cash or be accompanied by a cash alternative for all shareholders of that class at the highest price paid by the offeror in that period. Further, if an offeror acquires any interest in shares during the offer period, the offer for the shares must be in cash or accompanied by a cash alternative at a price at least equal to the price paid for such shares during the offer period.
- If after an announcement is made, the offeror acquires an interest in shares in an offeree company (i.e., a target) at a price higher than the value of the offer, the offer must be increased accordingly.
- The offeree company must appoint a competent independent adviser whose advice on the financial terms of the offer must be made known to all the shareholders, together with the opinion of the board of directors of the offeree company.
- Favorable deals for selected shareholders are not permitted, except in certain circumstances where independent shareholder approval is given and the arrangements are regarded as fair and reasonable in the opinion of the financial adviser to the offeree.
- All shareholders must be given the same information.
- Those issuing takeover circulars must include statements taking responsibility for the contents thereof.
- Profit forecasts, quantified financial benefits statements and asset valuations must be made to specified standards and must be reported on by professional advisers.
- Misleading, inaccurate or unsubstantiated statements made in documents or to the media must be publicly corrected immediately.
- Actions during the course of an offer by the offeree company, which might frustrate the offer are generally prohibited unless shareholders approve these plans. Frustrating actions would include, for example, lengthening the notice period for directors under their service contract or agreeing to sell off material parts of the target group.
- Stringent requirements are laid down for the disclosure of dealings in relevant securities during an offer, including the prompt disclosure of positions and dealing in relevant securities by the parties to an offer and any person who is interested (directly or indirectly) in 1% or more of any class of relevant securities.
- Employees of both the offeror and the offeree company and the trustees of the offeree company's pension scheme must be informed about an offer. In addition, the offeree company's employee representatives and pension scheme trustees have the right to have a separate opinion on the effects of the offer on employment appended to the offeree board of directors' circular or published on a website.

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

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

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

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

Item 1B. *Unresolved Staff Comments*

None.

Item 2. *Properties*

The following table lists the location, use and ownership interest of our principal properties as of February 21, 2020:

Location	Use	Ownership	Size (sq. ft.)
Dublin, Ireland	Offices	Leased	4,983
Bridgewater, New Jersey, USA	Offices	Leased	67,747

Effective November 1, 2011, we leased 320 square feet of office space in Dublin, Ireland. The office space was subsequently reduced to 270 square feet, effective November 1, 2013. The lease was terminated on May 1, 2019. Effective May 1, 2019 and October 1, 2019, we entered into Office Centre Sharing Agreements, leasing 4,983 square feet, to replace the office space with new office space in Dublin, Ireland which terminate on April 30, 2020 and September 30, 2020, respectively, and can be extended automatically for successive one year periods.

On July 1, 2011, the Company leased 9,747 square feet of office space in Bedminster, New Jersey. The lease, as amended, terminated on September 15, 2019. On January 26, 2019, the Company leased an additional 5,988 square feet in another building in Bedminster, New Jersey, effective February 1, 2019 which also terminated on September 15, 2019.

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.

Item 3. *Legal Proceedings*

On February 22, 2019, a purported investor in our publicly traded securities filed a putative class action lawsuit against Amarin Corporation plc, our chief executive officer and chief scientific officer in the U.S. District Court for the District of New Jersey, *Debendra Sharma v. Amarin Corporation plc*, *John F. Thero and Steven Ketchum*, No. 2:19-cv-06601 (D.N.J. Feb. 22, 2019). On March 12, 2019, another purported investor filed a substantially similar lawsuit captioned *Richard Borghesi v. Amarin Corporation plc*, *John F. Thero and Steven Ketchum*, No. 3:19-cv-08423 (D.N.J. March 12, 2019). 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 adds as defendants our current chief medical officer and our former chief executive officer, who is a current director. The Amended Complaint alleges that from September 24, 2018 to November 9, 2018 we 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 alleges 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 allege may have increased adverse outcomes in the placebo group. The Amended Complaint further allege that these purported misrepresentations and omissions inflated our share price. Based on these allegations, the suit asserts claims under the Securities Exchange Act of 1934 and seeks unspecified monetary damages and attorneys' fees and costs.

We believe that we have valid defenses and we will vigorously defend against the claims, but cannot predict the outcome. We are unable to reasonably estimate the loss exposure, if any, associated with these claims. We have insurance coverage that is anticipated to cover any significant loss exposure that may arise from this action after payment by us of the associated deductible obligation.

In September and October 2016, we received paragraph IV certification notices from four companies contending to varying degrees that certain of our patents are invalid, unenforceable and/or will not be infringed by the manufacture, use, sale or offer for sale of a generic form of Vascepa as described in those companies' abbreviated new drug applications, or ANDAs. We filed patent infringement lawsuits against three of these four ANDA applicants. In October 2016, Amarin filed a lawsuit against Roxane Laboratories, Inc. and related parties (collectively, "Roxane") in the U.S. District Court for the District of Nevada. The case against Roxane is captioned *Amarin Pharma, Inc. et al. v. Roxane Laboratories, Inc. et al.*, Civ. A. No. 2:16-cv-02525 (D. Nev.). According to a stipulation filed with the Nevada court, in December 2016, Roxane transferred its ANDA to West-Ward Pharmaceuticals International Limited, which then designated West-Ward Pharmaceuticals Corp. (or together with West-Ward Pharmaceuticals International Limited, West-Ward) as its agent for FDA communications. In view of the ANDA transfer, in February 2017, West-Ward replaced Roxane and related parties as Defendants in the above-referenced case. The case against West-Ward is now captioned *Amarin Pharma, Inc. et al. v. West-Ward Pharmaceuticals Corp. et al.*, Civ. A. No. 2:16-cv-02525 (D. Nev.). In November 2016, Amarin filed a lawsuit against Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. (collectively, "DRL") in the U.S. District Court for the District of Nevada. The case against DRL is captioned *Amarin Pharma, Inc. et al. v. Dr. Reddy's Laboratories, Inc. et al.*, Civ. A. No. 2:16-cv-02562 (D. Nev.). In November 2016, Amarin filed a lawsuit against Teva Pharmaceuticals USA, Inc. and Teva Pharmaceuticals Industries Limited (collectively, "Teva") in the U.S. District Court for the District of Nevada. The case against Teva is captioned *Amarin Pharma, Inc. et al. v. Teva Pharmaceuticals USA, Inc. et al.*, Civ. A. No. 2:16-cv-02658. In all three lawsuits, Amarin is seeking, among other remedies, an order enjoining each defendant from marketing generic versions of Vascepa before the last to expire of the asserted patents in 2030. The three lawsuits have been consolidated for pretrial proceedings. As a result of the statutory stay associated with the filing of these lawsuits under the Hatch-Waxman Act, the FDA was restricted from granting final approval to West-Ward, DRL, or Teva's respective ANDA before January 2020, unless there was an earlier court decision holding that the subject patents are not infringed and/or are invalid.

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

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

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

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

The ANDA patent litigation referenced above is currently pending in the United States District Court for the District of Nevada with parties DRL and West-Ward, now known as Hikma Pharmaceuticals USA Inc, or Hikma (Case No.: 2:16-cv-02525-MMD-NJK (consolidated with 2:16-cv-02562-MMD-NJK). The trial in this litigation took place from mid to late January 2020. Based on Court statements, judgment is expected by the end of March 2020.

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

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

Item 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

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 2019		Fiscal 2018	
	High	Low	High	Low
First Quarter	$ 23.25	$ 12.44	$ 4.60	$ 2.91
Second Quarter	$ 20.97	$ 16.20	$ 3.52	$ 2.66
Third Quarter	$ 23.91	$ 13.76	$ 16.34	$ 2.35
Fourth Quarter	$ 26.12	$ 13.87	$ 23.34	$ 11.78

Shareholders

As of January 31, 2020, there were approximately 350 holders of record of our ordinary shares. Because many ordinary shares are held by broker nominees, we are unable to estimate the total number of shareholders represented by these record holders. Our depositary, Citibank, N.A., constitutes a single record holder of our ordinary shares.

Dividends

We have never paid dividends on 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 stockholders, and may only be paid from our distributable profits available for the purpose, determined on an unconsolidated basis.

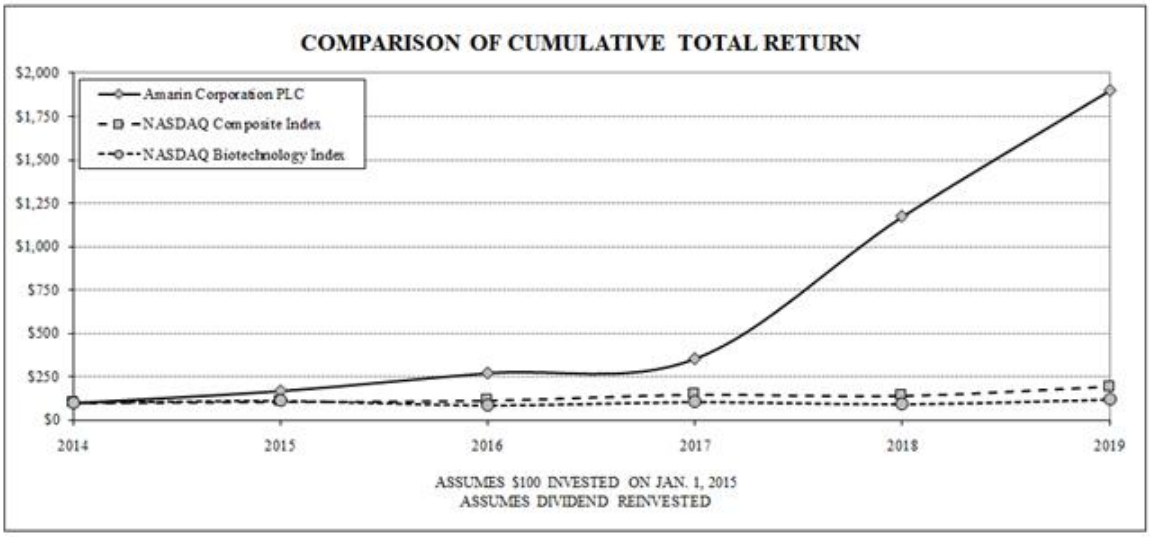
Under our Purchase and Sale Agreement with CPPIB Credit Europe S.à r.l., or CPPIB, as successor in interest to BioPharma Secured Debt Fund II Holdings Cayman LP, we are restricted from paying a dividend on our common shares, unless we have cash and cash equivalents in excess of a specified amount after such payment.

Performance Graph—5 Year

The following performance graph and related information shall not be deemed "soliciting material" or to be "filed" with the Securities and Exchange Commission, 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 stockholders of Amarin's 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 January 1, 2015 and its relative performance is tracked through December 31, 2019.

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



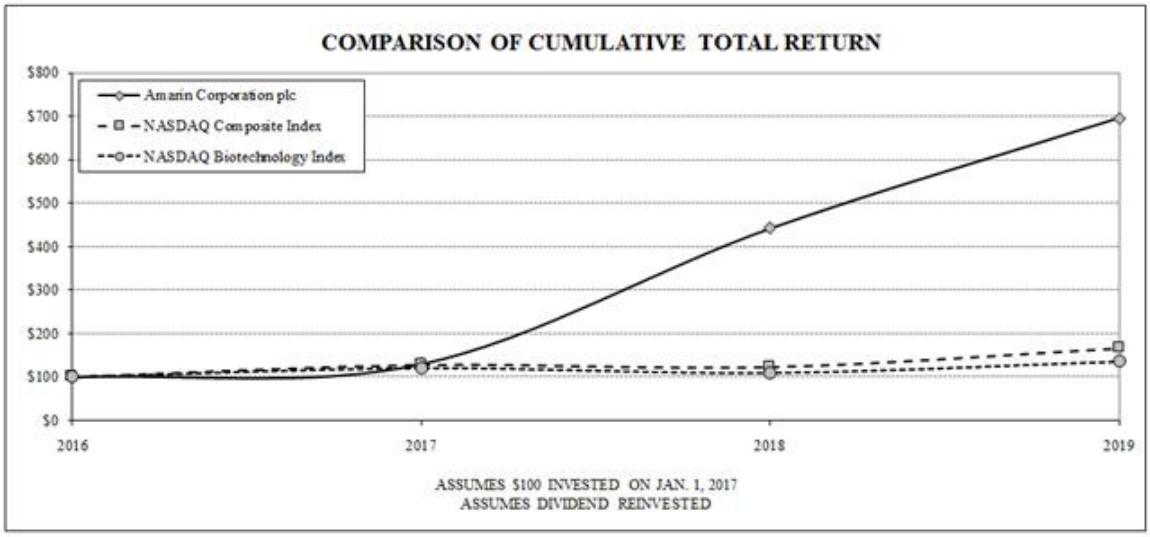
Company/Market/Peer Company	12/31/2015	12/31/2016	12/31/2017	12/31/2018	12/31/2019
Amarin Corporation PLC	$ 169.91	$ 272.57	$ 354.87	$ 1,171.68	$ 1,897.35
NASDAQ Composite Index	$ 106.81	$ 113.88	$ 146.05	$ 139.30	$ 189.82
NASDAQ Biotechnology Index	$ 110.96	$ 86.54	$ 104.77	$ 93.18	$ 118.19

Performance Graph—3 Year

The following performance graph and related information shall not be deemed "soliciting material" or to be "filed" with the Securities and Exchange Commission, 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 3-year return provided to stockholders of Amarin's 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 January 1, 2017 and its relative performance is tracked through December 31, 2019.

Included in this 3-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.



Company/Market/Peer Company	12/31/2017	12/31/2018	12/31/2019
Amarin Corporation PLC	$ 130.19	$ 441.88	$ 696.10
NASDAQ Composite Index	$ 128.24	$ 123.26	$ 166.68
NASDAQ Biotechnology Index	$ 121.06	$ 109.77	$ 136.56

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.

Unregistered Sales of Equity Securities and Use of Proceeds

Issuer Purchases of Equity Securities

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

Period	Total Number of Shares Purchased (1)	Average Price Paid per Share
October 1 – 31, 2019	1,069,377	$ 14.37
November 1 – 30, 2019	—	—
December 1 – 31, 2019	—	—
Total	1,069,377	$ 14.37

(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., U.K. 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 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 report, 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;
- 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 (1) that validly elects to be treated as a U.S. person for U.S. federal income tax purposes, or (2) 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 Amarin does not maintain calculations of its earnings and profits in accordance with U.S. federal income tax principles, U.S. Holders should assume that any distribution by Amarin 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 passive foreign investment company, or 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 shares, we believe that we will not be classified as a PFIC for the taxable year ended December 31, 2019 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 be classified as a PFIC for any taxable year.

In general terms, Amarin will be a PFIC for any taxable year in which either (i) 75% or more of its gross income is passive income, or the income test, or (ii) the average percentage, by fair market value, of its 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 Amarin is a PFIC for any year, subject to the discussion of QEF 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 Amarin was 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 Amarin was 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 Amarin is or was 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 Amarin is 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 Amarin is a PFIC and Amarin complies 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 Amarin’s ordinary earnings and net capital gain for any taxable year in which Amarin is 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, Amarin 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 Amarin is 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 Amarin is or becomes 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 Amarin 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 Amarin 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 Amarin is a PFIC and has a non-U.S. subsidiary that is also a PFIC, or a lower-tier PFIC. If Amarin is or becomes 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) Amarin receives a distribution from, or disposes of all or part of its 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, Amarin 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 Internal Revenue Service.

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. 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.

Certain Material U.K. 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). Tax considerations applicable to other types of securities will be described in the related prospectus supplement. 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 5 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 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 US 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 US 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. ***Selected Financial Data***

The selected financial data set forth below as of and for the years ended December 31, 2019, 2018, 2017, 2016, and 2015 have been derived from the audited consolidated financial statements of Amarin. This data should be read in conjunction with our audited consolidated financial statements and related notes which are included elsewhere in this Annual Report on Form 10-K, and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in Item 7 below. Historical results are not necessarily indicative of operating results to be expected in the future.

	Years Ended December 31,				
	2019	2018	2017	2016	2015
	(In thousands, except per share amounts)				
Consolidated Statements of Operations Data:					
Product revenue, net	$ 427,391	$ 228,371	$ 179,825	$ 128,966	$ 80,987
Licensing revenue	2,364	843	1,279	1,118	769
Total revenue, net	429,755	229,214	181,104	130,084	81,756
Less: Cost of goods sold	96,019	54,543	44,952	34,363	27,875
Gross margin	333,736	174,671	136,152	95,721	53,881
Operating expenses:					
Selling, general and administrative (1)	323,623	226,996	134,549	111,372	101,041
Research and development	34,392	55,900	47,158	49,975	51,062
Total operating expenses	358,015	282,896	181,707	161,347	152,103
Operating loss	(24,279)	(108,225)	(45,555)	(65,626)	(98,222)
Gain (loss) on change in fair value of derivative liabilities (2)	—	—	—	8,170	(1,106)
Gain on extinguishment of debt	—	—	—	—	1,314
Interest expense	(6,626)	(8,872)	(9,766)	(18,677)	(20,180)
Interest income	8,499	1,074	429	234	132
Other (expense) income, net	(75)	(326)	74	(482)	(228)
Loss from operations before taxes	(22,481)	(116,349)	(54,818)	(76,381)	(118,290)
(Provision for) benefit from income taxes (5)	(164)	(96)	(13,047)	(9,969)	3,086
Net loss	(22,645)	(116,445)	(67,865)	(86,350)	(115,204)
Preferred stock purchase option	—	—	—	—	(868)
Preferred stock beneficial conversion features	—	—	—	—	(32,987)
Net loss applicable to common shareholders	(22,645)	(116,445)	(67,865)	(86,350)	(149,059)
Loss per share:					
Basic	$ (0.07)	$ (0.39)	$ (0.25)	$ (0.41)	$ (0.83)
Diluted	$ (0.07)	$ (0.39)	$ (0.25)	$ (0.41)	$ (0.83)
Weighted average shares:					
Basic	342,538	297,237	270,652	211,874	180,654
Diluted	342,538	297,237	270,652	211,874	180,654

	As of December 31,				
	2019	2018	2017	2016	2015
	(In thousands)				
Consolidated Balance Sheet Data:					
Cash and cash equivalents	$ 644,588	$ 249,227	$ 73,637	$ 98,251	$ 106,961
Total assets (3) (4)	882,209	385,714	161,598	166,999	173,230
Long-term liabilities (3)	31,698	76,121	118,168	99,808	250,059
Stockholders' equity (deficit) (4)	608,263	152,330	(65,100)	(9,058)	(127,552)

(1) Includes non-cash warrant-related compensation income in 2015, reflecting the change in the fair value of the warrant derivative liability associated with warrants issued in October 2009 to former officers of Amarin.

(2) Includes non-cash charges resulting from changes in the fair value of derivative liabilities.

(3) Reflects reclassification of $1.9 million as of December 31, 2015 to present debt issuance costs as a direct deduction from the carrying amount of the related debt liability rather than as an asset, due to the retrospective application of Accounting Standards Update, or ASU, No. 2015-03, *Interest—Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs*, adopted in January 2016.

(4) Reflects recognition of deferred tax assets of approximately $1.6 million relating to excess tax benefits on stock-based compensation outstanding as of December 31, 2015 and corresponding cumulative-effect adjustment to Accumulated deficit as of December 31, 2015, due to the modified retrospective application of ASU No. 2016-09, *Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*, adopted in 2016.

(5) Included in the provision for the year ended December 31, 2017 is a non-cash charge related to the reduction in the amount of the U.S. subsidiary's deferred tax assets due to the decrease in the U.S. corporate tax rate to 21% resulting from the enactment of the Tax Cuts and Jobs Act. Also included in the provisions for the years ended December 31, 2017 and 2016 is non-cash tax expense resulting from our conclusion that it is not more likely than not that certain of the deferred tax benefits resulting from deferred tax assets generated from the U.S. subsidiary operations will be realized, based on evaluation of available evidence.

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 performance of the Company. When used in this report, 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; expectation on determinations and policy positions of the United States Food and Drug Administration, or 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 report 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 report represent periods or dates fixed with reference to our fiscal year ended December 31, 2019.

Overview

We are a pharmaceutical company with expertise in omega-3 fatty acids and lipid science focused on the commercialization and development of therapeutics to improve cardiovascular, or CV, health and reduce CV risk. Our lead product, Vascepa® (icosapent ethyl) was first approved by the U.S. Food and Drug Administration, or FDA, for use as an adjunct to diet to reduce triglyceride, or TG, levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia. On December 13, 2019 the FDA approved a new indication and label expansion for Vascepa based on the landmark results of our cardiovascular outcomes trial of Vascepa, REDUCE-IT®, or Reduction of Cardiovascular Events with EPA – Intervention Trial. Vascepa is the first and only drug approved by the FDA as an adjunct to maximally tolerated statin therapy for reducing persistent cardiovascular risk in select high risk patients.

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 publicly presented primary results of the REDUCE-IT study at the 2018 Scientific Sessions of the American Heart Association, or AHA, and the results were concurrently published in *The New England Journal of Medicine*. REDUCE-IT met its primary endpoint demonstrating a 25% relative risk reduction, or RRR, to a high degree of statistical significance ($p<0.001$), in first occurrence of major adverse cardiovascular events, or MACE, in the intent-to-treat patient population with use of Vascepa 4 grams/day as compared to placebo. REDUCE-IT also showed a 26% RRR in its key secondary composite endpoint of cardiovascular death, heart attacks and stroke ($p<0.001$). On March 18, 2019, we publicly presented the total cardiovascular events results, and the method of calculating such events, of the REDUCE-IT study at the American College of Cardiology's, or ACC, 68th Annual Scientific Session and such results and methods were concurrently published in the *Journal of the American College of Cardiology*. Included in such results were that Vascepa reduced total events (first and subsequent events) by 30% compared to placebo, reflecting that for every 1,000 patients treated for 5 years with Vascepa versus placebo in this trial, approximately 159 MACE would have been be prevented with Vascepa.

Based on REDUCE-IT results, several clinical treatment guidelines and position statements have been updated as follows:

- In March 2019, the American Diabetes Association, or ADA, issued important updates to the *Standard of Medical Care in Diabetes* for 2019, including a recommendation for the use of icosapent ethyl in treating at-risk patients based on the results of the REDUCE-IT cardiovascular outcomes study.
- In August 2019, the AHA recognized the results of REDUCE-IT and recommended directing medical care away from unproven fish oil dietary supplements and to prescription drug therapy in patients with elevated TG levels.

- In September 2019, the National Lipid Association issued a position statement recognizing the cardiovascular risk-lowering effects of icosapent ethyl based on the REDUCE-IT results.
- In September 2019, the European Society of Cardiology and the European Atherosclerosis Society updated their Clinical Practice Guidelines for the Management of Dyslipidemias to incorporate findings from the REDUCE-IT study.
- In February 2020, the American Association of Clinical Endocrinologists and the American College of Endocrinology released a consensus statement on the comprehensive management of type 2 diabetes. The statement included new guidance for managing patients with established or high risk for cardiovascular disease who have triglyceride levels between 135 – 499 mg/dL with icosapent ethyl which has proven benefits to prevent the new adverse cardiovascular event.

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. ICER's report indicated that Vascepa was cost effectiveness across all of the non-profit organization's analyses, including its quality-adjusted life year metrics of <$50,000. The conclusion from the report is that Vascepa easily meets "commonly cited thresholds for cost-effectiveness and therefore represents a high long-term value for money" based on the organization's value assessment framework. In addition, an independent academic, patient-level, cost-effectiveness analysis of icosapent ethyl led by Dr. William S. Weintraub, M.D., director of Outcomes Research with MedStar Cardiovascular Research Network, indicated that Vascepa was projected to not only be cost-effective but also to reduce long-term health care costs in a majority of the scenarios analyzed.

The 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 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. In November 2019, 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 FDA approved a new indication and label expansion for Vascepa capsules. Vascepa is the first and only drug approved by the 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 triglyceride, or TG, levels (≥150 mg/dL) and either established cardiovascular disease or diabetes mellitus and two or more additional risk factors for cardiovascular disease.

Commercialization

We commenced the commercial launch of Vascepa through sales and shipments to our network of U.S.-based wholesalers in the United States in January 2013. We began selling and marketing 1-gram size Vascepa capsules in January 2013, and in October 2016, introduced a smaller 0.5-gram capsule size. The FDA-approved dosing for Vascepa continues to be 4 grams per day, and, as expected, the majority of new and existing patients taking Vascepa continue to be prescribed the 1-gram size Vascepa capsule. Vascepa is sold principally to a limited number of major wholesalers, as well as selected regional wholesalers and specialty pharmacy providers, or collectively, our distributors or our customers, that in turn resell Vascepa to retail pharmacies for subsequent resale to patients and healthcare providers. Prior to results of the REDUCE-IT study we did not have outcomes data regarding the clinical effect of Vascepa and a substantial portion of our resources were being spent on the REDUCE-IT study. As a result, our commercialization of Vascepa was somewhat limited.

Prior to the REDUCE-IT results topline announcement in September 2018, our direct sales force consisted of approximately 170 sales professionals, including sales representatives and their managers. Based on the positive REDUCE-IT results, in early 2019, we increased the size of our sales team to approximately 440 sales professionals, including approximately 400 sales representatives. As a result of the FDA's newly approved indication and label expansion, we are close to completing the expansion of our direct sales force to approximately 900 sales professionals, including approximately 800 sales representatives. Hiring, training and deploying approximately 400 new sales representatives is a multi-stage process which commenced in July 2019 and is expected to be completed in early 2020. Most of the expanded sales management team needed to support this sales force expansion was hired, or internally promoted, and trained prior to December 31, 2019.

From May 2014 through the end of December 2018, in addition to Vascepa promotion by our sales representatives, Kowa Pharmaceuticals America, Inc. co-promoted Vascepa in conjunction with its promotion of its primary product, a branded statin for patients with high cholesterol. Amarin and Kowa Pharmaceuticals America, Inc. intentionally designed the co-promotion to naturally end as of December 31, 2018 and mutually agreed not to renew the agreement. During 2018, as a result of not renewing the agreement, we incurred expense for the accrual of co-promotion tail payments, which were calculated as a percentage of the 2018 co-promotion fee. Kowa Pharmaceuticals America, Inc. will receive $17.8 million in co-promotion tail payments, the present value of which, $16.6 million, was fully accrued as of December 31, 2018 and will be paid over three years with declining amounts each year. We made $7.3 million in tail payments as of December 31, 2019.

We also employ various medical affairs and marketing personnel to support our commercialization of Vascepa. We expanded certain medical education and market awareness initiatives following the reporting of positive REDUCE-IT results in 2018. We intend to further expand promotion of Vascepa, including direct to consumer advertising, as a result of the new indication and label expansion of Vascepa approved by the FDA on December 13, 2019. In January 2020, we launched an educational campaign, *True To Your Heart*, to help people learn more about cardiovascular disease and how to better protect against persistent cardiovascular risk.

Based on monthly compilations of data provided by a third party, Symphony Health, the estimated number of normalized total Vascepa prescriptions for the three months ended December 31, 2019 was approximately 992,000 compared to 865,000, 756,000, 618,000, and 539,000 in the three months ended September 30, 2019, June 30, 2019, March 31, 2019, and December 31, 2018, respectively. According to data from another third party, IQVIA, the estimated number of normalized total Vascepa prescriptions for the three months ended December 31, 2019 was approximately 909,000 compared to 787,000, 683,000, 553,000, and 492,000 in the three months ended September 30, 2019, June 30, 2019, March 31, 2019, and December 31, 2018, respectively. Normalized total prescriptions represent the estimated total number of Vascepa prescriptions dispensed to patients, calculated on a normalized basis (i.e., one month's supply, or total capsules dispensed multiplied by the number of grams per capsule divided by 120 grams). Inventory levels at wholesalers tend to fluctuate based on seasonal factors, prescription trends and other factors.

Companies such as Symphony Health and IQVIA collect and report estimates of weekly, monthly, quarterly and annual prescription information. There is a limited amount of information available to such companies to determine the actual number of total prescriptions for prescription products like Vascepa during such periods. Each vendor's estimates utilize a proprietary projection methodology and are based on a combination of data received from pharmacies and other distributors, and historical data when actual data is unavailable. Their calculations of changes in prescription levels between periods can be significantly affected by lags in data reporting from various sources or by changes in pharmacies and other distributors providing data. Such methods can from time to time result in significant inaccuracies in information when ultimately compared with actual results. These inaccuracies have historically been most prevalent and pronounced during periods of time of inflections upward or downward in rates of use. Further, data for a single and limited period may not be representative of a trend or otherwise predictive of future results. Data reported by Symphony Health and IQVIA is rarely identical. As such, the resulting conclusions from such sources should be viewed with caution. We are not responsible for the accuracy of these companies' information and Amarin does not receive prescription data directly from retail pharmacies.

We recognize revenue from product sales when the distributor obtains control of our product, which occurs at a point in time, typically upon delivery to the distributor. Timing of shipments to wholesalers, as used for revenue recognition purposes, and timing of prescriptions as estimated by these third parties may differ from period to period. Although we believe these data are prepared on a period-to-period basis in a manner that is generally consistent and that such results can be generally indicative of current prescription trends, these data are based on estimates and should not be relied upon as definitive. While we expect to be able to grow Vascepa revenues over time, no guidance should be inferred from the operating metrics described above. We also anticipate that such sales growth will be inconsistent from period to period. We believe that investors should view the above-referenced operating metrics with caution, as data for this limited period may not be representative of a trend consistent with the results presented or otherwise predictive of future results. Seasonal fluctuations in pharmaceutical sales, for example, may affect future prescription trends of Vascepa, as could changes in prescriber sentiment, quarterly changes in Distributor purchases, and other factors. We believe investors should consider our results over several quarters, or longer, before making an assessment about potential future performance.

In addition to promotion of Vascepa in the United States, based on REDUCE-IT, we have increased focus on expansion of our development efforts for Vascepa to major markets outside the United States. We currently have strategic collaborations to develop and commercialize Vascepa in select territories outside the United States. In February 2015, we announced an exclusive agreement with Eddingpharm to develop and commercialize Vascepa capsules in what we refer to as the China Territory, consisting of the territories of Mainland China, Hong Kong, Macau and Taiwan, for uses that are currently commercialized and under development by us in the United States. In March 2016, we entered into an agreement with Biologix to register and commercialize Vascepa in several Middle Eastern and North African countries. In September 2017, we entered into an agreement with HLS to register, commercialize and distribute Vascepa in Canada. In March 2019, HLS received formal confirmation from Health Canada that the Canadian regulatory authority has granted priority review status for the upcoming New Drug Submission, which was filed in April 2019, for Vascepa. 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. Commercial launch in Canada began in February 2020 on a limited scale with subsequent expansion intended. In 2020, we intend to explore potential development and commercial paths for Vascepa in other markets such as the European Union. In December 2019, the European Medicines Agency, or EMA, has validated the marketing authorization application seeking approval for Vascepa. The validation confirms the submission is sufficiently complete for the EMA to begin its review, which review is currently expected to be completed before the end of 2020.

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

Research and Development

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

The 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 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, 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 FDA approved a new indication and related label expansion based on REDUCE-IT. Vascepa is the first and only drug approved by the 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 triglyceride, or TG, levels (≥150 mg/dL) and either established cardiovascular disease or diabetes mellitus and two or more additional risk factors for cardiovascular disease.

In June 2018, we entered into a multi-faceted collaboration with Mochida related to the development and commercialization of drug products and indications based on the active pharmaceutical ingredient in Vascepa, the omega-3 acid, EPA. Among other terms in the agreement, we obtained an exclusive license to certain Mochida intellectual property to advance our interests in the United States and certain other territories. In addition, the parties will collaborate to research and develop new products and indications based on EPA for our commercialization in the United States and certain other territories. The potential new product and indication opportunities contemplated under this agreement are currently in early stages of development. Upon closing of the collaboration agreement, we made a non-refundable, non-creditable upfront payment of approximately $2.7 million. In addition, the agreement provides for milestone payments from us upon the achievement of certain product development milestones and royalties on net sales of future products arising from the collaboration, if any. In January 2020, we achieved certain milestones under the agreement, resulting in payment of $1.0 million to Mochida.

Commercial and Clinical Supply

We manage the manufacturing and supply of Vascepa internally and have done so since we began clinical development of Vascepa prior to the drug's marketing approval by FDA in 2012. We rely on contract manufacturers in each step of our commercial and clinical product supply chain. These steps include active pharmaceutical ingredient, or API, manufacturing, encapsulation of the API, product packaging and supply-related logistics. Our approach to product supply procurement is designed to mitigate risk of supply interruption and maintain an environment of cost competition through diversification of contract manufacturers at each stage of the supply chain and lack of reliance on any single supplier. We have multiple FDA-approved international API suppliers, encapsulators and packagers to support the Vascepa commercial franchise. The amount of supply we seek to purchase in future periods will depend on the level of growth of Vascepa revenues and minimum purchase commitments with certain suppliers. While our current supply chain is scalable, we continue efforts to expand, diversify and further enhance it.

Financial Operations Overview

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

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

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

Selling, general and administrative expense. Selling, general and administrative expense consists primarily of salaries and other related costs, including stock-based compensation expense, for personnel in our sales, marketing, executive, business development, finance and information technology functions, as well as until December 31, 2018, co-promotion fees payable to Kowa Pharmaceuticals America, Inc. and, in 2018, an accrual for the co-promotion tail payments. Other costs primarily include facility costs and professional fees for accounting, consulting and legal services.

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

Interest and Other (Expense) Income, Net. Interest expense consists of interest incurred under our December 2012 royalty-bearing instrument financing arrangement, and interest incurred in 2018 under our previously outstanding 3.5% exchangeable notes. Interest expense under our royalty-bearing instrument financing arrangement is calculated based on an estimated repayment schedule. Interest expense under our previously outstanding exchangeable notes includes the amortization of the conversion option related to our exchangeable debt, the amortization of the related debt discounts and debt obligation coupon interest. Interest income consists of interest earned on our cash and cash equivalents. Other (expense) income, net, consists primarily of foreign exchange losses and gains.

Provision for Income Taxes. Provision for income taxes, deferred tax assets and liabilities, and reserves for unrecognized tax benefits reflect management's best assessment of estimated future taxes to be paid. We are subject to income taxes in both the United States and foreign jurisdictions. In applying 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, 2019 and 2018 are not more likely than not to be realized. Therefore, the appropriate amount of income tax benefit to recognize for the year-ended December 31, 2019 and 2018 is $0.2 million and $0.1 million, respectively.

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. 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. For a complete discussion of our accounting for net product revenue and licensing revenues, 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 $427.4 million and $228.4 million based on sales to distributors during the years ended December 31, 2019 and 2018, 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, 2019 and 2018.

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, 2019, 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, 2019 and 2018. 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

Comparison of Fiscal Years Ended December 31, 2019 and December 31, 2018

Product revenue, net. We recorded product revenue, net, of $427.4 million and $228.4 million during the years ended December 31, 2019 and 2018, respectively, an increase of $199.0 million, or 87%. This increase was driven primarily by volume of Vascepa sales to our customers in the United States. Orders by such customer were supported by an increase in estimated normalized total Vascepa prescriptions in the United States. Based on data provided by Symphony Health and IQVIA, estimated normalized total Vascepa prescriptions in the United States increased in 2019 by approximately 1,412,000 and 1,274,000, respectively, over the year ended December 31, 2018, representing growth of 78% and 77%, respectively. In addition, we recognized net product revenue of approximately $0.7 million and $0.1 million as of December 31, 2019 and 2018, respectively for Vascepa sales outside of the United States.

All of our product revenue in the years ended December 31, 2019 and 2018 was derived from product sales of 1-gram and 0.5-gram size capsules of Vascepa, net of allowances, discounts, incentives, rebates, chargebacks and returns. The FDA-approved dosing for Vascepa continues to be 4 grams per day and, as expected, the majority of new and existing patients taking Vascepa continue to be prescribed the 1-gram size Vascepa capsules. Timing of shipments to wholesalers, as used for revenue recognition, and timing of prescriptions as estimated by third-party sources such as Symphony Health and IQVIA may differ from period to period.

During the years ended December 31, 2019 and 2018, our Product revenue, net included adjustment for co-pay mitigation rebates provided by us to commercially insured patients. Such rebates are intended to offset the differential for patients of Vascepa not covered by commercial insurers at the time of launch on Tier 2 for formulary purposes, resulting in higher co-pay amounts for such patients. Our cost for these co-payment mitigation rebates during the years ended December 31, 2019 and 2018 was up to $70 per 30-day prescription filled and, beginning in March 2017, included up to $140 per 90-day prescription filled. Since launch, certain third-party payors have added Vascepa to their Tier 2 coverage, which results in lower co-payments for patients covered by these third-party payors. In connection with such Tier 2 coverage, we have agreed to pay customary rebates to these third-party payors on the resale of Vascepa to patients covered by these third-party payors.

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

Licensing revenue. Licensing revenue during the years ended December 31, 2019 and 2018 was $2.4 million and $0.8 million, respectively, an increase of $1.5 million, or 180%. Licensing revenue relates to the recognition of amounts received in connection with the following Vascepa licensing agreements:

- Eddingpharm – 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 and a $2.5 million milestone payment that was received following FDA approval of a new indication and label expansion in December 2019.

The up-front and milestone payments are being recognized over the estimated period in which we are required to provide regulatory and development support pursuant to the agreements. The amount of licensing revenue is expected to vary from period to period based on timing of milestones achieved and changes in estimates of the timing and level of support required. We do not anticipate significant revenues from international sources in 2020.

Cost of goods sold. Cost of goods sold during the years ended December 31, 2019 and 2018 was $96.0 million and $54.5 million, respectively, an increase of $41.5 million, or 76%. 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, 2019 and 2018 was sourced from multiple API suppliers. These suppliers compete with each other based on cost, consistent quality, capacity, timely delivery and other factors. In the future, we may see the average cost of supply change based on numerous potential factors including increased volume purchases, continued improvement in manufacturing efficiency, the mix of purchases made among suppliers, currency exchange rates and other factors. We currently anticipate API average cost in 2020 to be similar to or modestly lower than 2019. 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, 2019 and 2018 was 78% and 76%, respectively, reflecting modestly lower API average cost in 2019 compared to 2018 reflecting multiple factors including efficiencies associated with economies of expanded scale.

Selling, General and Administrative Expense. Selling, general and administrative expense for the years ended December 31, 2019 and 2018 was $323.6 million and $227.0 million, respectively, an increase of $96.6 million, or 43%. Selling, general and administrative expenses for the years ended December 31, 2019 and 2018 are summarized in the table below:

	Year Ended December 31,	
In thousands	**2019**	**2018**
Selling, general and administrative expense (1)	$ 297,321	$ 164,267
Co-promotion fees (2)	—	46,821
Non-cash stock-based compensation expense (3)	26,302	15,908
Total selling, general and administrative expense	$ 323,623	$ 226,996

(1) Selling, general and administrative expense, excluding co-promotion fees and non-cash compensation charges for stock compensation, for the years ended December 31, 2019 and 2018 was $297.3 million and $164.3 million, respectively, an increase of $133.1 million, or 81%. This increase is due primarily to increased commercial and other promotional spend as well as costs for sales force expansion in preparation for the launch of Vascepa in early 2020 for the new indication and expanded label approved based on the REDUCE-IT results. Partially offsetting this increase is a payment of $2.0 million made in connection with the settlement agreement reached with Teva Pharmaceuticals USA, Inc. in May 2018.

(2) Co-promotion fees payable to Kowa Pharmaceuticals America, Inc. were nil and $46.8 million in the years ended December 31, 2019 and 2018, respectively, a decrease of $46.8 million, or 100%. Amarin and Kowa Pharmaceuticals America, Inc. intentionally designed the co-promotion agreement to naturally end as of December 31, 2018 and mutually agreed not to renew the agreement.

(3) Non-cash stock-based compensation expense for the years ended December 31, 2019 and 2018 was $26.3 million and $15.9 million, respectively, an increase of $10.4 million, or 65%. 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 increase is due primarily to an increase in the number of employees receiving equity awards as a result of the growth of our sales force and an increase in the underlying fair value of the equity awards resulting from the increase in the price of our stock.

We anticipate our selling, general and administrative expenses to increase in 2020 as a result of increased promotional activities and direct to consumer promotion pertaining to the launch of Vascepa in early 2020 for the new indication and expanded label approved by FDA in December 2019, including increased costs associated with expanding the size of our sales force. In early 2019, we increased the size of our United States-based sales team to approximately 440 sales professionals, including approximately 400 sales representatives. We are close to completing the expansion of our United States-based direct sales force to approximately 900 sales professionals, including approximately 800 sales representatives. Hiring, training and deploying approximately 400 new sales representatives is expected to be completed in early 2020.

Research and Development Expense. Research and development expense for the years ended December 31, 2019 and 2018 was $34.4 million and $55.9 million, respectively, a decrease of $21.5 million, or 38%. Research and development expenses for the years ended December 31, 2019 and 2018 are summarized in the table below:

	Year Ended December 31,	
In thousands	**2019**	**2018**
REDUCE-IT study (1)	$ 10,680	$ 38,098
Regulatory filing fees and expenses (2)	1,502	1,052
Internal staffing, overhead and other (3)	17,595	13,852
Research and development expense, excluding non-cash expense	29,777	53,002
Non-cash stock-based compensation expense (4)	4,615	2,898
Total research and development expense	$ 34,392	$ 55,900

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

(1) In September 2018, we announced landmark positive topline results of the REDUCE-IT cardiovascular outcomes trial. We managed the study through a contract research organization, or CRO, through which all costs for the conduct of this outcomes study were incurred with the exception of costs for clinical trial material, or CTM, and costs for internal management. The decrease in expenses is primarily driven by a decline in REDUCE-IT related costs after the successful REDUCE-IT results. Following the completion of the REDUCE-IT trial, costs consisted primarily of the clinical study's wrap-up activities, regulatory support and publications.

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

(3) Internal staffing, overhead and other research and development expenses primarily relate to the costs of our personnel employed to manage research, development and regulatory affairs activities and related overhead costs including consulting and other professional fees that are not allocated to specific projects. Also included are costs related to qualifying suppliers. The increase in costs is primarily driven by an increase in support of publishing results of the REDUCE-IT study and preparation for sNDA submission based on the result of the REDUCE-IT study and in support of the FDA review process which led to FDA approval in December 2019 of an expanded indication for Vascepa in the United States. Such costs also include costs for supporting Vascepa approval in December 2019 by Health Canada and submission of Vascepa for approval in the European Union. Partially offsetting this increase, is a non-refundable, non-creditable upfront payment made during the year ended December 31, 2018 of $2.7 million related to our strategic collaboration with Mochida Pharmaceutical Co., Ltd.

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

Interest Income (Expense), net. Net interest income (expense) for the years ended December 31, 2019 and 2018 was income of $1.9 million and expense of $7.8 million, respectively, an increase of $9.7 million, or 124%. Net interest income (expense) for the years ended December 31, 2019 and 2018 is summarized in the table below:

	Year ended December 31,	
In thousands	**2019**	**2018**
Exchangeable senior notes (1):		
Amortization of debt discounts	$ —	$ (186)
Contractual coupon interest	—	(881)
Total exchangeable senior notes interest expense	—	(1,067)
Long-term debt from royalty-bearing instrument (2):		
Cash interest	(4,381)	(5,646)
Non-cash interest	(1,643)	(1,997)
Total long-term debt from royalty-bearing instrument interest expense	(6,024)	(7,643)
Other interest expense	(602)	(162)
Total interest expense	(6,626)	(8,872)
Interest income (3)	8,499	1,074
Total interest income (expense), net	$ 1,873	$ (7,798)

(1) Cash and non-cash interest expense related to the exchangeable senior notes, which were fully exchanged and retired for equity in November 2018, for the years ended December 31, 2019 and 2018 was nil and $1.1 million, respectively.

(2) Cash and non-cash interest expense related to the December 2012 royalty-bearing instrument for the years ended December 31, 2019 and 2018 was $6.0 million and $7.6 million, respectively. These amounts reflect the assumption that our Vascepa net revenue levels will not be high enough to support repayment in accordance with the contractual repayment schedule without the optional reduction which is allowed to be elected by us if the threshold revenue levels are not achieved. To date, our revenues have been below the contractual threshold amount each quarter such that each payment reflects the calculated optional reduction amount as opposed to the contractual threshold payments for each quarterly period.

(3) Interest income for the years ended December 31, 2019 and 2018 was $8.5 million and $1.1 million, respectively. Interest income represents income earned on cash balances, which cash balances were on average higher in 2019 than in 2018.

Other Expense, net. Other expense, net, for the year ended December 31, 2019 and 2018 was $0.1 million and $0.3 million, respectively. Other expense, net, in the years ended December 31, 2019 and 2018 primarily consists of gains and losses on foreign exchange transactions.

Provision for Income Taxes. Provision for income taxes for the year ended December 31, 2019 and 2018 was $0.2 million and $0.1 million, respectively. The provision for each year is the result of losses generated by our U.S. and non-U.S. operations for which no tax benefit has been recognized based on our position that deferred tax benefits are not more likely than not to be realized based on available evidence.

The provisions for income taxes for the years ended December 31, 2019 and 2018 include excess tax benefits of $17.2 million and $7.7 million, respectively, arising from share-based payments as a result of adopting ASU No. 2016-09, *Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*, which 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.

Comparison of Fiscal Years Ended December 31, 2018 and December 31, 2017

Product Revenue, net. We recorded net product revenue of $228.4 million and $179.8 million during the years ended December 31, 2018 and 2017, respectively, an increase of $48.5 million, or 27%. This increase in revenue was driven primarily by an increase in estimated normalized total Vascepa prescriptions in the United States. Based on data provided by Symphony Health and IQVIA, estimated normalized total Vascepa prescriptions in the United States increased in 2018 by approximately 365,000 and 381,000, respectively, over the year ended December 31, 2017, representing growth of 25% and 27%, respectively.

All of our product revenue in the years ended December 31, 2018 and 2017 was derived from product sales of 1-gram and 0.5-gram size capsules of Vascepa, net of allowances, discounts, incentives, rebates, chargebacks and returns. The FDA-approved dosing for Vascepa continues to be 4 grams per day and, as expected, the majority of new and existing patients taking Vascepa continue to be prescribed the 1-gram size Vascepa capsules. Timing of shipments to wholesalers, as used for revenue recognition, and timing of prescriptions as estimated by third-party sources such as Symphony Health and IQVIA may differ from period to period.

During the years ended December 31, 2018 and 2017, our net product revenue included adjustment for co-pay mitigation rebates provided by us to commercially insured patients. Such rebates are intended to offset the differential for patients of Vascepa not covered by commercial insurers at the time of launch on Tier 2 for formulary purposes, resulting in higher co-pay amounts for such patients. Our cost for these co-payment mitigation rebates during the years ended December 31, 2018 and 2017 was up to $70 per 30-day prescription filled and, beginning in March 2017, included up to $140 per 90-day prescription filled. Since launch, certain third-party payors have added Vascepa to their Tier 2 coverage, which results in lower co-payments for patients covered by these third-party payors. In connection with such Tier 2 coverage, we have agreed to pay customary rebates to these third-party payors on the resale of Vascepa to patients covered by these third-party payors.

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

Licensing Revenue. Licensing revenue during the years ended December 31, 2018 and 2017 was $0.8 million and $1.3 million, respectively, a decrease of $0.4 million, or 34%. Licensing revenue relates to the recognition of amounts received in connection with a Vascepa licensing agreement for the China Territory, specifically a $15.0 million up-front payment received in February 2015 and a $1.0 million milestone payment achieved in March 2016, as well as recognition of amounts received in connection with a Vascepa licensing agreement for Canada, specifically a $5.0 million up-front payment which was received upon closing of the agreement in September 2017 and a $2.5 million milestone payment that was received following achievement of the REDUCE-IT trial primary endpoint in September 2018. The up-front and milestone payments are being recognized over the estimated period in which we are required to provide regulatory and development support pursuant to the agreements. The amount of licensing revenue is expected to vary from period to period based on timing of milestones achieved and changes in estimates of the timing and level of support required.

Cost of Goods Sold. Cost of goods sold during the years ended December 31, 2018 and 2017 was $54.5 million and $45.0 million, respectively, an increase of $9.6 million, or 21%. Cost of goods sold includes the cost of API for Vascepa on which revenue was recognized during the period, as well as the associated costs for encapsulation, packaging, shipment, supply management, insurance and quality assurance. The cost of the API included in cost of goods sold reflects the average cost of API included in inventory. This average cost reflects the actual purchase price of Vascepa API.

The API included in the calculation of the average cost of goods sold during the years ended December 31, 2018 and 2017 was sourced from multiple API suppliers. These suppliers compete with each other based on cost, consistent quality, capacity, timely delivery and other factors. In the future, we may see the average cost of supply change based on numerous potential factors including increased volume purchases, continued improvement in manufacturing efficiency, the mix of purchases made among suppliers, currency exchange rates and other factors. The average cost may be variable from period to period depending upon the timing and quantity of API purchased from each supplier.

Our gross margin on product sales for the years ended December 31, 2018 and 2017 was 76% and 75%, respectively.

Selling, General and Administrative Expense. Selling, general and administrative expense for the years ended December 31, 2018 and 2017 was $227.0 million and $134.5 million, respectively, an increase of $92.4 million, or 69%. Selling, general and administrative expenses for the years ended December 31, 2018 and 2017 are summarized in the table below:

	Year Ended December 31,	
In thousands	**2018**	**2017**
Selling, general and administrative expense (1)	$ 164,267	$ 100,204
Co-promotion fees (2)	46,821	22,507
Non-cash stock-based compensation expense (3)	15,908	11,838
Total selling, general and administrative expense	$ 226,996	$ 134,549

(1) Selling, general and administrative expense, excluding co-promotion fees and non-cash compensation charges for stock compensation, for the years ended December 31, 2018 and 2017 was $164.3 million and $100.2 million, respectively, an increase of $64.1 million, or 64%. This increase is due primarily to increased promotional activities, including commercial spend in preparation for successful REDUCE-IT results (announced on September 24, 2018) as well as costs for sales force expansion and other increased promotional activities following positive REDUCE-IT results. Incurred in 2018 and not incurred in 2017 were costs for direct to consumer activities of approximately $28 million, as well as payment of $2.0 million made in connection with the settlement agreement reached with Teva Pharmaceuticals USA, Inc. in May 2018.

(2) Co-promotion fees payable to Kowa Pharmaceuticals America, Inc. were $46.8 million and $22.5 million in the years ended December 31, 2018 and 2017, respectively, an increase of $24.3 million, or 108%. The increase is due primarily to an accrual for co-promotion tail payments of $16.4 million in 2018 as well as an increase in gross margin on product sales, upon which the co-promotion fees are calculated for the twelve months ended December 31, 2018 compared to the same period in 2017.

(3) Non-cash stock-based compensation expense for the years ended December 31, 2018 and 2017 was $15.9 million and $11.8 million, respectively, an increase of $4.1 million, or 34%. Non-cash stock-based compensation expense represents the estimated costs associated with equity awards issued to internal staff supporting our selling, general and administrative functions. The increase is due primarily to the determination in 2018 that certain performance awards are probable to be achieved following positive REDUCE-IT results, as well as an increase in the number of employees receiving equity awards as a result of the growth of our sales force and an increase in the underlying fair value of the equity awards resulting from the increase in the price of our stock.

Research and Development Expense. Research and development expense for the years ended December 31, 2018 and 2017 was $55.9 million and $47.2 million, respectively, an increase of $8.7 million, or 19%. Research and development expenses for the years ended December 31, 2018 and 2017 are summarized in the table below:

	Year Ended December 31,	
In thousands	**2018**	**2017**
REDUCE-IT study (1)	$ 38,098	$ 34,886
Regulatory filing fees and expenses (2)	1,052	1,011
Internal staffing, overhead and other (3)	13,852	9,139
Research and development expense, excluding non-cash expense	53,002	45,036
Non-cash stock-based compensation expense (4)	2,898	2,122
Total research and development expense	$ 55,900	$ 47,158

The increase in research and development expenses for the year ended December 31, 2018, as compared to the prior year period, is primarily due to timing of REDUCE-IT and related costs.

(1) In September 2018, we announced landmark positive topline results of the REDUCE-IT cardiovascular outcomes trial. The REDUCE-IT study met its primary endpoint demonstrating an approximately 25% relative risk reduction in composite of major adverse cardiovascular events with high statistical significance. This result was supported by robust demonstrations of efficacy across multiple secondary endpoints. The REDUCE-IT study results were further presented at the 2018 Scientific Sessions of the American Heart Association, or AHA, on November 10, 2018 and concurrently published in *The New England Journal of Medicine*. We managed the study through a contract research organization, or CRO, through which all costs for the conduct of this outcomes study were incurred with the exception of costs for clinical trial material, or CTM, and costs for internal management. We expense costs for CTM when allocated to clinical research. For the years ended December 31, 2018 and 2017, we incurred expenses through our CRO in connection with this trial of approximately $29.1 million and $29.9 million, respectively. Inclusive of CTM costs, the combined CRO and CTM costs during the years ended December 31, 2018 and 2017 for REDUCE-IT were approximately $38.1 million and $34.9 million, respectively. Our internal personnel are responsible for managing multiple projects and their costs are not specifically allocated to REDUCE-IT or any other individual project. The increase in expenses in 2018 as compared to 2017 is primarily due to costs associated with last patient study visits and data collection and analysis related to the REDUCE-IT study.

(2) The regulatory filing fees in each of the years ended December 31, 2018 and 2017 included annual FDA fees for maintaining manufacturing sites. Such fees primarily represent fees for qualification of new suppliers, including increasing capacity capabilities, and fees for sites used for the manufacture of product used in the REDUCE-IT clinical outcomes study.

(3) Internal staffing, overhead and other research and development expenses primarily relate to the costs of our personnel employed to manage research, development and regulatory affairs activities and related overhead costs including consulting and other professional fees that are not allocated to specific projects. Also included are costs related to qualifying suppliers. These costs increased in 2018 compared to 2017 in support of publishing results of the REDUCE-IT study and preparing potential regulatory filings based on the results of the study. Other research and development expenses for the year ended December 31, 2018 include a non-refundable, non-creditable upfront payment of approximately $2.7 million related to our strategic collaboration with Mochida Pharmaceutical Co., Ltd.

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

Interest Expense, net. Net interest expense for the years ended December 31, 2018 and 2017 was $7.8 million and $9.3 million, respectively, a decrease of $1.5 million, or 9%. Net interest expense for the years ended December 31, 2018 and 2017 is summarized in the table below:

	Year ended December 31,	
In thousands	**2018**	**2017**
Exchangeable senior notes (1):		
Amortization of debt discounts	$ 186	$ 200
Contractual coupon interest	881	1,004
Total exchangeable senior notes interest expense	1,067	1,204
Long-term debt from royalty-bearing instrument (2):		
Cash interest	5,646	6,425
Non-cash interest	1,997	2,132
Total long-term debt from royalty-bearing instrument interest expense	7,643	8,557
Other interest expense	162	5
Total interest expense	8,872	9,766
Interest income (3)	(1,074)	(429)
Total interest expense, net	$ 7,798	$ 9,337

(1) Cash and non-cash interest expense related to the exchangeable senior notes, which were fully exchanged and retired for equity in November 2018, for the years ended December 31, 2018 and 2017 was $1.1 million and $1.2 million, respectively.

(2) Cash and non-cash interest expense related to the December 2012 royalty-bearing instrument for the years ended December 31, 2018 and 2017 was $7.6 million and $8.6 million, respectively. These amounts reflect the fact that our Vascepa net revenue levels have not been, and during these years were not assumed to be, high enough to support repayment in accordance with the contractual repayment schedule without the optional reduction which is allowed to be elected by us if the threshold revenue levels are not achieved. To date, our revenues have been below the contractual threshold amount each quarter such that each payment reflects the calculated optional reduction amount as opposed to the contractual threshold payments for each quarterly period.

(3) Interest income for the years ended December 31, 2018 and 2017 was $1.1 million and $0.4 million, respectively. Interest income represents income earned on cash balances.

Other (Expense) Income, net. Other (expense) income, net, for the year ended December 31, 2018 and 2017 was expense of $0.3 million and income of $0.1 million, respectively. Other (expense) income, net, in the years ended December 31, 2018 and 2017 primarily consists of gains and losses on foreign exchange transactions.

Provision for Income Taxes. Provision for income taxes for the year ended December 31, 2018 and 2017 was $0.1 million and $13.0 million, respectively. The 2018 provision is the result of losses generated by our U.S. and non-U.S. operations for which no tax benefit has been recognized based on our position that deferred tax benefits are not more likely than not to be realized based on available evidence. The 2017 provision recorded related entirely to the U.S. subsidiary operations. At the date of enactment of the Tax Cuts and Jobs Act, we had net deferred tax assets for the excess of the net tax value over the book basis of our U.S. assets and liabilities which will generate future tax deductions in excess of book expense. As a result of the Tax Cuts and Jobs Act, future tax deductions will result in a decreased reduction in tax expense. Consequently, we reduced the amount of the U.S. subsidiary's net deferred tax assets as of the date of enactment and recorded a non-cash charge of $2.4 million in the provision for income taxes for the year ended December 31, 2017 due to the decrease in the U.S. corporate tax rate from 34% to 21%. In addition, based on our evaluation of the available evidence, we recognized non-cash tax expense during the year ended December 31, 2017 of $8.7 million related to the recording of additional valuation allowance to reduce the deferred tax assets on the balance sheet to zero as we concluded that it is not more likely than not that certain of the deferred tax benefits resulting from the deferred tax assets generated from the U.S. subsidiary operations will be realized.

The provisions for income taxes for the years ended December 31, 2018 and 2017 include excess tax benefits of $7.7 million and $1.3 million, respectively, arising from share-based payments as a result of adopting ASU No. 2016-09, *Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*, which 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.

Liquidity and Capital Resources

Our sources of liquidity as of December 31, 2019 include cash and cash equivalents and restricted cash of $648.5 million. 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	**2019**	**2018**	**2017**
Cash (used in) provided by:			
Operating activities	$ (9.4)	$ (94.7)	$ (32.8)
Investing activities	(2.5)	(0.1)	—
Financing activities	409.6	271.3	8.2
Increase (decrease) in cash and cash equivalents and restricted cash	$ 397.7	$ 176.5	$ (24.6)

Net cash used in operating activities during 2019 compared to 2018 decreased primarily as a result of higher collections due to an increase in product sales and a decrease in R&D activities associated with the REDUCE-IT study, partially offset by increased costs of promotional activities following the successful REDUCE-IT study results, including costs associated with expanding the Company's United States-based sales force.

Net cash used in investing activities during 2019 is due to payments on the purchase of furniture, fixtures and equipment associated with the Company's new office space in Bridgewater, NJ.

Net cash provided by financing activities increased 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. In February 2018, we completed a public offering of 19,178,082 ADSs and, in March 2018, we issued an additional 1,438,356 ADSs upon the underwriter's partial exercise of a 30-day option to purchase additional shares. The underwriter purchased the ADSs from us at a price of $3.41 per ADS after commission, resulting in net proceeds to us of approximately $70.0 million, after deducting customary commissions and offering expenses. In November 2018, we completed a public offering of 11,111,112 ADSs. The underwriters purchased the ADSs from us at a price of $17.575 per ADS after commission, resulting in net proceeds to us of approximately $194.8 million, after deducting customary commissions and offering expenses.

In December 2012, we entered into a financing agreement with BioPharma. Under this agreement, we granted to BioPharma a security interest in future receivables and all related rights to Vascepa, in exchange for $100.0 million received at the closing of the agreement which closing occurred in December 2012. In December 2017, BioPharma assigned all rights under this agreement to CPPIB. We have agreed to repay up to $150.0 million of future revenue and receivables. As of December 31, 2019, the net remaining amount to be repaid to CPPIB is $52.4 million, which will be repaid in quarterly installments calculated as 10% of quarterly Vascepa net revenues. We can prepay the net remaining amount at any time.

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

As of December 31, 2019, we had net accounts receivable of $116.4 million and inventory of $76.8 million. We have incurred annual operating losses since our inception and, as a result, we had an accumulated deficit of $1.4 billion as of December 31, 2019. We anticipate that quarterly net cash outflows in future periods will continue to be variable as a result of the timing of certain items, including our purchases of API and expanded Vascepa promotional activities from approval by the FDA for the new indication and expanded label. We believe that our cash and cash equivalents of $644.6 million as of December 31, 2019, will be sufficient to fund our projected operations for at least twelve months and is adequate to achieve positive cash flow from the commercial launch of Vascepa based on our current plans.

Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2019 and the effects such obligations are expected to have on our liquidity and cash flows in future periods:

Payments Due by Period

In millions	Total	2020	2021 to 2022	2023 to 2024	After 2024
Contractual obligations:					
Purchase obligations (1)	$ 192.4	$ 117.0	$ 30.7	$ 30.7	$ 14.0
Operating lease obligations (2)	18.2	0.4	3.3	3.6	10.9
Total contractual cash obligations	$ 210.6	$ 117.4	$ 34.0	$ 34.3	$ 24.9

(1) Our agreements with certain supply chain contracting parties contain minimum annual purchase levels to enable us to maintain certain supply exclusivity and also contain a provision that any shortfall in the minimum purchase commitments is payable in cash. Each such supplier is required to meet certain performance obligations and the agreements may be terminated by us in the event of non-performance.

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

As of December 31, 2019, we had certain marketing commitments, consisting of communication costs related to our direct-to-consumer activities, totaling approximately $19.9 million.

Under the terms of the agreement with CPPIB, as successor in interest to BioPharma, we agreed to repay up to $150.0 million of future revenue and receivables. As of December 31, 2019, the net remaining amount to be repaid is $52.4 million, which will be repaid in quarterly installments calculated as 10% of quarterly Vascepa net revenues. We can prepay the net remaining amount at any time.

Under the 2004 share repurchase agreement with Laxdale Limited, or Laxdale, upon receipt of marketing approval in Europe for the first indication for Vascepa (or first indication of any product containing Amarin Neuroscience Limited intellectual property acquired from Laxdale in 2004), we must make an aggregate stock or cash payment to the former shareholders of Laxdale (at the sole option of each of the sellers) of £7.5 million (approximately $9.9 million as of December 31, 2019). Additionally, upon receipt of a marketing approval in Europe for a further indication of Vascepa (or further indication of any other product using Amarin Neuroscience Limited intellectual property), we must make an aggregate stock or cash payment (at the sole option of each of the sellers) of £5 million (approximately $6.6 million as of December 31, 2019) .

We do not enter into financial instruments for trading or speculative purposes. As of December 31, 2019 and 2018, we had no outstanding forward exchange contracts.

Off-Balance Sheet Arrangements

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 and Yen. The majority of cash and cash equivalents 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. 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.

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. We invest funds not needed for near-term operating expenses in diversified short-term investments, consisting primarily of investment grade securities. As of December 31, 2019, the fair value of our cash and cash equivalents maturing in one year or less was $644.6 million and represented 100% of our cash, cash

equivalents and investment portfolio. A hypothetical 50 basis point change in interest rates would not result in a material decrease or increase in the fair value of our securities due to the general short-term nature of our investment portfolio.

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

Our consolidated financial statements are annexed to this report 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 in the reports that we file or submit under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is (1) recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our Principal Executive Officer and Principal Financial Officer, to allow timely decisions regarding required disclosure.

As of December 31, 2019, or the Evaluation Date, our management, with the participation of our Principal Executive Officer and Principal Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our Principal Executive Officer and Principal Financial Officer have concluded based upon the evaluation described above that, as of the Evaluation Date, 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) promulgated 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 controls 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, 2019. 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 believes that, as of December 31, 2019, our internal controls over financial reporting were effective.

Ernst & Young LLP, 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, 2019. 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 2019 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, 2019, 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, 2019, 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, 2019 and 2018, the related consolidated statements of operations, stockholders' deficit and cash flows for each of the three years in the period ended December 31, 2019, and the related notes and our report dated February 25, 2020 expressed an unqualified opinion thereon.

Basis for Opinion

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

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

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

Definition and Limitations of Internal Control Over Financial Reporting

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

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

/s/ Ernst & Young LLP
Iselin, New Jersey
February 25, 2020

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 Securities Exchange Act of 1934, as amended. 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.

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 2020 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 ethics 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. Any waivers from or amendments to the code will be filed with the SEC on Form 8-K. 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.

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 2020 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 2020 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 2020 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 2020 Annual General Meeting of Shareholders. Such information is incorporated herein by reference.

PART IV

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

Exhibit Number	Description	Incorporated by Reference Herein	
		Form	Date
3.1	Articles of Association of the Company	Quarterly Report on Form 10-Q, File No. 0-21392, 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, File No. 0-21392, 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, File No. 0-21392, 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, File No. 0-21392, as Exhibit 4.4	February 29, 2012
4.4	Form of Series A Preference Share Terms	Current Report on Form 8-K dated March 5, 2015, File No. 0-21392, as Exhibit 4.1	March 11, 2015
4.5	Preferred Share Deposit Agreement by and among the Company, Citibank, N.A., as depositary, and all holders and beneficial owners of restricted ADSs issued thereunder	Current Report on Form 8-K dated March 30, 2015, File No. 0-21392, as Exhibit 4.1	March 30, 2015
4.6	Form of American Depositary Receipt evidencing restricted ADSs representing Series A Preference Shares	Current Report on Form 8-K dated March 30, 2015, File No. 0-21392, as Exhibit 4.2	March 30, 2015
4.7	Description of Registrant's Securities	Filed herewith	
10.1	The Company 2002 Stock Option Plan*	Annual Report on Form 20-F for the year ended December 31, 2006, File No. 0-21392, as Exhibit 4.17	March 5, 2007
10.2	The Company 2011 Stock Option Plan*	Quarterly Report on Form 10-Q for the period ended June 30, 2011, File No. 0-21392, 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 quarterly period ended June 30, 2012, File No. 0-21392, as Exhibit 10.1	August 8, 2008
10.4	Amendment No. 2 to 2011 Stock Option Incentive Plan*	Quarterly Report on Form 10-Q for quarterly period ended June 30, 2012, File No. 0-21392, as Exhibit 10.2	August 8, 2008
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, File No. 0-21392, as Exhibit 10.5	February 28, 2012
10.6	Amendment No. 4 to 2011 Stock Option and Incentive Plan*	Quarterly Report on Form 10-Q for quarterly period ended June 30, 2015, File No. 0-21392, 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 quarterly period ended June 30, 2015, File No. 0-21392, as Exhibit 4.2	August 6, 2015

Exhibit Number	Description	Incorporated by Reference Herein	
		Form	Date
10.8	Amarin Corporation plc Management Incentive Compensation Plan*	Annual Report on Form 10-K for the year ended December 31, 2010, File No. 0-21392, as Exhibit 10.44	March 16, 2011
10.9	Form of Incentive Stock Option Award Agreement	Annual Report on Form 10-K for the year ended December 31, 2011, File No. 0-21392, as Exhibit 10.3	February 29, 2012
10.10	Form of Non-Qualified Stock Option Award Agreement	Annual Report on Form 10-K for the year ended December 31, 2011, File No. 0-21392, as Exhibit 10.4	February 29, 2012
10.11	Form of Restricted Stock Unit Award Agreement	Annual Report on Form 10-K for the year ended December 31, 2011, File No. 0-21392, as Exhibit 10.5	February 29, 2012
10.12	Letter Agreement, dated November 15, 2010, between the Company and John F. Thero*	Annual Report on Form 10-K for the year ended December 31, 2010, File No. 0-21392, as Exhibit 10.42	March 16, 2011
10.13	Letter Agreement with Joseph Kennedy, dated December 13, 2011*	Current Report on Form 8-K dated December 23, 2011, File No. 0-21392, as Exhibit 10.5	December 23, 2011
10.14	Letter Agreement with John Thero, dated December 23, 2011*	Current Report on Form 8-K dated December 23, 2011, File No. 0-21392, as Exhibit 10.1	December 23, 2011
10.15	Letter Agreement with Steve Ketchum, dated February 8, 2012*	Current Report on Form 8-K dated February 16, 2012, File No. 0-21392, as Exhibit 10.1	February 16, 2012
10.16	Letter Agreement with John Thero, dated January 10, 2014*	Current Report on Form 8-K dated January 8, 2014, File No. 0-21392, as Exhibit 10.1	January 10, 2014
10.17	Amendment, dated July 6, 2015, to Letter Agreement with Joseph Kennedy, dated December 13, 2011*	Quarterly Report on Form 10-Q for the period ended June 30, 2015, File No. 0-21392, as Exhibit 10.1	August 6, 2015
10.18	Amendment, dated July 6, 2015, to Letter Agreement with Steven Ketchum, dated February 8, 2012*	Quarterly Report on Form 10-Q for the period ended June 30, 2015, File No. 0-21392, as Exhibit 10.2	August 6, 2015
10.19	Amendment, dated July 6, 2015, to Letter Agreement with John Thero, dated December 23, 2011*	Quarterly Report on Form 10-Q for the period ended June 30, 2015, File No. 0-21392, as Exhibit 10.3	August 6, 2015
10.20	2011 Long Term Incentive Award with Joseph Kennedy dated December 16, 2011*	Form S-8, File No. 333-180180, as Exhibit 4.1	March 16, 2012
10.21	2012 Long Term Incentive Award with Steven Ketchum dated March 1, 2012*	Form S-8, File No. 333-180180, as Exhibit 4.2	March 16, 2012
10.22	Employment Agreement dated November 5, 2009 with John F. Thero*	Registration Statement on Form F-1, File No. 333-163704, as Exhibit 4.104	December 14, 2009
10.23	Stock Purchase Agreement, dated December 5, 2007, between the Company, the selling shareholders of Ester Neurosciences Limited, Ester Neurosciences Limited and Medica II Management L.P. ††	Report of Foreign Private Issuer filed on Form 6-K, File No. 0-21392, as Exhibit 99.1	January 28, 2008

Exhibit Number	Description	Incorporated by Reference Herein	
		Form	Date
10.24	Letter Agreement, dated December 6, 2007, between the Company and the Sellers' Representative of the selling shareholders of Ester Neurosciences Limited	Report of Foreign Private Issuer filed on Form 6-K, File No. 0-21392, as Exhibit 99.1	February 1, 2008
10.25	Amendment No. 1 to Stock Purchase Agreement, dated April 7, 2008, between the Company and Medica II Management L.P.	Annual Report on Form 20-F for the year ended December 31, 2007, File No. 0-21392, as Exhibit 4.79	May 19, 2008
10.26	Securities Purchase Agreement, dated May 12, 2008, among the Company and the Purchasers named therein	Annual Report on Form 20-F for the year ended December 31, 2008, File No. 0-21392, as Exhibit 4.80	October 22, 2009
10.27	Form of Securities Purchase Agreement, dated May 13, 2008, between the Company and the Purchasers named therein ††	Annual Report on Form 20-F for the year ended December 31, 2007, File No. 0-21392, as Exhibit 4.81	May 19, 2008
10.28	Amendment and Waiver Agreement, dated May 25, 2009, between Ester Neurosciences Limited, Medica II Management L.P. and the Company††	Annual Report on Form 20-F/A for the year ended December 31, 2008, File No. 0-21392, as Exhibit 4.88	December 4, 2009
10.29	Form of Securities Purchase Agreement dated October 12, 2009 between the Company and the Purchasers named therein	Annual Report on Form 20-F for the year ended December 31, 2008, File No. 0-21392, as Exhibit 4.94	October 22, 2009
10.30	Amendment No. 1, dated December 2, 2009, to Securities Purchase Agreement dated October 12, 2009 between the Company and the Purchasers named therein	Registration Statement on Form F-1, File No. 333-163704, as Exhibit 4.105	December 14, 2009
10.31	Amendment Agreement dated October 12, 2009, to the Form of Equity Securities Purchase Agreement dated May 13, 2008 between the Company and the Purchasers named therein	Annual Report on Form 20-F for the year ended December 31, 2008, File No. 0-21392, as Exhibit 4.97	October 22, 2009
10.32	Management Rights Deed of Agreement dated October 16, 2009 by and among the Company and Purchasers named therein	Annual Report on Form 20-F for the year ended December 31, 2009, File No. 0-21392, as Exhibit 4.100	June 25, 2010
10.33	Supply Agreement, dated November 1, 2010, between Nisshin Pharma Inc. and Amarin Pharmaceuticals Ireland Limited ††	Annual Report on Form 10-K for the year ended December 31, 2010, File No. 0-21392, as Exhibit 10.40	March 16, 2011
10.34	API Commercial Supply Agreement, dated May 25, 2011, between Amarin Pharmaceuticals Ireland Ltd. and Chemport Inc. ††	Quarterly Report on Form 10-Q for the period ended June 30, 2011, File No. 0-21392, as Exhibit 10.2	August 9, 2011
10.35	Amendment to API Commercial Supply Agreement by and between Amarin Pharmaceuticals Ireland Ltd and Chemport Inc., dated April 4, 2012 ††	Quarterly Report on Form 10-Q for quarterly period ended June 30, 2012, File No. 0-21392, as Exhibit 10.6	August 8, 2008
10.36	Second Amendment to API Commercial Supply Agreement by and between Amarin Pharmaceuticals Ireland Ltd. and Chemport Inc., dated July 19, 2012††	Quarterly Report on Form 10-Q for quarterly period ended September 30, 2012, File No. 0-21392, as Exhibit 10.1	November 8, 2012

Exhibit Number	Description	Incorporated by Reference Herein	
		Form	Date
10.37	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††	Annual Report on Form 10-K for the year ended December 31, 2012, File No. 0-21392, as Exhibit 10.76	February 28, 2012
10.38	Co-Promotion Agreement dated March 31, 2014, by and among the Company and Kowa Pharmaceuticals America, Inc. ††	Quarterly Report on Form 10-Q for quarterly period ended March 31, 2014, File No. 0-21392, as Exhibit 10.1	May 9, 2014
10.39	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, File No. 0-21392, as Exhibit 10.1	May 8, 2015
10.40	Securities Subscription Agreement dated March 5, 2015, by and among Amarin Corporation plc, 667, L.P., Baker Brothers Life Sciences, L.P., Stonepine Capital, L.P. and Broadfin Healthcare Master Fund	Current Report on Form 8-K dated March 5, 2015, File No. 0-21392, File No. 0-21392, as Exhibit 10.1	March 11, 2015
10.41	Securities Subscription Agreement dated March 30, 2015, by and between Amarin Corporation plc and Sofinnova Venture Partners VII, L.P.	Current Report on Form 8-K dated March 30, 2015, File No. 0-21392, as Exhibit 10.1	March 30, 2015
10.42	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, File No. 0-21392, as Exhibit 10.1	June 30, 2016
10.43	Amendment No. 6 to 2011 Stock Incentive Plan*	Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2017, File No. 0-21392, as Exhibit 4.1	August 2, 2017
10.44	2017 Employee Stock Purchase Plan*	Annual Report on Form 10-K for the year ended December 31, 2017, File No. 0-21392, as Exhibit 10.64	February 27, 2018
10.45	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, File No. 0-21392, as Exhibit 10.1	August 2, 2017
10.46	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, File No. 0-21392, as Exhibit 10.66	February 27, 2018
10.47	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, File No. 0-21392, as Exhibit 10.67	February 27, 2018
10.48	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, File No. 0-21392, as Exhibit 10.68	February 27, 2018

Exhibit Number	Description	Incorporated by Reference Herein	
		Form	Date
10.49	Lease Agreement, dated February 5, 2019, by and between 440 Route 22 LLC and Amarin Pharma, Inc.	Annual Report on Form 10-K for the year ended December 31, 2018, File No. 0-21392, as Exhibit 10.69	February 27, 2019
10.50	Employment Agreement, dated April 20, 2018, by and between Amarin Pharma Inc. and Aaron Berg*	Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2019, File No. 0-21392, as Exhibit 10.1	May 1, 2019
10.51	Sixth Amendment to Lease Agreement, dated April 1, 2019, by and between Amarin Pharma, Inc. and Bedminster 2 Funding, LLC	Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2019, File No. 0-21392, as Exhibit 10.1	July 31, 2019
10.52	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, File No. 0-21392, as Exhibit 10.2	July 31, 2019
10.53	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, File No. 0-21392, as Exhibit 10.3	July 31, 2019
10.54	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, File No. 0-21392, as Exhibit 10.4	July 31, 2019
14.1	Code of Ethics	Registration Statement on Form F-3, File No. 333-170505, as Exhibit 99.1	November 10, 2010
21.1	List of Subsidiaries	Filed herewith	
23.1	Consent of Independent Registered Public Accounting Firm	Filed herewith	
31.1	Certification of President and Chief Executive Officer (Principal Executive Officer) pursuant to Section 302 of Sarbanes-Oxley Act of 2002	Filed herewith	
31.2	Certification of Senior Vice President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer) pursuant to Section 302 of Sarbanes-Oxley Act of 2002	Filed herewith	
32.1	Certification of President and Chief Executive Officer (Principal Executive Officer) and Senior Vice President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer) pursuant to Section 906 of Sarbanes-Oxley Act of 2002	Filed herewith	
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 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.

* 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/ John F. Thero
John F. Thero
President and *Chief Executive Officer*
(Principal Executive Officer)

Date: February 25, 2020

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/ John F. Thero John F. Thero	Director, President and Chief Executive Officer (Principal Executive Officer)	February 25, 2020
/s/ Michael W. Kalb Michael W. Kalb	Senior Vice President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 25, 2020
/s/ Lars Ekman, M.D., Ph.D. Lars Ekman, M.D., Ph.D.	Director	February 25, 2020
/s/ Patrick O'Sullivan Patrick O'Sullivan	Director	February 25, 2020
/s/ Kristine Peterson Kristine Peterson	Director	February 25, 2020
/s/ David Stack David Stack	Director	February 25, 2020
/s/ Jan van Heek Jan van Heek	Director	February 25, 2020
/s/ Joseph Zakrzewski Joseph Zakrzewski	Director	February 25, 2020

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, 2019 and 2018, the related consolidated statements of operations, stockholders' deficit and cash flows for each of the three years in the period ended December 31, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, 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, 2019, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 25, 2020 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, 2019, the Company recorded a liability for product returns totaling $4.6 million. As discussed in Note 15 of the financial statements, the Company sells its product to distributors that in turn resell the product to retail pharmacies for subsequent sale to patients and healthcare providers. The Company estimates variable consideration resulting from product returns based on quantitative and qualitative data from various internal and external sources.

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

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design and tested the operating effectiveness of the controls over the Company's estimation process for product returns including inventory in the distribution channel. These procedures included controls over management's review of the inputs used and assumptions applied in the returns reserve calculation and channel inventory analysis.

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

/s/ Ernst & Young LLP

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

Iselin, New Jersey
February 25, 2020

AMARIN CORPORATION PLC

CONSOLIDATED BALANCE SHEETS
(in thousands, except share amounts)

	As of December 31,	
	2019	**2018**
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 644,588	$ 249,227
Restricted cash	3,907	1,500
Accounts receivable, net	116,430	66,523
Inventory	76,769	57,802
Prepaid and other current assets	13,311	2,945
Total current assets	855,005	377,997
Property, plant and equipment, net	2,361	63
Operating lease right-of-use asset	8,511	—
Other long-term assets	1,074	174
Intangible asset, net	15,258	7,480
TOTAL ASSETS	$ 882,209	$ 385,714
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 49,950	$ 37,632
Accrued expenses and other current liabilities	139,826	84,171
Current portion of long-term debt from royalty-bearing instrument	50,130	34,240
Deferred revenue, current	2,342	1,220
Total current liabilities	242,248	157,263
Long-Term Liabilities:		
Long-term debt from royalty-bearing instrument	—	46,108
Deferred revenue, long-term	18,504	19,490
Long-term operating lease liability	9,443	—
Other long-term liabilities	3,751	10,523
Total liabilities	273,946	233,384
Commitments and contingencies (Note 8)		
Stockholders' Equity:		
Series A Convertible Preferred Stock, £0.05 par, unlimited authorized; 289,317,460 shares issued and outstanding as of December 31, 2019 and December 31, 2018 (equivalent to 28,931,746 ordinary shares upon future consolidation and redesignation at a 10:1 ratio)	21,850	21,850
Common stock, £0.50 par, unlimited authorized; 365,014,893 issued, 360,103,901 outstanding as of December 31, 2019; 329,110,863 issued, 325,850,013 outstanding as of December 31, 2018	269,173	246,663
Additional paid-in capital	1,764,317	1,282,762
Treasury stock; 4,910,992 shares as of December 31, 2019; 3,260,850 shares as of December 31, 2018	(35,900)	(10,413)
Accumulated deficit	(1,411,177)	(1,388,532)
Total stockholders' equity	608,263	152,330
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 882,209	$ 385,714

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,		
	2019	2018	2017
Product revenue, net	$ 427,391	$ 228,371	$ 179,825
Licensing revenue	2,364	843	1,279
Total revenue, net	429,755	229,214	181,104
Less: Cost of goods sold	96,019	54,543	44,952
Gross margin	333,736	174,671	136,152
Operating expenses:			
Selling, general and administrative	323,623	226,996	134,549
Research and development	34,392	55,900	47,158
Total operating expenses	358,015	282,896	181,707
Operating loss	(24,279)	(108,225)	(45,555)
Interest expense	(6,626)	(8,872)	(9,766)
Interest income	8,499	1,074	429
Other (expense) income, net	(75)	(326)	74
Loss from operations before taxes	(22,481)	(116,349)	(54,818)
Provision for income taxes	(164)	(96)	(13,047)
Net loss	(22,645)	(116,445)	(67,865)
Loss per share:			
Basic	$ (0.07)	$ (0.39)	$ (0.25)
Diluted	$ (0.07)	$ (0.39)	$ (0.25)
Weighted average shares outstanding:			
Basic	342,538	297,237	270,652
Diluted	342,538	297,237	270,652

See the notes to the consolidated financial statements.

AMARIN CORPORATION PLC

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
(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, 2016	**328,184,640**	**270,183,201**	**(819,505)**	**$ 24,364**	**$ 207,166**	**$ 964,914**	**$ (1,498)**	**$ (1,204,004)**	**$ (9,058)**
Exercise of stock options	—	356,656	—	—	229	409	—	—	638
Vesting of restricted stock units	—	2,179,187	(877,528)	—	1,373	(1,409)	(2,731)	—	(2,767)
Stock-based compensation	—	—	—	—	—	13,952	—	—	13,952
Loss for the period	—	—	—	—	—	—	—	(67,865)	(67,865)
December 31, 2017	**328,184,640**	**272,719,044**	**(1,697,033)**	**$ 24,364**	**$ 208,768**	**$ 977,866**	**$ (4,229)**	**$ (1,271,869)**	**$ (65,100)**
Cumulative-effect adjustment	—	—	—	—	—	—	—	(218)	(218)
January 1, 2018	**328,184,640**	**272,719,044**	**(1,697,033)**	**$ 24,364**	**$ 208,768**	**$ 977,866**	**$ (4,229)**	**$ (1,272,087)**	**$ (65,318)**
Issuance of common stock, net of transaction costs	—	31,727,550	—	—	21,744	243,096	—	—	264,840
Issuance of common stock under employee stock purchase plan	—	312,257	—	—	203	840	—	—	1,043
Exchange of exchangeable senior notes, net of transaction costs	—	7,716,046	—	—	5,011	24,358	—	—	29,369
Conversion of Series A Convertible Preferred Stock, net	(38,867,180)	3,886,718	—	(2,514)	2,514	(39)	—	—	(39)
Exercise of stock options	—	8,138,305	—	—	5,309	21,093	—	—	26,402
Vesting of restricted stock units	—	4,610,943	(1,563,817)	—	3,114	(3,114)	(6,184)	—	(6,184)
Stock-based compensation	—	—	—	—	—	18,662	—	—	18,662
Loss for the period	—	—	—	—	—	—	—	(116,445)	(116,445)
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**

See the notes to the consolidated financial statements.

AMARIN CORPORATION PLC

CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,		
	2019	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (22,645)	$ (116,445)	$ (67,865)
Adjustments to reconcile loss to net cash used in operating activities:			
Depreciation and amortization	180	23	62
Stock-based compensation	30,917	18,806	13,960
Amortization of debt discount and debt issuance costs	1,644	2,183	2,332
Amortization of intangible asset	679	646	646
Deferred income taxes	—	—	11,082
Changes in assets and liabilities:			
Accounts receivable, net	(49,907)	(21,205)	(25,333)
Inventory	(18,967)	(27,542)	(9,753)
Prepaid and other current assets	(10,366)	510	6,028
Other long-term assets	(900)	—	567
Accrued interest payable	(210)	(310)	(6,491)
Deferred revenue	136	1,656	1,221
Accounts payable and other current liabilities	65,913	37,602	40,267
Other long-term liabilities	(5,840)	9,373	440
Net cash used in operating activities	(9,366)	(94,703)	(32,837)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchases of furniture, fixtures and equipment	(2,478)	(58)	(12)
Net cash used in investing activities	(2,478)	(58)	(12)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of exchangeable debt	—	—	30,000
Proceeds from issuance of common stock, net of transaction costs	440,108	264,840	—
Proceeds from issuance of common stock under employee stock purchase plan	2,165	1,043	—
Proceeds from exercise of stock options, net of transaction costs	24,478	26,402	638
Payment of debt issuance costs	—	—	(1,207)
Payment of transaction costs for conversion of preferred stock	—	(39)	—
Repurchase of exchangeable senior notes, including transaction costs	—	—	(15,107)
Payment on long-term debt from royalty-bearing instrument	(31,652)	(14,690)	(3,322)
Transaction costs related to exchange of exchangeable senior notes	—	(121)	—
Taxes related to stock-based awards	(25,487)	(6,184)	(2,767)
Net cash provided by financing activities	409,612	271,251	8,235
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS AND RESTRICTED CASH	397,768	176,490	(24,614)
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH, BEGINNING OF PERIOD	250,727	74,237	98,851
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH, END OF PERIOD	$ 648,495	$ 250,727	$ 74,237
Supplemental disclosure of cash flow information:			
Cash paid during the year for:			
Interest	$ 4,591	$ 21,527	$ 17,241
Income taxes	$ 67	$ 850	$ 1,753
Supplemental disclosure of non-cash transactions:			
Laxdale milestone	$ 8,457	$ —	$ —
Initial recognition of operating lease right-of-use asset	$ 8,995	$ —	$ —
Exchange of exchangeable senior notes into common stock	$ —	$ 29,490	$ —
Conversion of Series A Convertible Preferred Stock into common stock	$ —	$ 2,514	$ —

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 with expertise in omega-3 fatty acids and lipid science focused on the commercialization and development of therapeutics to improve cardiovascular health and reduce cardiovascular risk. The Company's lead product, Vascepa® (icosapent ethyl), was first approved by the U.S. Food and Drug Administration, or 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. On December 13, 2019, the FDA approved a new 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 FDA as an adjunct to maximally tolerated statin therapy for reducing persistent cardiovascular risk in select high risk patients. Vascepa is available in the United States, or the U.S., by prescription only. In January 2013, the Company began selling and marketing 1-gram size Vascepa capsules in the United States, and in October 2016, introduced a smaller 0.5-gram capsule size.

The Company, since inception, has devoted substantial resources to research and development efforts, most significantly, the development and conduct of a long-term cardiovascular outcomes study of Vascepa, REDUCE-IT. The Company announced topline results from REDUCE-IT on September 24, 2018. On November 10, 2018, the Company presented primary results of REDUCE-IT 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, the Company 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, or ACC, 68th Annual Scientific Session and such results and methods were concurrently published in the *Journal of the American College of Cardiology*.

The FDA granted Priority Review designation to the Company's 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. In November 2019, the 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 FDA approved a new indication and related label expansion based on REDUCE-IT.

In the United States, the Company sells Vascepa principally to a limited number of major wholesalers, as well as selected regional wholesalers and specialty pharmacy providers, or collectively, its distributors or its customers, that in turn resell Vascepa to retail pharmacies for subsequent resale to patients and healthcare providers. The Company markets Vascepa in the United States through its direct sales force. Prior to the REDUCE-IT results topline announcement in September 2018, our commercialization of Vascepa was somewhat limited. Subsequent to learning the positive cardiovascular outcomes results of the REDUCE-IT study, we have increased our promotional efforts. Based on the positive REDUCE-IT results, in early 2019, we increased the size of our sales force to approximately 440 sales professionals, including approximately 400 sales representatives. As a result of the FDA's newly approved indication and label expansion, we are close to completing the expansion of our direct sales force to approximately 900 sales professionals, including 800 sales representatives, which is expected to be completed in early 2020. Most of the expanded sales management team needed to support this sales force expansion was hired, or internally promoted, and trained prior to December 31, 2019. In addition to promotion of Vascepa in the United States, based on REDUCE-IT, we have increased focus on expansion of our development efforts for Vascepa to major markets outside the United States. We currently have strategic collaborations to develop and commercialize Vascepa in select territories outside the United States. 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, 2019, 2018 and 2017 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. Certain prior year balances related to beginning and ending cash and cash equivalents and restricted cash in the consolidated statements of cash flows have been conformed to the current year presentation. The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

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

At December 31, 2019, the Company had Current assets of $855.0 million, including Cash and cash equivalents of $644.6 million, Accounts receivable, net, of $116.4 million and Inventory of $76.8 million. The Company's consolidated balance sheet at December 31, 2019 also includes a royalty-bearing instrument which is expected to be fully paid during 2020 based on the percentage of Vascepa net revenues calculated quarterly. As of December 31, 2019, the Company had no other 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; and valuations of derivative and long-term debt instruments. 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 derivatives, debt instrument and 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*, 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 15—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.

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

In thousands	December 31, 2019	December 31, 2018
Gross trade accounts receivable	$ 149,567	$ 86,133
Trade allowances	(29,261)	(19,495)
Chargebacks	(3,876)	(115)
Accounts receivable, net	$ 116,430	$ 66,523

Inventory

The Company states inventories at the lower of cost or net realizable value. Cost is determined based on actual cost using the average cost method. Net realizable value is the estimated selling price in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. An allowance is established when management determines that certain inventories may not be saleable. If inventory cost exceeds expected net realizable value due to obsolescence, damage or quantities in excess of expected demand, changes in price levels or other causes, the Company will reduce the carrying value of such inventory to net realizable value and recognize the difference as a component of cost of goods sold in the period in which it occurs. The Company capitalizes inventory purchases of saleable product from approved suppliers while inventory purchases from suppliers prior to regulatory approval are included as a component of research and development expense. The Company expenses inventory identified for use as marketing samples when they are packaged. The average cost reflects the actual purchase price of Vascepa active pharmaceutical ingredient, or API.

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 related to the 2004 acquisition of the rights to Vascepa, which is the result of Vascepa receiving marketing approval for the first indication in 2012 and a new indication in 2019 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.

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 as well as co-promotion fees to Kowa Pharmaceuticals America, Inc. which in 2018 included costs for accrual of tail co-promotion fees.

Income Taxes

On December 22, 2017, the U.S. enacted the Tax Cuts and Jobs Act, or the Act, which instituted fundamental changes to the taxation of multinational corporations. The Act includes changes to the taxation of foreign earnings by implementing a dividend exemption system, expansion of the current anti-deferral rules, a minimum tax on low-taxed foreign earnings and new measures to deter base erosion. The Act also includes a permanent reduction in the corporate tax rate to 21%, repeal of the corporate alternative minimum tax, expensing of capital investment, and limitation of the deduction of interest expense. Furthermore, as part of the transition to the new tax system, a one-time transition tax is imposed on a U.S. shareholder's historical undistributed earnings of foreign affiliates. The Company applied the guidance in Staff Accounting Bulletin 118 when accounting for the enactment-date effects of the Act in the prior year. As of December 31, 2017, the Company had recorded provisional amounts to account for the impact of tax effects of the Act related to the change in corporate tax rate from 34% to 21% and the changes to executive compensation deductibility. As of December 31, 2018, the Company completed its accounting for all of the tax effects of the Act. Based on the additional analysis performed, no adjustments to the provisional amounts were made which had an impact to the tax provision or consolidated financial statements.

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 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 completed the audit by the IRS for the years 2013 to 2014 in the prior year with no material changes to the filed income tax returns. In addition, the Company was notified by the IRS in January 2020 that it will be auditing the Company's 2018 U.S. income tax return and the examination is expected to begin in the first quarter of 2020. Although the outcome of tax audits is always uncertain and could result in significant cash tax payments, the Company does not believe the outcome of these audits will have a material adverse effect on its consolidated financial position or results of operations.

Loss per Share

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

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

The calculation of net loss and the number of shares used to compute basic and diluted net loss per share for the years ended December 31, 2019, 2018, and 2017 are as follows:

In thousands	2019	2018	2017
Net loss—basic and diluted	$ (22,645)	$ (116,445)	$ (67,865)
Weighted average shares outstanding—basic and diluted	342,538	297,237	270,652
Net loss per share—basic and diluted	$ (0.07)	$ (0.39)	$ (0.25)

For the years ended December 31, 2019, 2018 and 2017, the following potentially dilutive securities were not included in the computation of net loss per share because the effect would be anti-dilutive:

In thousands	2019	2018	2017
Stock options	15,619	19,263	24,108
Restricted stock and restricted stock units	6,921	9,633	12,006
Exchangeable senior notes (if converted)	—	—	7,716
Preferred stock (if converted)	28,932	28,932	32,818

Debt Instruments

Debt instruments are initially recorded at fair value, with coupon interest and amortization of debt issuance discounts recognized in the consolidated statement of operations as interest expense each period in which such instruments are outstanding. The Company records debt issuance costs related to a recognized debt liability in the consolidated balance sheets as a direct deduction from the carrying amount of that debt liability and amortized to interest expense using the effective interest method over the expected term of the related debt. Unamortized debt issuance costs related to the extinguishment of debt are expensed at the time the debt is extinguished and recorded in Other (expense) income, net, in the consolidated statements of operations. If the Company issues shares to discharge the liability, the debt obligation is derecognized and common stock and additional paid-in capital are recognized upon the issuance of those shares.

The 2017 Notes could only be settled in ADSs upon conversion. The terms of the 2017 Notes also allowed for repurchase in cash by the Company at the option of the holders as well as redemption by the Company for cash at specified times. The conversion feature in the 2017 Notes qualified for the exception from derivative accounting in accordance with ASC 815-40 and was therefore accounted for as part of the debt host. The conversion feature in the 2017 Notes was evaluated on a quarterly basis to determine if it still received an exception from derivative accounting in accordance with ASC 815-40. The 2017 Notes were recognized at par of $30.0 million. The Company also recognized a $1.2 million discount related to placement agent fees and offering expenses. This discount was amortized through interest expense through the date of mandatory exchange.

See Note 7—Debt for further discussion.

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 and accounts receivable. The Company maintains substantially all of its cash and cash equivalents in financial institutions believed to be of high-credit quality.

A significant portion of the Company's sales are to wholesalers in the pharmaceutical industry. The Company monitors the creditworthiness of customers to whom it grants credit terms and has not experienced any credit losses. The Company does not require collateral or any other security to support credit sales. Three customers individually accounted for 10% or more of the Company's gross product sales. Customers A, B, and C accounted for 36%, 29%, and 25%, respectively, of gross product sales for the year ended December 31, 2019 and represented 35%, 20%, and 37%, respectively, of the gross accounts receivable balance as of December 31, 2019. Customers A, B, and C accounted for 31%, 30% and 27%, respectively, of gross product sales for the year ended December 31, 2018 and represented 26%, 24%, and 39%, respectively, of the gross accounts receivable balance as of December 31, 2018. The Company has not experienced any significant write-offs of its accounts receivable.

Concentration of Suppliers

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

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

The Company currently has manufacturing agreements with multiple independent FDA-approved API manufacturers and several independent FDA-approved API encapsulators and packagers for Vascepa manufacturing. Each of these companies has qualified and validated its manufacturing processes and is capable of manufacturing Vascepa. There can be no guarantee that these or other suppliers with which the Company may contract in the future to manufacture Vascepa or Vascepa API will remain qualified to do so to its specifications or that these and any future suppliers will have the manufacturing capacity to meet anticipated demand for Vascepa.

Foreign Currency

All subsidiaries use the U.S. dollar as the functional 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.

Fair Value of Financial Instruments

The Company provides disclosure of financial assets and financial liabilities that are carried at fair value based on the price that would be received upon sale of an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Fair value measurements may be classified based on the amount of subjectivity associated with the inputs to fair valuation of these assets and liabilities using the following three levels:

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

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

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

The following tables present information about the Company's assets and liabilities as of December 31, 2019 and 2018 that are measured at fair value on a recurring basis and indicate the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value:

	December 31, 2019			
In thousands	Total	Level 1	Level 2	Level 3
Asset:				
Cash equivalents—money markets	$ 10,078	$ 10,078	$ —	$ —

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

The carrying amounts of cash, cash equivalents, accounts payable and accrued liabilities approximate fair value because of their short-term nature. The carrying amounts and the estimated fair values of debt instruments as of December 31, 2019 and 2018 are as follows:

	December 31, 2019		December 31, 2018	
In thousands	Carrying Value	Estimated Fair Value	Carrying Value	Estimated Fair Value
Current portion of long-term debt from royalty-bearing instrument, net of accrued interest	$ 49,702		$ 33,602	
Long-term debt from royalty-bearing instrument	—		46,108	
Total long-term debt from royalty-bearing instrument	$ 49,702	$ 50,400	$ 79,710	$ 78,600

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

Derivative Liabilities

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

Long-Term Debt Redemption Feature

The Company's December 2012 royalty-bearing instrument financing arrangement (discussed in Note 7—Debt) contains a redemption feature whereby, upon a change of control, the Company would be required to repay $150.0 million, less any previously repaid amount. The Company determined this redemption feature to be an embedded derivative, which is carried at fair value and is classified as Level 3 in the fair value hierarchy due to the use of significant unobservable inputs. The fair value of the embedded derivative was calculated using a probability-weighted model incorporating management estimates of future revenues and for a potential change in control, and by determining the fair value of the debt with and without the change in control provision included.

The difference between the two was determined to be the fair value of the embedded derivative. The fair value of this derivative liability is remeasured at each reporting period, with changes in fair value recognized in the consolidated statement of operations. As of December 31, 2019, the fair value of the derivative was determined to be nil, and the debt was valued by comparing debt issues of similar companies with (i) remaining terms of between 1.9 and 7.3 years, (ii) coupon rates of between 6.0% and 11.5% and (iii) market yields of between 5.2% and 16.8%. As of December 31, 2018, the fair value of the derivative was determined to be nil based on underlying assumptions, and the debt was valued by comparing debt issues of similar companies with (i) remaining terms of between 1.3 and 4.0 years, (ii) coupon rates of between 5.4% and 10.8% and (iii) market yields of between 6.7% and 15.8%. As such,

the Company recognized no gain or loss on change in fair value of derivative liability for the year ended December 31, 2019 and 2018.

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

Segment and Geographical Information

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

Recent Accounting Pronouncements

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

In February 2016, the FASB issued Accounting Standard Update, or ASU, 2016-02, *Leases (ASC 842)*, which supersedes the existing guidance for lease accounting, Leases (Topic 840). ASU 2016-02 requires lessees to recognize a lease liability and a right-of-use asset for virtually all of their leases (other than leases that meet the definition of a short-term lease). Lessor accounting remains largely unchanged except for changes in the definition and classification of leases. ASU 2016-02 requires a modified retrospective approach for all leases existing at, or entered into after the date of initial adoption, with an option to elect to use certain transition relief. The FASB also proposed a transition method to allow entities to not apply the new leases standard in the comparative periods they present in their financial statements in the year of adoption.

On January 1, 2019, the Company adopted ASC 842 using the modified retrospective method for all leases that existed at or commenced after January 1, 2019. The adoption of ASC 842 did not have a material impact on the Company's consolidated financial statements as of the effective date. See Note 17 – Leases for further details. The Company elected to apply the practical expedients in ASC 842-10-65-1 (f) and therefore:

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

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

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

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 new guidance is effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Early adoption of all amendments in the same period is permitted. The Company is currently evaluating the impact that this standard will have on the Company's consolidated financial statements.

In November 2018, the FASB issued ASU No. 2018-18, *Collaborative Arrangements (Topic 808), Clarifying the Interaction between Topic 808 and Topic 606*, which clarified that in collaborative arrangements where the counterparty is a customer for a good or service that is a distinct unit of account is required to be accounted for under ASC 606. The new guidance is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption is permitted for entities that have adopted ASC 606. The Company has evaluated the standard and does not expect it to have a material impact on the Company's consolidated financial statements.

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

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments – Credit Losses (Topic 326), Measurement of Credit Losses on Financial Instruments*, which requires earlier recognition of credit losses on loans and other financial instruments held by entities, including trade receivables. The new standard requires entities to measure all expected credit losses for financial assets held at each reporting date based on historical experience, current conditions, and reasonable and supportable forecasts. The new guidance is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. The Company has evaluated the accounting and disclosure requirements of this standard and does not expect it to have a material 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 the historical acquisition cost of certain technology rights for Vascepa. Upon approval by FDA on December 13, 2019 of a new indication of Vascepa, a milestone for £5 million was achieved, which resulted in the Intangible asset increasing by $8.5 million. Refer to Note 9 — Equity for further discussion of the milestone payment. The Intangible asset has an estimated weighted-average remaining useful life of 10.6 years. The carrying value as of December 31, 2019 and 2018 is as follows:

In thousands	December 31, 2019	December 31, 2018
Technology rights	$ 20,081	$ 11,624
Accumulated amortization	(4,823)	(4,144)
Intangible asset, net	$ 15,258	$ 7,480

Amortization expense for the years ended December 31, 2019 and 2018 was $0.7 million and $0.6 million, respectively. Estimated future amortization expense, based upon the Company's intangible asset, as of December 31, 2019 is as follows:

In thousands Year Ending December 31,	Amount
2020	$ 1,442
2021	1,442
2022	1,442
2023	1,442
2024	1,442
Thereafter	8,048
Total	$ 15,258

(4) Inventory

The Company capitalizes its purchases of saleable inventory of Vascepa from suppliers that have been qualified by the FDA. Inventories as of December 31, 2019 and 2018 consist of the following:

In thousands	December 31, 2019	December 31, 2018
Raw materials	$ 19,455	$ 14,142
Work in process	12,031	8,590
Finished goods	45,283	35,357
Total inventory, gross	76,769	58,089
Inventory cost adjustment	—	(287)
Inventory	76,769	57,802

(5) Property, Plant and Equipment

Property, plant and equipment as of December 31, 2019 and 2018 consist of the following:

In thousands	Useful Life (in years)	December 31, 2019	December 31, 2018
Furniture and fixtures	5	$ 1,636	$ 66
Leasehold improvements	lesser of useful life or lease term	714	156
Software	3 - 5	617	617
Computer equipment	3 - 5	290	63
Construction in progress		123	—
Property, plant and equipment		3,380	902
Accumulated depreciation and amortization		(1,019)	(839)
Property, plant and equipment, net		2,361	63

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, 2019, 2018, and 2017 were $0.2 million, less than $0.1 million, and $0.1 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, 2019 and 2018:

In thousands	December 31, 2019	December 31, 2018
Payroll and payroll-related expenses	$ 21,204	$ 12,170
Sales and marketing accruals	8,221	20,003
Accrued revenue allowances	93,815	44,286
All other	16,586	7,712
Accrued expenses and other current liabilities	$ 139,826	$ 84,171

(7) Debt

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

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

As of December 31, 2019, the remaining amount to be repaid to CPPIB is $52.4 million. During the year ended December 31, 2019, the Company made repayments under the agreement of $36.2 million to CPPIB and an additional $14.2 million was paid in February 2020 for the fourth quarter of 2019. These payments, as well as additional quarterly repayments scheduled in the future, are calculated as 10% of Vascepa net revenues. All such payments reduce the remainder of the $150.0 million in aggregate payments to CPPIB. Except upon a change of control in Amarin, the agreement does not expire until $150.0 million in aggregate has been repaid. The Company can prepay the net remaining amount at any time.

The Company determined the redemption feature upon a change of control to be an embedded derivative requiring bifurcation. The fair value of the embedded derivative was calculated by determining the fair value of the debt with the change in control provision included and also without the change in control provision. The fair value of this derivative liability is remeasured at each reporting period, with changes in fair value recognized in the consolidated statement of operations and any changes in the assumptions used in measuring the fair value of the derivative liability could result in a material increase or decrease in its carrying value. Based on current assumptions underlying the valuation, the Company recognized no gain or loss on change in fair value of derivative liability during the years ended December 31, 2019 and 2018.

As of December 31, 2019 and 2018, the carrying value of the royalty-bearing instrument, net of the unamortized debt discount and issuance costs, was $49.7 million and $79.7 million, respectively. During the year ended December 31, 2019, the Company recorded cash and non-cash interest expense of $4.4 million and $1.6 million, respectively, in connection with the royalty-bearing instrument. During the year ended December 31, 2018, the Company recorded $5.6 million and $2.0 million of cash and non-cash interest expense, respectively, in connection with the royalty-bearing instrument. The Company will periodically evaluate the remaining term of the agreement and the effective interest rate is recalculated each period based on the Company's most current estimate of repayment.

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

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

January 2017 Exchangeable Senior Notes

On January 20, 2017, the Company and Corsicanto II DAC, or Corsicanto II, a designated activity company formed under the laws of Ireland and a wholly owned subsidiary of the Company, entered into separate, privately negotiated purchase agreements with certain investors pursuant to which Corsicanto II issued and sold $30.0 million in aggregate principal amount of 3.5% exchangeable senior notes due 2047, or the 2017 Notes, at an issue price of 100%. In October 2018, Corsicanto II mandatorily exchanged $30.0 million of aggregate principal amount of the 2017 Notes for equity, such that no 2017 Notes remained outstanding as of December 31, 2019 and 2018.

(8) Commitments and Contingencies

Litigation

On February 22, 2019, a purported investor in our publicly traded securities filed a putative class action lawsuit against Amarin Corporation plc, our chief executive officer and chief scientific officer in the U.S. District Court for the District of New Jersey, *Debendra Sharma v. Amarin Corporation plc, John F. Thero and Steven Ketchum*, No. 2:19-cv-06601 (D.N.J. Feb. 22, 2019). On March 12, 2019, another purported investor filed a substantially similar lawsuit captioned *Richard Borghesi v. Amarin Corporation plc, John F. Thero and Steven Ketchum*, No. 3:19-cv-08423 (D.N.J. March 12, 2019). 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 adds as defendants our current chief medical officer and our former chief executive officer, who is a current director. The Amended Complaint alleges 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 alleges 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 allege may have increased adverse outcomes in the placebo group. The Amended Complaint further allege that these purported misrepresentations and omissions inflated our share price. Based on these allegations, the suit asserts claims under the Securities Exchange Act of 1934 and seeks unspecified monetary damages and attorneys' fees and costs.

The Company believes that 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. 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 August 30, 2017, Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Limited, each wholly-owned subsidiaries of Amarin Corporation plc, filed a lawsuit with the United States International Trade Commission, or the ITC, captioned *In the Matter of Certain Synthetically Produced, Predominantly EPA Omega-3 Products in Ethyl Ester or Re-esterified Triglyceride Form*, USITC Docket 337-3247, 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 under Section 337 of the Tariff Act of 1930 (19 U.S.C. §1337), which makes unlawful unfair methods of competition and unfair acts involving the importation and sale of articles in the United States that injure or threaten injury to a domestic industry. On October 27, 2017, the ITC determined to not institute our requested investigation. On December 1, 2017, the Company appealed the ITC's non-institution decision to the United States Court of Appeals for the Federal Circuit (Case Nos. 18-1247, 18-114). That appeal is ongoing. The Company intends to pursue this matter vigorously.

In September and October 2016, the Company received paragraph IV certification notices from four companies contending to varying degrees that certain of its patents are invalid, unenforceable and/or will not be infringed by the manufacture, use, sale or offer for sale of a generic form of Vascepa as described in those companies' abbreviated new drug applications, or ANDAs. The Company filed patent infringement lawsuits against three of these four ANDA applicants. In October 2016, Amarin filed a lawsuit against Roxane Laboratories, Inc. and related parties (collectively, "Roxane") in the U.S. District Court for the District of Nevada. The case against Roxane is captioned *Amarin Pharma, Inc. et al. v. Roxane Laboratories, Inc. et al.*, Civ. A. No. 2:16-cv-02525 (D. Nev.). According to a stipulation filed with the Nevada court, in December 2016, Roxane transferred its ANDA to West-Ward Pharmaceuticals International Limited, which then designated West-Ward Pharmaceuticals Corp. (or together with West-Ward Pharmaceuticals International Limited, West-Ward) as its agent for FDA communications. In view of the ANDA transfer, in February 2017, West-Ward replaced Roxane and related parties as Defendants in the above-referenced case. The case against West-Ward is now captioned *Amarin Pharma, Inc. et al. v. West-Ward Pharmaceuticals Corp. et al.*, Civ. A. No. 2:16-cv-02525 (D. Nev.). In November 2016, Amarin filed a lawsuit against Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. (collectively, "DRL") in the U.S. District Court for the District of Nevada. The case against DRL is captioned *Amarin Pharma, Inc. et al. v. Dr. Reddy's Laboratories, Inc. et al.*, Civ. A. No. 2:16-cv-02562 (D. Nev.). In November 2016, Amarin filed a lawsuit against Teva Pharmaceuticals USA, Inc. and Teva Pharmaceuticals Industries Limited (collectively, "Teva") in the U.S. District Court for the District of Nevada. The case against Teva is captioned *Amarin Pharma, Inc. et al. v. Teva Pharmaceuticals USA, Inc. et al.*, Civ. A. No. 2:16-cv-02658. In all three lawsuits, Amarin is seeking, among other remedies, an order enjoining each defendant from marketing generic versions of Vascepa before the last to expire of the asserted patents in 2030. The three lawsuits have been consolidated for pretrial proceedings. As a result of the statutory stay associated with the filing of these lawsuits under the Hatch-Waxman Act, the FDA cannot grant final approval to West-Ward, DRL, or Teva's respective ANDA before January 2020, unless there is an earlier court decision holding that the subject patents are not infringed and/or are invalid.

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

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

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

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

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.

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 FDA-approved API suppliers and encapsulators. Certain supply agreements require annual minimum volume commitments by the Company and certain volume shortfalls may require payments for such shortfalls.

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

Pursuant to the supply agreements, there is a total of approximately $192.4 million that is potentially payable over the term of such agreements based on minimum purchase obligations. The Company continues to meet its contractual purchase obligations.

Under the 2004 share repurchase agreement with Laxdale Limited, or Laxdale, upon receipt of marketing approval in Europe for the first indication for Vascepa (or first indication of any product containing Amarin Neuroscience Limited intellectual property acquired from Laxdale in 2004), the Company must make an aggregate stock or cash payment to the former shareholders of Laxdale (at the sole option of each of the sellers) of £7.5 million (approximately $9.9 million as of December 31, 2019). 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 using Amarin Neuroscience Limited intellectual property), the Company must make an aggregate stock or cash payment (at the sole option of each of the sellers) of £5 million (approximately $6.6 million as of December 31, 2019) for the potential market approval .

The Company has no provision for any of the obligations above since the amounts are either not paid or payable as of December 31, 2019.

(9) Equity

Preferred Stock

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

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

Each ten (10) Series A Preference Shares may be consolidated and redesignated as one (1) ordinary share, par value £0.50 per share, in the capital of the Company, each ordinary share to be represented by American Depositary Shares, or ADSs, provided that consolidation will be prohibited if, as a result, the holder of such Series A Preference Shares and its affiliates would beneficially own more than 4.99% of the total number of Amarin ordinary shares or ADSs outstanding following such redesignation, or the Beneficial Ownership Limitation. By written notice to the Company, a holder may from time to time increase or decrease the Beneficial Ownership Limitation to any other percentage not in excess of 19.9% specified in such notice; provided that any such increase will not be effective until the sixty-first (61st) day after such notice is delivered to the Company. This consolidation and redesignation may be effected by a holder of Series A Preference Shares following the first to occur of the resale of the ADSs representing the ordinary shares being registered for resale under the Securities Act pursuant to an effective registration statement, following any sale of the ADSs representing the ordinary shares pursuant to Rule 144 under the Securities Act, or if such ADSs representing the ordinary shares are eligible for sale under Rule 144, following the expiration of the one-year holding requirement under Rule 144.

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

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

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

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

On March 30, 2015, in connection with the closing of the private placement, and pursuant to a pre-existing contractual right to participate in certain private placement transactions effected by the Company, the Company entered into a separate subscription agreement with an existing investor, Sofinnova Venture Partners VII L.P., or Sofinnova, for the purchase of an additional $5.8 million of restricted American Depositary Shares, each representing one (1) share of the Company's Series A Preference Shares, at the same price per share and otherwise on substantially the same terms as the initial private placement, or the Second Private Placement. In accordance with applicable marketplace rules of the NASDAQ Stock Market, the consummation of the Second Private Placement was conditioned upon approval by the Company's shareholders at a future meeting of the Company's shareholders. Such approval was received at the Company's Annual General Meeting of Shareholders on July 6, 2015 and as a result, the closing of the Second Private Placement occurred on July 10, 2015. The Company issued 38,867,180 restricted ADSs, each representing one Series A Preference Share, which could be consolidated and redesignated from time to time up to a maximum of 3,886,718 ordinary shares, each ordinary share to be represented by one ADS. For each restricted ADS, Sofinnova 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 $5.8 million.

The Company filed another registration statement with the SEC covering the resale of these restricted American Depositary Shares and the ADSs representing ordinary shares created by the consolidation and redesignation of the Series A Preference Shares, or the Sofinnova Registrable Securities, on July 24, 2015, which was declared effective by the SEC on August 7, 2015. In addition, the Company agreed to use its commercially reasonable best efforts to keep the registration, and any qualification, exemption or compliance under state securities laws which the Company determines to obtain, continuously effective, and to keep the registration statement free of any material misstatements or omissions, until the earlier of (a) July 10, 2017 or (b) the date on which all Sofinnova Registrable Securities held by Sofinnova may be sold or transferred in compliance with Rule 144 under the Securities Act, without any volume or manner of sale restrictions.

The existence of this preferred stock purchase option was determined to be a derivative liability effective March 5, 2015, the date on which the private placement was initially subscribed. The fair value of this liability was calculated using a Black-Scholes model and was determined to be $0.9 million at inception and was charged to accumulated deficit as a deemed non-cash dividend to Sofinnova. The liability was then marked to fair value as of March 30, 2015, the date on which the Company executed a subscription agreement with Sofinnova, resulting in a charge of $0.9 million through gain (loss) on change in fair value of derivatives. The liability of $1.8 million was reclassified to permanent equity (additional paid-in capital) on such date. Subsequent to approval of the Second Private Placement at the Company's Annual General Meeting of Shareholders in July 2015, the Company recorded the remaining value of the BCF related to this share issuance as a non-cash dividend to preferred shareholders through accumulated deficit. The value of the BCF was determined on the same basis as the first private placement and amounted to $3.4 million less $1.8 million previously recorded for the preferred stock purchase option for a net non-cash charge of $1.6 million in the year ended December 31, 2015.

During the years ended December 31, 2015 and 2018, the Company issued 6,283,333 and 3,886,718 ADSs, respectively, upon consolidation and redesignation of Series A Preference Shares at the request of the holders, such that a maximum of 28,931,746 ordinary shares remain issuable upon future consolidation and redesignation of the remaining Series A Preference Shares as of December 31, 2019, subject to certain adjustments for dilutive events.

Common Stock

On December 13, 2019, in connection with approval by the FDA for a new indication of Vascepa, the Company was required to make an aggregate milestone payment of £5 million (in either stock or cash at the sole option of each of the sellers) to Laxdale's former shareholders. One of the shareholders' elected to receive payment in stock, resulting in the issuance of 257,713 shares at a price of $24.12 per share. The Company recorded a liability of $2.2 million in Accrued expenses and other current liabilities on the consolidated balance sheet as of December 31, 2019.

On July 18, 2019, the Company completed a public offering of 22,222,223 ADSs with each ADS representing one ordinary share of the Company, at a price of $18.00 per ADS, $17.235 per ADS after commission. In addition, the Company granted the underwriters a 30-day option to purchase up to an additional 3,333,333 ADSs 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 gross proceeds of approximately $460.0 million and, after deducting customary commissions and offering expenses, net proceeds to the Company of approximately $440.1 million.

On November 29, 2018, the Company completed a public offering of 11,111,112 ADSs, with each ADS representing one ordinary share of the Company. The underwriters purchased the ADSs from the Company at a price of $17.575 per ADS after commission, resulting in net proceeds to the Company of approximately $194.8 million, after deducting customary commissions and offering expenses.

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

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

As of December 31, 2019, there were an aggregate of 15,619,123 stock options and 6,921,071 restricted stock units, or RSUs, outstanding, representing approximately 4% and 2%, respectively, of outstanding shares (including common and preferred shares) on a fully diluted basis.

During the years ended December 31, 2019 and 2018, the Company issued 5,997,919 and 8,138,305 shares, respectively, as a result of the exercise of stock options, resulting in gross and net proceeds of $24.5 million during the year ended December 31, 2019 and $26.4 million during the year ended December 31, 2018.

In October 2019, in connection with achievement of a predetermined performance-based formula tied to company cash flow, the Company issued 2,436,750 shares upon vesting of performance-based RSUs granted in 2015, of which 1,069,377 shares were retained as treasury shares as settlement of employee tax obligations.

On May 20, 2019, the Company granted a total of 45,163 RSUs and 58,721 stock options to members of the Company's Board of Directors under the Amarin Corporation plc Stock Incentive Plan, or the 2011 Plan. The RSUs vest in equal installments over a three-year period upon the earlier of the anniversary of the grant date or the Company's annual general meeting of shareholders in such anniversary year. The stock options vest in full upon the earlier of the one-year anniversary of the grant date or the Company's annual general meeting of shareholders in such anniversary year. Upon termination of service to the Company or upon a change of control, each Director shall be entitled to a payment equal to the fair market value of one share of Amarin common stock per award vested or granted, respectively, which is required to be made in shares.

Also on May 20, 2019, the Company granted an additional 20,000 RSUs to employees under the 2011 Plan that vest upon the achievement of a specified sales performance condition.

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

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

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

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

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

Refer to Note 11—Stock Incentive Plans and Stock Based Compensation for further information regarding the Company's incentive equity awards.

(10) Income Taxes

Interest and penalties related to any uncertain tax positions have historically been insignificant. The Company recognizes interest and penalties related to uncertain tax positions within the provision for income taxes. The total amount of unrecognized tax benefits that would affect the Company's effective tax rate if recognized is nil as of both December 31, 2019 and 2018.

The following is a reconciliation of the total amounts of unrecognized tax benefits for the years ended December 31, 2019, 2018 and 2017:

In thousands	2019	2018	2017
Beginning uncertain tax benefits	$ 6,815	$ 1,734	$ 1,633
Prior year—increases	295	296	—
Prior year—decreases	—	(762)	(20)
Current year—increases	19,633	5,547	121
Ending uncertain tax benefits	$ 26,743	$ 6,815	$ 1,734

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, 2019:

Jurisdiction	Tax Years
United States—Federal	2016-2019
United States—State	2012-2019
Ireland	2015-2019
United Kingdom	2018-2019

The Company does not expect any gross liabilities to expire in 2020 based on statutory lapses or audits.

The components of loss from operations before taxes were as follows for the years ended December 31, 2019, 2018 and 2017:

In thousands	2019	2018	2017
United States	$ 10,269	$ (13,583)	$ (2,075)
Ireland and United Kingdom	(32,750)	(102,766)	(52,743)
	$ (22,481)	$ (116,349)	$ (54,818)

The provision for income taxes shown in the accompanying consolidated statements of operations consists of the following for fiscal 2019, 2018 and 2017:

In thousands	2019	2018	2017
Current:			
United States—Federal	$ —	$ 4	$ 1,769
United States—State	164	92	196
Total current	$ 164	$ 96	$ 1,965
Deferred:			
United States—Federal	1,777	(1,968)	5,760
United States—State	(914)	(1,325)	(487)
Ireland and United Kingdom	1,278	(5,435)	(16,306)
Change in valuation allowance	(2,141)	8,728	22,115
Total deferred	$ —	$ —	$ 11,082
Provision for income taxes	$ 164	$ 96	$ 13,047

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 2019, 2018 and 2017:

In thousands	2019	2018	2017
Benefits from taxes at statutory rate	$ (5,620)	$ (29,087)	$ (13,698)
Rate differential	3,009	9,796	3,071
Change in valuation reserves	(2,141)	8,728	22,115
Derivative liabilities	—	337	—
Nondeductible employee compensation	5,472	3,058	1,668
Stock option/RSU windfall	(14,342)	(7,684)	(1,182)
ISO Disqualifying Disposition Windfall	(2,849)	—	—
Research and development credits	(1,607)	(1,438)	(1,177)
Tax return to provision adjustments	(3,222)	6,736	5,788
U.S. rate change—tax reform	—	—	7,398
Cumulative translation adjustment	2,025	5,711	(12,554)
Permanent and other	(443)	(404)	1,635
Non-deductible interest expense	—	267	(17)
Tax reserves	18,799	4,956	—
Corscianto Liquidation	1,727	—	—
Long-term debt from royalty-bearing instrument	(644)	(880)	—
Provision for income taxes	$ 164	$ 96	$ 13,047

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, 2019, 2018, and 2017, 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 December 22, 2017, the U.S. enacted the Act that instituted fundamental changes to the taxation of multinational corporations. The Act includes changes to the taxation of foreign earnings by implementing a dividend exemption system, expansion of the current anti-deferral rules, a minimum tax on low-taxed foreign earnings and new measures to deter base erosion. The Act also includes a permanent reduction in the corporate tax rate to 21%, repeal of the corporate alternative minimum tax, expensing of capital investment, and limitation of the deduction of interest expense. Furthermore, as part of the transition to the new tax system, a one-time transition tax is imposed on a U.S. shareholder's historical undistributed earnings of foreign affiliates. Although the Act was generally effective January 1, 2018, U.S. GAAP required recognition of the tax effects of new legislation during the reporting period that included the enactment date, which was December 22, 2017.

As a result of the financial reporting implications of the Act, the SEC provided guidance that allowed the Company to record provisional amounts for those impacts, with the requirement that the accounting be completed in a period not to exceed one year from the date of enactment. As of December 31, 2018, the Company has finalized the amounts related to tax reform to account for the impact of the Act. No adjustments to the financial statements were recorded in connection with the finalization of the accounting.

The primary impact of the Act on the Company related to the re-measurement of deferred tax assets and liabilities resulting from the change in the corporate tax rate from 34% to 21%. At the date of enactment, the Company had net deferred tax assets for the excess of the net tax value over the book basis of its U.S. assets and liabilities which will generate future tax deductions in excess of book expense. As a result of the Act, future tax deductions will result in a decreased reduction in tax expense. Consequently, the Company reduced the amount of the U.S. subsidiary's net deferred tax assets as of the date of enactment and recorded a non-cash charge of $2.4 million in the provision for income taxes for the year ended December 31, 2017 due to the decrease in the corporate tax rate. In addition, based on the Company's evaluation of available evidence, the Company recognized non-cash tax expense during the year ended December 31, 2017 of $8.7 million related to the recording of additional valuation allowance to reduce the deferred tax assets on the balance sheet to zero as the Company concluded that it is not more likely than not that certain of the deferred tax benefits resulting from deferred tax assets generated from the U.S. subsidiary operations will be realized.

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, 2019, 2018 and 2017 includes $21.9 million, $7.7 million and $1.3 million of excess tax benefits, respectively, arising from share-based payments during the period of adoption. Additionally, the new standard requires that historical excess tax benefits that were not previously recognized because the related tax deduction had not reduced current taxes should be recognized on a modified retrospective basis as a cumulative-effect adjustment to retained earnings as of the beginning of the annual period of adoption. Consequently, the Company recognized deferred tax assets of approximately $1.6 million relating to excess tax benefits on stock-based compensation during the year of adoption, with a corresponding cumulative-effect adjustment to accumulated deficit.

The income tax effect of each type of temporary difference comprising the net deferred tax asset as of December 31, 2019 and 2018 is as follows:

In thousands	December 31, 2019	December 31, 2018
Deferred tax assets:		
Net operating losses	$ 118,220	$ 119,355
Stock-based compensation	7,111	8,113
Tax credits	9,149	7,816
Lease Liability	2,715	—
Other reserves and accrued liabilities	5,580	6,344
Gross deferred tax assets	142,775	141,628
Less: valuation allowance	(137,976)	(140,117)
Total deferred tax assets	4,799	1,511
Deferred tax liabilities:		
Depreciation and amortization	(2,544)	(1,011)
Lease Asset	(2,242)	—
Other liabilities	(13)	(500)
Total deferred tax liabilities	(4,799)	(1,511)
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, 2019 and 2018:

In thousands	2019	2018
Beginning valuation allowance	$ 140,117	$ 131,389
Increase as reflected in income tax expense	(114)	13,609
Cumulative translation adjustment	(2,027)	(4,881)
Ending valuation allowance	$ 137,976	$ 140,117

During 2019, 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 in non-U.S. entities.

The Company has combined U.S., Irish, UK, and Israeli net operating loss carryforwards of $861.8 million, which do not expire. The total net operating loss carryforwards increased by approximately $73.1 million from the prior year primarily as a result of current year losses 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 2018 foreign tax returns. In addition, the Company has U.S. Federal tax credit carryforwards of $8.4 million and state tax credit carryforwards of $2.4 million. These amounts exclude the impact of any unrecognized tax benefits and valuation allowances. These carryforwards, which will expire between 2024 and 2039, may be used to offset future taxable income, if any.

As of December 31, 2019, 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 New Jersey Department of Treasury for the years 2012 to 2015. In addition, the Company was notified by the IRS in January 2020 that it will be auditing the Company's 2018 US income tax return and the examination is expected to begin in the first quarter of fiscal year 2020. 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 April 29, 2011 the Board, upon the recommendation of the Remuneration Committee, adopted the 2011 Stock Incentive Plan, or 2011 Plan, which was approved by the Company's shareholders on July 12, 2011. The 2011 Plan replaced the Company's 2002 Stock Option Plan, or 2002 Plan, which expired on January 1, 2012. The maximum number of the Company's Ordinary Shares of £0.50 each or any ADS's, as to be issued under the 2011 Plan, as amended, shall not exceed the sum of (i) 51.5 million newly authorized Shares available for award and (ii) the number of Shares that remained available for grants under the Company's 2002 Plan and (iii) the number of Shares underlying then outstanding awards under the 2002 Plan that could be subsequently forfeited, cancelled, expire or are otherwise terminated. 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 2011 Plan is administered by the Remuneration Committee of the Company's Board of Directors and expires on July 12, 2021.

In addition to the grants under the 2011 Plan, the Company grants non-qualified stock options to employees to purchase the Company's ordinary shares. These grants are made pursuant to employment agreements on terms consistent with the 2011 Plan.

Under the terms of the 2011 Plan, and grants made pursuant to employment agreements, 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, 2019:

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, 2019	19,263	$ 4.29		
Granted	2,648	17.07		
Forfeited	(291)	10.31		
Expired	(3)	4.04		
Exercised	(5,998)	4.09		
Outstanding as of December 31, 2019	15,619	6.43	6.5 years	$ 234,499
Exercisable as of December 31, 2019	10,310	3.75	5.4 years	182,417
Vested and expected to vest as of December 31, 2019	15,354	$ 6.34	6.4 years	$ 231,895
Available for future grant as of December 31, 2019	7,851			

The weighted average grant date fair value of stock options granted during the years ended December 31, 2019, 2018, and 2017 was $17.07, $7.82, and $3.09, respectively. The total grant date fair value of options vested during the years ended December 31, 2019, 2018, and 2017 was $14.5 million, $7.7 million, and $7.1 million, respectively.

During the years ended December 31, 2019, 2018 and 2017, the Company received proceeds from the exercise of options of $24.5 million, $26.4 million, and $0.6 million, respectively. The total intrinsic value of options exercised during the years ended December 31, 2019, 2018, and 2017 was $90.5 million, $69.7 million, and $0.5 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, 2019, there was $40.5 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 2.6 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 $16.3 million, $8.2 million, and $7.0 million for the years ended December 31, 2019, 2018, and 2017, respectively.

For 2019, 2018, and 2017, the Company used the following assumptions to estimate the fair value of share-based payment awards:

	2019	2018	2017
Risk-free interest rate	1.55% - 2.95%	2.18% - 3.00%	1.77% - 2.01%
Expected dividend yield	0.00%	0.00%	0.00%
Expected option life (years)	6.25	6.25	6.25
Expected volatility	92% - 94%	71% - 92%	73% - 82%

Restricted Stock Units

The 2011 Plan also allows for granting of restricted stock unit awards under the terms of the Plan. 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, 2019 and 2018:

In thousands (except per share amounts)	Shares	Weighted Average Grant Date Fair Value
Outstanding as of January 1, 2018	12,006	$ 2.50
Granted	2,633	4.32
Vested	(4,611)	2.20
Forfeited	(395)	3.43
Outstanding as of December 31, 2018	9,633	3.12
Granted	1,473	16.83
Vested	(3,970)	2.56
Forfeited	(215)	3.25
Outstanding as of December 31, 2019	6,921	$ 6.34

The Company recorded compensation expense in relation to restricted stock units of $14.6 million, $10.6 million, and $7.0 million for the years ended December 31, 2019, 2018, and 2017 respectively.

The following table presents the stock-based compensation expense related to stock-based awards for the years ended December 31, 2019, 2018, and 2017:

In thousands	2019	2018	2017
Research and development	$ 4,615	$ 2,898	$ 2,122
Selling, general and administrative	26,302	15,908	11,838
Stock-based compensation expense	$ 30,917	$ 18,806	$ 13,960

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, 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. For the offering periods ended on the last business day on or before each of May 31, 2018 and November 30, 2018, the Company issued 127,872 shares and 184,385 shares, respectively, at a purchase price of $2.81 per share and $2.86 per share, respectively. No shares were issued under the ESPP during the year ended December 31, 2017 as the initial enrollment and offering periods commenced in 2018. As of December 31, 2019, 2,564,712 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 $1.1 million, $0.7 million and $0.4 million of related compensation expense for the year ended December 31, 2019, 2018 and 2017, respectively.

(13) Quarterly Summarized Financial Information (Unaudited)

	Fiscal years ended December 31, 2019 and 2018							
	1st Quarter		2nd Quarter		3rd Quarter		4th Quarter	
	2019	2018	2019	2018	2019	2018	2019	2018
	(In thousands, except per share amounts)							
Total revenue, net	$ 73,278	$ 43,919	$ 100,792	$ 52,643	$ 112,408	$ 55,323	$ 143,277	$ 77,330
Gross margin	56,138	33,271	78,022	39,797	86,964	41,782	112,612	59,821
Net (loss) income	(24,431)	(24,095)	(1,820)	(34,210)	(3,462)	(24,471)	7,068	(33,670)
(Loss) earnings per share:								
Basic	$ (0.07)	$ (0.08)	$ (0.01)	$ (0.12)	$ (0.01)	$ (0.08)	$ 0.02	$ (0.11)
Diluted	$ (0.07)	$ (0.08)	$ (0.01)	$ (0.12)	$ (0.01)	$ (0.08)	$ 0.02	$ (0.11)

(14) 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. Under the terms of the Agreement, the Company granted to Kowa Pharmaceuticals America, Inc. the right to be the sole co-promoter, together with the Company, of Vascepa in the United States during the term. The Agreement was amended on July 25, 2017 to reflect evolving promotional needs, including refinement of target lists. The Company and Kowa Pharmaceuticals America, Inc. intentionally designed the co-promotion to naturally end as of December 31, 2018 and mutually agreed not to renew the agreement.

During 2018, which was the last year of the Agreement, as amended, the Company incurred expense for 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. The accrued tail payments are paid over three years with declining amounts each year. Kowa Pharmaceuticals America, Inc. is eligible to receive $17.8 million in co-promotion tail payments, the present value of which $16.6 million, was fully accrued as of December 31, 2018. There were $7.3 million in tail payments made as of December 31, 2019.

As of December 31, 2019 and 2018, the Company had a net payable to Kowa Pharmaceuticals America, Inc. of $10.0 million and $27.6 million, respectively, of which $6.5 million and $18.1 million, respectively, was classified as current on the consolidated balance sheets, representing co-promotion fees, including accrual of the tail payments, net of reimbursable amounts incurred for samples and other marketing expenses.

(15) Revenue Recognition

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

Revenues from product sales are recognized when the distributor obtains control of the Company's product, which occurs at a point in time, typically upon delivery to the distributor. Payments from distributors are generally received 30-60 days from 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 that the Company charges its distributors for Vascepa.

Reserves for Variable Consideration

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

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

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

Product Returns: The Company's distributors have the right to return unopened unprescribed Vascepa during the 18-month period beginning six months prior to the labeled expiration date and ending twelve months after the labeled expiration date. The expiration date for Vascepa 1-gram and 0.5-gram size capsules is currently four years and three years, respectively, after being converted into capsule form, which is the last step in the manufacturing process for Vascepa and generally occurs within a few months before Vascepa is delivered to distributors. The Company estimates future product returns on sales of Vascepa based on: (i) data provided to the Company by its distributors (including weekly reporting of distributors' sales and inventory held by distributors that provided the Company with visibility into the distribution channel in order to determine what quantities were sold to retail pharmacies and other providers), (ii) information provided to the Company from retail pharmacies, (iii) data provided to the Company by a third-party data provider which collects and publishes prescription data, and other third parties, (iv) historical industry information regarding return rates for similar pharmaceutical products, (v) the estimated remaining shelf life of Vascepa previously shipped and currently being shipped to distributors and (vi) contractual agreements intended to limit the amount of inventory maintained by the Company's distributors. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses and other current liabilities on the 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 table summarizes activity in each of the net product revenue allowance and reserve categories described above for the years ended December 31, 2019 and 2018:

In thousands	Trade Allowances	Rebates, Chargebacks and Discounts	Product Returns	Other Incentives	Total
Balance as of January 1, 2018	**$ 12,035**	**$ 32,064**	**$ 1,887**	**$ 2,107**	**$ 48,093**
Provision related to current period sales	46,002	190,329	1,211	20,732	258,274
Provision related to prior period sales	—	(1,845)	—	(69)	(1,914)
Credits/payments made for current period sales	(29,202)	(148,857)	—	(19,307)	(197,366)
Credits/payments made for prior period sales	(9,340)	(30,057)	(150)	(2,296)	(41,843)
Balance as of December 31, 2018	**19,495**	**41,634**	**2,948**	**1,167**	**65,244**
Provision related to current period sales	92,378	403,865	2,430	47,169	545,842
Provision related to prior period sales	—	(324)	—	—	(324)
Credits/payments made for current period sales	(63,288)	(312,790)	5	(43,416)	(419,489)
Credits/payments made for prior period sales	(19,324)	(41,388)	(804)	(1,200)	(62,716)
Balance as of December 31, 2019	**$ 29,261**	**$ 90,997**	**$ 4,579**	**$ 3,720**	**$ 128,557**

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

Licensing Revenue

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

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

In determining performance obligations, management evaluates whether the license is distinct from the other performance obligations with the collaborative partner based on the consideration of the relevant facts and circumstances for each arrangement. Factors considered in the determination 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.

(16) 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, which was recorded in research and development expense in the consolidated statement of operations for the year ended December 31, 2018. In addition, the agreement provides for the Company to pay milestone payments upon the achievement of certain product development milestones and royalties on net sales of future products arising from the collaboration, if any.

Out-licenses

Eddingpharm (Asia) Macao Commercial Offshore Limited

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

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

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

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

Upon closing of the DCS Agreement, the Company received a non-refundable $15.0 million up-front payment. In March 2016, Eddingpharm submitted its clinical trial application, 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, Eddingpharm commenced a pivotal clinical trial aimed to support the regulatory approval of the first indication of Vascepa in a patient population with severe hypertriglyceridemia in Mainland China.

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

The Company assessed this arrangement in accordance with Topic 606 and concluded that the contract counterparty, Eddingpharm, is a customer. The Company identified the following performance obligations at the inception of the DCS Agreement: (1) the exclusive license to develop and commercialize Vascepa in the China Territory for uses that are currently commercialized and under development by the Company, (2) the obligation to participate in various steering committees, 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, 2019 and 2018, the Company recognized $0.3 million and $0.1 million, respectively, as licensing revenue related to the up-front and milestone payments received in connection with the Eddingpharm agreement. From contract inception through December 31, 2019 and 2018, the Company recognized $3.0 million and $2.8 million, respectively, as licensing revenue under the DCS Agreement concurrent with the support provided by Amarin to Eddingpharm in achieving the combined 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 $13.0 million and $13.2 million is recorded in deferred revenue as of December 31, 2019 and 2018, respectively, on the consolidated balance sheets and will be recognized as revenue over the remaining period of 15 years.

Biologix FZCo

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

In March 2018 and July 2018, the Company received approval for Vascepa as a prescription medication for use in Lebanon and United Arab Emirates, respectively, as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. The Company recognized net product revenue of approximately $0.7 million and $0.1 million as of December 31, 2019 and 2018, respectively.

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 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 $53.8 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 and the $2.5 million milestone related to obtaining approval from Health Canada. The other regulatory milestone has not been included in the transaction price, as it was fully constrained. As part of its evaluation of the constraint, the Company considered numerous factors, including that receipt of the milestone is outside the control of the Company and contingent upon the licensee's efforts. Any consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur 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, 2019 and 2018, the Company recognized $2.1 million and $0.6 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, 2019 and 2018, the Company has recognized $2.9 million and $0.9 million, respectively, as licensing revenue is recognized under the agreement concurrent with the support provided by Amarin to HLS in achieving 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 $7.1 million and $6.6 million is recorded in deferred revenue as of December 31, 2019 and 2018, respectively, on the consolidated balance sheets and will be recognized as revenue over the remaining period of 11 years.

The following table presents changes in the balances of the Company's contract assets and liabilities for years ended December 31, 2019 and 2018:

In thousands	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
Year ended December 31, 2019:				
Contract assets	$ —	$ —	$ —	$ —
Contract liabilities:				
Deferred revenue	$ 20,710	$ 2,500	$ (2,364)	$ 20,846
Year ended December 31, 2018:				
Contract assets	$ —	$ —	$ —	$ —
Contract liabilities:				
Deferred revenue	$ 19,054	$ 2,500	$ (843)	$ 20,710

During the years ended December 31, 2019 and 2018, 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:	2019	2018
Amounts included in contract liability at the beginning of the period	$ 1,633	$ 650
Performance obligations satisfied in previous periods	$ 299	$ 193

(17) 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 September 30, 2011, the Company entered into an agreement for office space in Dublin, Ireland which terminated on May 1, 2019. On April 12, 2019 and July 4, 2019, the Company entered into Office Centre Sharing Agreements effective May 1, 2019 and October 1, 2019, respectively, to replace the office space with new office space in Dublin, Ireland which terminates on April 30, 2020 and September 30, 2020, respectively, and can be extended automatically for successive one year periods. These leases have been determined to be short-term leases and the Company is committed to making nominal payments during the next twelve months.

On July 1, 2011, the Company leased office space in Bedminster, New Jersey. The lease, as amended, terminated on September 15, 2019. On January 26, 2019, the Company leased additional space in another building in Bedminster, New Jersey, effective February 1, 2019 which also terminated on September 15, 2019.

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 ninety-seventh month after the Commencement Date upon advance written notice and a termination payment specified in the Lease. Under the Lease, the Company pays monthly rent of approximately $0.1 million for the first year following the Commencement Date, and such rent will increase by a nominal percentage every year following the first anniversary of the Commencement Date. In addition, Amarin receives certain abatements subject to the limitations in the Lease. The operating lease liability is $9.8 million and the operating lease right-of-use asset is $8.5 million, as of December 31, 2019. The lease expense for the twelve months ended December 31, 2019 is approximately $1.5 million.

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

	Undiscounted lease payments ($000s)
2020	$ 390
2021	1,495
2022	1,776
2023	1,809
2024	1,843
2025 and thereafter	10,910
Total undiscounted payments	$ 18,223
Discount Adjustments	$ (8,390)
Operating lease liability	$ 9,833

Exhibit 4.7

DESCRIPTION OF REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

Description of Ordinary Shares

In the following summary, a "shareholder" is the person registered in our register of members as the holder of the relevant securities, including ordinary shares that have been deposited in our American Depositary Share, or ADS, facility with Citibank, N.A., or the Depositary.

Dividends

Holders of ordinary shares are entitled to receive such dividends as may be declared by the board of directors. All dividends are declared and paid according to the amounts paid up on the shares in respect of which the dividend is paid. To date there have been no dividends paid to holders of ordinary shares.

Any dividend unclaimed after a period of twelve years from the date of declaration of such dividend shall be forfeited and shall revert to us. In addition, the payment by the board of directors of any unclaimed dividend, interest or other sum payable on or in respect of an ordinary share into a separate account shall not constitute us as a trustee in respect thereof.

Rights in a Liquidation

Holders of ordinary shares are entitled to participate in any distribution of assets upon a liquidation, subject to prior satisfaction of the claims of creditors and preferential payments to holders of outstanding preference shares.

Voting Rights

Voting at any general meeting of shareholders is by a show of hands, unless a poll is demanded. A poll may be demanded by:

- the chairman of the meeting;
- at least two shareholders entitled to vote at the meeting;
- any shareholder or shareholders representing in the aggregate not less than one-tenth of the total voting rights of all shareholders entitled to vote at the meeting; or
- any shareholder or shareholders holding shares conferring a right to vote at the meeting on which there have been paid up sums in the aggregate equal to not less than one-tenth of the total sum paid up on all the shares conferring that right.

In a vote by a show of hands, every shareholder who is present in person or by proxy at a general meeting has one vote. In a vote on a poll, every shareholder who is present in person or by proxy shall have one vote for every share of which they are registered as the holder. No shareholder shall have more than one vote on a show of hands notwithstanding that he may have appointed more than one proxy to vote on his behalf. The quorum for a shareholders' meeting is a minimum of two persons entitled to vote at the meeting, present in person or by proxy. To the extent our Articles of Association provide for a vote by a show of hands in which each shareholder has one vote, this differs from U.S. law, under which each shareholder typically is entitled to one vote per share at all meetings.

Unless otherwise required by law or our Articles of Association, voting in a general meeting is by ordinary resolution. An ordinary resolution is approved by a majority vote of the shareholders present at a meeting at which there is a quorum. Examples of matters that can be approved by an ordinary resolution include:

- the election of directors;
- the approval of financial statements;
- the declaration of final dividends;
- the appointment of auditors; or
- the grant of authority to issue shares.

A special resolution requires the affirmative vote of not less than three-fourths of the eligible votes of shareholders present at the meeting. Examples of matters that must be approved by a special resolution include modifications to the rights of any class of shares, changes to the Articles of Association, or our winding-up.

Capital Calls

The board of directors has the authority to make calls upon the shareholders in respect of any money unpaid on their shares and each shareholder shall pay to us as required by such notice the amount called on his shares. If a call remains unpaid after it has become due and payable, and the fourteen clear days' notice provided by the board of directors has not been complied with, any share in respect of which such notice was given may be forfeited by a resolution of the board.

Limitations on Ownership

Under English law and our Articles of Association, there are no limitations on the right of nonresidents of the United Kingdom or owners who are not citizens of the United Kingdom to hold or vote our ordinary shares.

Description of American Depositary Shares

Citibank, N.A. acts as the depositary bank for ADSs, which we also refer to as the Depositary. Citibank's depositary offices are located at 388 Greenwich Street, New York, New York 10013. ADSs represent ownership interests in securities that are on deposit with the Depositary. ADSs may be represented by certificates that are commonly known as American Depositary Receipts, or ADRs. The Depositary typically appoints a custodian to safekeep the securities on deposit. In this case, the custodian is Citibank, N.A., London Branch, having its principal office at Citigroup Centre, Canada Square, Canary Wharf, London E14 5LB, England.

We have appointed Citibank as Depositary pursuant to an amended and restated deposit agreement, dated as of November 4, 2011. A copy of the deposit agreement is on file with the SEC under cover of a Registration Statement on Form F-6 filed on September 16, 2011. A copy of the deposit agreement may be obtained from the SEC's website (www.sec.gov). Please refer to Registration Number 333-176898 when retrieving such copy.

We are providing a summary description of the material terms of the ADSs and of material rights as an owner of ADSs. Please remember that summaries by their nature lack the precision of the information summarized and that the rights and obligations of an owner of ADSs will be determined by reference to the terms of the deposit agreement and not by this summary. We urge all investors to review the deposit agreement in its entirety.

Each ADS represents the right to receive one ordinary share on deposit with the custodian. An ADS also represents the right to receive, and to exercise the beneficial interests in, any other property received by the Depositary or the custodian on behalf of the owner of the ADS but that has not been distributed to the owners of ADSs because of legal restrictions or practical considerations.

The custodian, the Depositary and their respective nominees will hold all deposited property for the benefit of the holders and beneficial owners of ADSs. The deposited property does not constitute the proprietary assets of the Depositary, the custodian or their nominees. Beneficial ownership in the deposited property will under the terms of the deposit agreement be vested in the beneficial owners of the ADSs. The Depositary, the custodian and their respective nominees will be the record holders of the deposited property represented by the ADSs for the benefit of the holders and beneficial owners of the corresponding ADSs. A beneficial owner of ADSs may or may not be the holder of ADSs. Beneficial owners of ADSs will be able to receive, and to exercise beneficial ownership interests in the deposited property only through the registered holders of the ADSs, by the registered holders of the ADSs (on behalf of the applicable ADS owners) only through the Depositary, and by the Depositary (on behalf of the owners of the corresponding ADSs) directly, or indirectly through the custodian or their respective nominees, in each case upon the terms of the deposit agreement.

As an owner of our ADSs, such holders will become a party to the deposit agreement and therefore will be bound to its terms and to the terms of any ADR that represents such ADSs. The deposit agreement and the ADR specify our rights and obligations as well as rights of the holders of our ADSs and obligations as owner of ADSs and those of the Depositary. Holders of our ADSs appoint the Depositary to act on such holders behalf in certain circumstances. The deposit agreement and the ADRs are governed by New York law. However, our obligations to the holders of ordinary shares will continue to be governed by the laws of England and Wales, which may be different from the laws in the United States.

The manner in which holders own the ADSs (e.g., in a brokerage account vs. as registered holder, or as holder of certificated vs. uncertificated ADSs) may affect holders of our ADSs' rights and obligations, and the manner in which, and extent to which, the Depositary's services are made available to such holders. Owners of our ADSs may hold ADSs either by means of an ADR registered in such holders name, through a brokerage or safekeeping account, or through an account established by the Depositary in such holders name reflecting the registration of uncertificated ADSs directly on the books of the Depositary (commonly referred to as the "direct registration system" or "DRS"). The direct registration system reflects the uncertificated (book-entry) registration of ownership of ADSs by the Depositary. Under the direct registration system, ownership of ADSs is evidenced by periodic statements issued by the Depositary to the holders of the ADSs. The direct registration system includes automated transfers between the Depositary and The Depository Trust Company, or DTC, the central book-entry clearing and settlement system for equity securities in the United States. If holders of our ADSs decide to hold such ADSs through a brokerage or safekeeping account, such holders must rely on the procedures of a broker or bank to assert rights as ADS owner. Banks and brokers typically hold securities such as the ADSs through clearing and settlement systems such as DTC. The procedures of such clearing and settlement systems may limit the ability of holders of our ADSs to exercise rights as an owner of ADSs. Please consult a broker or bank with any questions concerning these limitations and procedures. All ADSs held through DTC will be registered in the name of a nominee of DTC. This summary description assumes holders of our ADSs have opted to own the ADSs directly by means of an ADS registered in such holders name.

Dividends and distributions

Holders of our ADSs generally have the right to receive the distributions we make on the securities deposited with the custodian. Receipt of these distributions may be limited, however, by practical considerations and legal limitations. Holders of ADSs will receive such distributions under the terms of the deposit agreement in proportion to the number of ADSs held as of a specified record date, after deduction the applicable fees, taxes and expenses.

Distributions of cash

Whenever we make a cash distribution for the securities on deposit with the custodian, we will deposit the funds with the custodian. Upon receipt of confirmation of the deposit of the requisite funds, the Depositary will arrange for the funds to be converted into U.S. dollars and for the distribution of the U.S. dollars to the holders, subject to English laws and regulations.

The conversion into U.S. dollars will take place only if practicable and if the U.S. dollars are transferable to the United States. The Depositary will apply the same method for distributing the proceeds of the sale of any property (such as undistributed rights) held by the custodian in respect of securities on deposit.

The distribution of cash will be made net of the fees, expenses, taxes and governmental charges payable by holders under the terms of the deposit agreement. The Depositary will hold any cash amounts it is unable to distribute in a non-interest bearing account for the benefit of the applicable holders and beneficial owners of ADSs until the distribution can be effected or the funds that the Depositary holds must be escheated as unclaimed property in accordance with the laws of the relevant states of the United States.

Distributions of shares

Whenever we make a free distribution of shares for the securities on deposit with the custodian, we will deposit the applicable number of shares with the custodian. Upon receipt of confirmation of such deposit, the Depositary will either distribute to holders new ADSs representing the ordinary shares deposited or modify the ADS-to-shares ratio, in which case each ADS held by such holder will represent rights and interests in the additional ordinary shares or preference shares so deposited. Only whole new ADSs will be distributed. Fractional entitlements will be sold and the proceeds of such sale will be distributed as in the case of a cash distribution.

The distribution of new ADSs or the modification of the ADS-to-ordinary shares ratio upon a distribution of ordinary shares or preference shares will be made net of the fees, expenses, taxes and governmental charges payable by holders under the terms of the deposit agreement. In order to pay such taxes or governmental charges, the Depositary may sell all or a portion of the new ordinary shares so distributed. No such distribution of new ADSs will be made if it would violate a law (i.e., the U.S. securities laws) or if it is not operationally practicable. If the Depositary does not distribute new ADSs as described above, it may sell the shares received upon the terms described in the deposit agreement and will distribute the proceeds of the sale as in the case of a distribution of cash.

Distributions of rights

Whenever we intend to distribute rights to purchase additional ordinary shares, we will give prior notice to the Depositary and we will assist the Depositary in determining whether it is lawful and reasonably practicable to distribute rights to purchase additional ADSs to holders.

The Depositary will establish procedures to distribute rights to purchase additional ADSs to holders and to enable such holders to exercise such rights if it is lawful and reasonably practicable to make the rights available to holders of ADSs, and if we provide all of the documentation contemplated in the deposit agreement (such as opinions to address the lawfulness of the transaction). Holders of our ADSs may have to pay fees, expenses, taxes and other governmental charges to subscribe for the new ADSs upon the exercise of the rights of the holders of our ADSs. The Depositary is not obligated to establish procedures to facilitate the distribution and exercise by holders of rights to purchase new ordinary shares other than in the form of ADSs.

The Depositary will not distribute the rights to holders of our ADSs if:

- we do not timely request that the rights be distributed to holders of our ADSs or we request that the rights not be distributed to holders of our ADSs; or
- we fail to deliver satisfactory documents to the Depositary; or
- it is not reasonably practicable to distribute the rights.

The Depositary will sell the rights that are not exercised or not distributed if such sale is lawful and reasonably practicable. The proceeds of such sale will be distributed to holders as in the case of a cash distribution. If the Depositary is unable to sell the rights, it will allow the rights to lapse.

Elective distributions

Whenever we intend to distribute a dividend payable at the election of shareholders either in cash or in additional shares, we will give prior notice thereof to the Depositary and will indicate whether we wish the elective distribution to be made available to holders of our ADSs. In such case, we will assist the Depositary in determining whether such distribution is lawful and reasonably practicable.

The Depositary will make the election available to holders of our ADSs only if it is reasonably practicable and if we have provided all of the documentation contemplated in the deposit agreement. In such case, the Depositary will establish procedures to enable holders of our ADSs to elect to receive either cash or additional ADSs, in each case as described in the deposit agreement.

If the election is not made available to holders of our ADSs, such holder will receive either cash or additional ADSs, depending on what a shareholder under English law would receive upon failing to make an election, as more fully described in the deposit agreement.

Other distributions

Whenever we intend to distribute property other than cash, ordinary shares or rights to purchase additional ordinary shares, we will notify the Depositary in advance and will indicate whether we wish such distribution to be made to holders of our ADSs. If so, we will assist the Depositary in determining whether such distribution to holders is lawful and reasonably practicable. If it is reasonably practicable to distribute such property to holders of our ADSs and if we provide all of the documentation contemplated in the deposit agreement, the Depositary will distribute the property to the holders in a manner it deems practicable.

The distribution will be made net of fees, expenses, taxes and governmental charges payable by holders under the terms of the deposit agreement. In order to pay such taxes and governmental charges, the Depositary may sell all or a portion of the property received.

The Depositary will *not* distribute the property to holders of our ADSs and will sell the property if:

- we do not request that the property be distributed to holders of our ADSs or if we ask that the property not be distributed to holders of our ADSs; or
- we do not deliver satisfactory documents to the Depositary; or
- the Depositary determines that all or a portion of the distribution to holders of our ADSs is not reasonably practicable.

The proceeds of such a sale will be distributed to holders as in the case of a cash distribution.

Redemption

Whenever we decide to redeem any of the securities on deposit with the custodian, we will notify the Depositary in advance. If it is practicable and if we provide all of the documentation contemplated in the deposit agreement, the Depositary will provide notice of the redemption to the holders.

The custodian will be instructed to surrender the shares being redeemed against payment of the applicable redemption price. The Depositary will convert the redemption funds received into U.S. dollars upon the terms of the deposit agreement and will establish procedures to enable holders to receive the net proceeds from the redemption upon surrender of their ADSs to the Depositary. Holders of our ADSs may have to pay fees, expenses, taxes and other governmental charges upon the redemption of such holder's ADSs. If less than all ADSs are being redeemed, the ADSs to be retired will be selected by lot or on a pro rata basis, as the Depositary may determine.

Changes affecting ordinary shares and preference shares

The ordinary shares held on deposit for each holder's ADSs may change from time to time. For example, there may be a change in nominal or par value, a split-up, cancellation, consolidation or reclassification of such ordinary shares or a recapitalization, reorganization, merger, consolidation or sale of assets.

If any such change were to occur, such holder's ADSs would, to the extent permitted by law, represent the right to receive the property received or exchanged in respect of the new ordinary shares held on deposit. The Depositary may in such circumstances deliver new ADSs to such holder, amend the deposit agreement, the ADRs and the applicable Registration Statement(s) on Form F-6, call for the exchange of such holder's existing ADSs for new ADSs and take any other actions that are appropriate to reflect as to the ADSs the change affecting the Shares. If the Depositary may not lawfully distribute such property to such holder, the Depositary may sell such property and distribute the net proceeds to such holder as in the case of a cash distribution.

Issuance of ADSs upon deposit of ordinary shares

The Depositary may create ADSs on each holder's behalf if such holder or such holder's broker deposit ordinary shares with the custodian. The Depositary will deliver these ADSs to the person such holder indicates only after any applicable issuance fees are paid and any charges and taxes payable for the transfer of the ordinary shares to the custodian. A holder's ability to deposit ordinary shares and receive ADSs may be limited by U.S. and U.K. legal considerations applicable at the time of deposit.

The issuance of ADSs may be delayed until the Depositary or the custodian receives confirmation that all required approvals have been given and that the ordinary shares or preference shares have been duly transferred to the custodian. The Depositary will only issue ADSs in whole numbers.

When a holders of our ADSs make a deposit of ordinary shares such holders will be responsible for transferring good and valid title to the Depositary. As such, holders of our ADSs will be deemed to represent and warrant that:

- the ordinary shares are duly authorized, validly issued, fully paid, non-assessable and legally obtained;
- all preemptive (and similar) rights, if any, with respect to such ordinary shares have been validly waived or exercised;
- such holder is duly authorized to deposit the ordinary shares;
- the ordinary shares presented for deposit are free and clear of any lien, encumbrance, security interest, charge, mortgage or adverse claim, and the ADSs issuable upon such deposit will not be, "restricted securities" (as defined in the deposit agreement); and
- the ordinary shares presented for deposit have not been stripped of any rights or entitlements.

If any of the representations or warranties are incorrect in any way, we and the Depositary may, at such holder's cost and expense, take any and all actions necessary to correct the consequences of the misrepresentations.

Transfer, combination and split up of ADRs

Holders of our ADRs will be entitled to transfer, combine or split up such ADRs and the ADSs evidenced thereby. For transfers of ADRs, holders will have to surrender the ADRs to be transferred to the Depositary and also must:

- ensure that the surrendered ADR is properly endorsed or otherwise in proper form for transfer;
- provide such proof of identity and genuineness of signatures as the Depositary deems appropriate;
- provide any transfer stamps required by the State of New York or the United States; and
- pay all applicable fees, charges, expenses, taxes and other government charges payable by ADR holders pursuant to the terms of the deposit agreement, upon the transfer of ADRs.

To have such ADRs either combined or split up, holders must surrender the ADRs in question to the Depositary with such holders request to have them combined or split up, and such holder must pay all applicable fees, charges and expenses payable by ADR holders, pursuant to the terms of the deposit agreement, upon a combination or split up of ADRs.

Withdrawal of ordinary shares upon cancellation of ADSs

Holders of our ADSs are entitled to present ADSs to the Depositary for cancellation and then receive the corresponding number of underlying ordinary shares at the custodian's offices. The ability of holders of our ADSs to withdraw the ordinary shares may be limited by U.S. and U.K. legal considerations applicable at the time of withdrawal. In order to withdraw the ordinary shares represented by such ADSs, holders of our ADSs will be required to pay to the Depositary the fees for cancellation of ADSs and any charges and taxes payable upon the transfer of the ordinary shares being withdrawn. Holders of our ADSs assume the risk for delivery of all funds and securities upon withdrawal. Once canceled, the ADSs will not have any rights under the deposit agreement.

The Depositary may ask holders of our ADSs to provide proof of identity and genuineness of any signature and such other documents as the Depositary may deem appropriate before it will cancel such ADSs. The withdrawal of the ordinary shares represented by such ADSs may be delayed until the Depositary receives satisfactory evidence of compliance with all applicable laws and regulations. Please keep in mind that the Depositary will only accept ADSs for cancellation that represent a whole number of securities on deposit.

Holders of our ADSs will have the right to withdraw the securities represented by such ADSs at any time except for:

- Temporary delays that may arise because (i) the transfer books for the ordinary shares or ADSs are closed, or (ii) ordinary shares are immobilized on account of a shareholders' meeting or a payment of dividends.
- Outstanding obligations to pay fees, taxes and similar charges.
- Restrictions imposed because of laws or regulations applicable to ADSs or the withdrawal of securities on deposit.

The deposit agreement may not be modified to impair the right of holders of our ADSs to withdraw the securities represented by such ADSs except to comply with mandatory provisions of law.

Voting rights

Holders of our ADSs representing ordinary shares generally have the right under the deposit agreement to instruct the Depositary to exercise the voting rights for the ordinary shares represented by such ADSs. The voting rights of holders of ordinary shares are described under the heading "Description of Securities —Description of Ordinary Shares" in this prospectus.

At our request, the Depositary will distribute to holders of our ADSs any notice of shareholders' meeting received from us together with information explaining how to instruct the Depositary to exercise the voting rights of the securities represented by ADSs.

If the Depositary timely receives voting instructions from a holder of ADSs, it will endeavor to vote the securities (in person or by proxy) represented by the holder's ADSs in accordance with such voting instructions.

Please note that the ability of the Depositary to carry out voting instructions may be limited by practical and legal limitations and the terms of the securities on deposit. We cannot assure that holders of our ADSs will receive voting materials in time to enable such holders to return voting instructions to the Depositary in a timely manner. Securities for which no voting instructions have been received will not be voted.

Fees and charges

Holders of our ADSs will be required to pay the following service fees to the Depositary:

Service	Fees
• Issuance of ADSs upon deposit of Shares (excluding issuances as a result of distributions described in paragraph (4) below).	Up to U.S. $5.00 per 100 ADSs (or fraction thereof) issued.
• Delivery of Deposited Securities against surrender of ADSs.	Up to U.S. $5.00 per 100 ADSs (or fraction thereof) surrendered.
• Distribution of cash dividends or other cash distributions (*i.e.*, sale of rights and other entitlements).	Up to U.S. $5.00 per 100 ADSs (or fraction thereof) held.
• Distribution of ADSs pursuant to (i) stock dividends or other free stock distributions, or (ii) exercise of rights to purchase additional ADSs.	Up to U.S. $5.00 per 100 ADSs (or fraction thereof) held.
• Distribution of securities other than ADSs or rights to purchase additional ADSs (*i.e.*, spin-off shares).	Up to U.S. $5.00 per 100 ADSs (or fraction thereof) held.
• Depositary Services.	Up to U.S. $5.00 per 100 ADSs (or fraction thereof) held on the applicable record date(s) established by the Depositary.

Holders of our ADSs will also be responsible to pay certain fees and expenses incurred by the Depositary and certain taxes and governmental charges such as:

- Fees for the transfer and registration of ordinary shares charged by the registrar and transfer agent for the ordinary shares or preference shares in England (*i.e.*, upon deposit and withdrawal of ordinary shares or preference shares).
- Expenses incurred for converting foreign currency into U.S. dollars.
- Expenses for cable, telex and fax transmissions and for delivery of securities.
- Taxes and duties upon the transfer of securities (*i.e.*, when ordinary shares are deposited or withdrawn from deposit).
- Fees and expenses incurred in connection with the delivery or servicing of ordinary shares on deposit.

Depositary fees payable upon the issuance and cancellation of ADSs are typically paid to the Depositary by the brokers (on behalf of their clients) receiving the newly issued ADSs from the Depositary and by the brokers (on behalf of their clients) delivering the ADSs to the Depositary for cancellation. The brokers in turn charge these fees to their clients. Depositary fees payable in connection with distributions of cash or securities to ADS holders and the depositary services fee are charged by the Depositary to the holders of record of ADSs as of the applicable ADS record date.

The Depositary fees payable for cash distributions are generally deducted from the cash being distributed. In the case of distributions other than cash (i.e., stock dividend, rights), the Depositary charges the applicable fee to the ADS record date holders concurrent with the distribution. In the case of ADSs registered in the name of the investor (whether certificated or uncertificated in direct registration), the Depositary sends invoices to the applicable record date ADS holders. In the case of ADSs held in brokerage and custodian accounts (via DTC), the Depositary generally collects its fees through the systems provided by DTC (whose nominee is the registered holder of the ADSs held in DTC) from the brokers and custodians holding ADSs in their DTC accounts. The brokers and custodians who hold their clients' ADSs in DTC accounts in turn charge their clients' accounts the amount of the fees paid to the Depositary.

In the event of refusal to pay the depositary fees, the Depositary may, under the terms of the deposit agreement, refuse the requested service until payment is received or may set off the amount of the depositary fees from any distribution to be made to the ADS holder.

Note that the fees and charges that holders of our ADSs may be required to pay may vary over time and may be changed by us and by the Depositary. Holders of our ADSs will receive prior notice of such changes.

The Depositary may reimburse us for certain expenses incurred by us in respect of the ADR program established pursuant to the deposit agreement, by making available a portion of the depositary fees charged in respect of the ADR program or otherwise, upon such terms and conditions as we and the Depositary may agree from time to time.

Amendments and termination

We may agree with the Depositary to modify the deposit agreement at any time without the consent of the holders of our ADSs. We undertake to give holders 30 days' prior notice of any modifications that would materially prejudice any of their substantial rights under the deposit agreement. We will not consider to be materially prejudicial to the substantial rights of the holders of our ADSs any modifications or supplements that are reasonably necessary for the ADSs to be registered under the Securities Act or to be eligible for book-entry settlement, in each case without imposing or increasing the fees and charges holders of our ADSs are required to pay. In addition, we may not be able to provide holders of our ADSs with prior notice of any modifications or supplements that are required to accommodate compliance with applicable provisions of law.

Holders of our ADSs will be bound by the modifications to the deposit agreement if holders continue to hold such ADSs after the modifications to the deposit agreement become effective. The deposit agreement cannot be amended to prevent holders of our ADS from withdrawing the ordinary shares represented by such ADSs (except in order to comply with applicable by law).

We have the right to direct the Depositary to terminate the deposit agreement. Similarly, the Depositary may in certain circumstances on its own initiative terminate the deposit agreement. In either case, the Depositary must give notice to the holders at least 30 days before termination. Until termination, rights of the holders of our ADSs under the deposit agreement will be unaffected.

After termination, the Depositary will continue to collect distributions received (but will not distribute any such property until holders of our ADSs request the cancellation of such ADSs) and may sell the securities held on deposit. After the sale, the Depositary will hold the proceeds from such sale and any other funds then held for the holders of ADSs in a non-interest bearing account. At that point, the Depositary will have no further obligations to holders other than to account for the funds then held for the holders of ADSs still outstanding (after deduction of applicable fees, taxes and expenses).

Books of depositary

The Depositary will maintain ADS holder records at its depositary office. Holders of our ADSs may inspect such records at such office during regular business hours but solely for the purpose of communicating with other holders in the interest of business matters relating to the ADSs and the deposit agreement.

The Depositary will maintain in New York facilities to record and process the issuance, cancellation, combination, split-up and transfer of ADSs. These facilities may be closed from time to time, to the extent not prohibited by law.

Limitations on obligations and liabilities

The deposit agreement limits our obligations and the Depositary's obligations to holders of our ADSs. Please note the following:

- We and the Depositary are obligated only to take the actions specifically stated in the deposit agreement without negligence or bad faith.
- The Depositary disclaims any liability for any failure to carry out voting instructions, for any manner in which a vote is cast or for the effect of any vote, provided it acts in good faith and in accordance with the terms of the deposit agreement.
- The Depositary disclaims any liability for any failure to determine the lawfulness or practicality of any action, for the content of any document forwarded to holders of our ADSs on our behalf or for the accuracy of any translation of such a document, for the investment risks associated with investing in ordinary shares, for the validity or worth of the ordinary shares, for any tax consequences that result from the ownership of ADSs, for the credit-worthiness of any third party, for allowing any rights to lapse under the terms of the deposit agreement, for the timeliness of any of our notices or for our failure to give notice.
- We and the Depositary will not be obligated to perform any act that is inconsistent with the terms of the deposit agreement.

- We and the Depositary disclaim any liability if we or the Depositary are prevented or forbidden from or subject to any civil or criminal penalty or restraint on account of, or delayed in, doing or performing any act or thing required by the terms of the deposit agreement, by reason of any provision, present or future of any law or regulation, or by reason of present or future provision of any provision of our Articles of Association, or any provision of or governing the securities on deposit, or by reason of any act of God or war or other circumstances beyond our control.
- We and the Depositary disclaim any liability by reason of any exercise of, or failure to exercise, any discretion provided for in the deposit agreement or in our Articles of Association or in any provisions of or governing the securities on deposit.
- We and the Depositary further disclaim any liability for any action or inaction in reliance on the advice or information received from legal counsel, accountants, any person presenting Shares for deposit, any holder of ADSs or authorized representatives thereof, or any other person believed by either of us in good faith to be competent to give such advice or information.
- We and the Depositary also disclaim liability for the inability by a holder to benefit from any distribution, offering, right or other benefit that is made available to holders of ordinary shares but is not, under the terms of the deposit agreement, made available to such holder.
- We and the Depositary may rely without any liability upon any written notice, request or other document believed to be genuine and to have been signed or presented by the proper parties.
- We and the Depositary also disclaim liability for any consequential or punitive damages for any breach of the terms of the deposit agreement.
- No disclaimer of any Securities Act liability is intended by any provision of the deposit agreement.

Pre-release transactions

Subject to the terms and conditions of the deposit agreement, the depositary may issue to broker/dealers ADSs before receiving a deposit of ordinary shares or release ordinary shares to broker/dealers before receiving ADSs for cancellation. These transactions are commonly referred to as “pre-release transactions,” and are entered into between the Depositary and the applicable broker/dealer. The deposit agreement limits the aggregate size of pre-release transactions (not to exceed 30% of the number of ADSs outstanding) and imposes a number of conditions on such transactions (i.e., the need to receive collateral, the type of collateral required, the representations required from brokers, etc.). The Depositary may retain the compensation received from the pre-release transactions.

Taxes

Holders of our ADSs will be responsible for the taxes and other governmental charges payable on the ADSs and the securities represented by the ADSs. We, the Depositary and the custodian may deduct from any distribution the taxes and governmental charges payable by holders and may sell any and all property on deposit to pay the taxes and governmental charges payable by holders. Holders of our ADSs will be liable for any deficiency if the sale proceeds do not cover the taxes that are due.

The Depositary may refuse to issue ADSs, to deliver, transfer, split and combine ADRs or to release securities on deposit until all taxes and charges are paid by the applicable holder. The Depositary and the custodian may take reasonable administrative actions to obtain tax refunds and reduced tax withholding for any distributions on such holders behalf. However, holders of our ADSs may be required to provide to the Depositary and to the custodian proof of taxpayer status and residence and such other information as the Depositary and the custodian may require to fulfill legal obligations. Holders of our ADSs are required to indemnify us, the Depositary and the custodian for any claims with respect to taxes based on any tax benefit obtained for such holders.

Foreign currency conversion

The Depositary will arrange for the conversion of all foreign currency received into U.S. dollars if such conversion is practical, and it will distribute the U.S. dollars in accordance with the terms of the deposit agreement. Holders of our ADSs may have to pay fees and expenses incurred in converting foreign currency, such as fees and expenses incurred in complying with currency exchange controls and other governmental requirements.

If the conversion of foreign currency is not practical or lawful, or if any required approvals are denied or not obtainable at a reasonable cost or within a reasonable period, the Depositary may take the following actions in its discretion:

- Convert the foreign currency to the extent practical and lawful and distribute the U.S. dollars to the holders for whom the conversion and distribution is lawful and practical.
- Distribute the foreign currency to holders for whom the distribution is lawful and practical.
- Hold the foreign currency (without liability for interest) for the applicable holders.

Governing Law/Waiver of Jury Trial

The deposit agreement, the ADRs and the ADSs will be interpreted in accordance with the laws of the State of New York. The rights of holders of ordinary shares and preference shares (including ordinary shares and preference shares represented by ADSs) are governed by the laws of England and Wales.

Holders of our ADSs irrevocably agree that any legal action arising out of the Deposit Agreement, the ADSs or the ADRs, involving the Company or the Depositary, may only be instituted in a state or federal court in the city of New York.

Nasdaq Capital Market

ADSs representing our ordinary shares are listed on the NASDAQ Capital Market under the symbol “AMRN.”

EXHIBIT 21.1

Subsidiaries of the Registrant as of December 31, 2019

Name	Jurisdiction
Amarin Pharmaceuticals Ireland Limited	Ireland
Amarin Pharma, Inc.	Delaware
Amarin Neuroscience Limited	Scotland
Corsicanto II DAC (placed into liquidation in September 2019)	Ireland
Ester Neurosciences Limited	Israel

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 (Form F-1 No. 333-163704) of Amarin Corporation plc,

(2) Registration Statement (Form S-8 Nos. 333-146839, 333-143358, 333-132520, 333-110704, 333-101775, and 333-168055) pertaining to the 2002 Stock Option Plan of Amarin Corporation plc,

(3) Registration Statement (Form S-8 No. 333-168054) pertaining to the 2008 Long Term Incentive Award dated May 20, 2008 issued to Mr. Tom Maher, Mr. Alan Cooke, and Dr. Declan Doogan of Amarin Corporation plc

(4) Registration Statement (Form S-8 Nos. 333-176877, 333-183160, 333-205863 and 333-219644) pertaining to the 2011 Stock Incentive Plan of Amarin Corporation plc,

(5) Registration Statement (Form S-8 No. 333-180180) pertaining to the Employment Inducement Award of Amarin Corporation plc,

(6) Registration Statement (Form S-8 No. 333-84152) of Amarin Corporation plc,

(7) Registration Statement (Form S-3 No. 333-216384) of Amarin Corporation plc, and

Registration Statement (Form S-3 No. 333-216385) of Amarin Corporation plc;

(8)Registration Statement (Form S-3 No. 333-216385) of Amarin Corporation plc;

of our reports dated February 25, 2020, 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, 2019.

/s/ Ernst & Young LLP

Iselin, New Jersey
February 25, 2020

EXHIBIT 31.1

CERTIFICATION

I, John F. Thero, 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 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 and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 25, 2020

/s/ John F. Thero

John F. Thero
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 and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 25, 2020

/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), John F. Thero, 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, 2019, 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/ John F. Thero

Date: February 25, 2020

John F. Thero
President and Chief Executive Officer (Principal Executive Officer)

/s/ Michael W. Kalb

Date: February 25, 2020

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.