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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**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, 2017**

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**

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**Amarin Corporation plc**

(Exact name of registrant as specified in its charter)

**England and Wales**  
(State or other jurisdiction of  
incorporation or organization)

**Not applicable**  
(I.R.S. Employer  
Identification No.)

**2 Pembroke House  
Upper Pembroke Street 28-32, 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:**

<u>Title of Each Class</u>	<u>Name of Each Exchange on Which Registered</u>
American Depositary Shares, each representing one Ordinary Share	
Ordinary Shares, 50 pence par value per share	The NASDAQ Stock Market LLC

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

**None**

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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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). YES ☒ NO ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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, 2017 was approximately \$1.1 billion, based upon the closing price on the NASDAQ Capital Market reported for such date.

292,318,731 shares were outstanding as of February 23, 2018, including 291,318,286 shares held as American Depositary Shares (ADSs), each representing one Ordinary Share, 50 pence par value per share and 1,000,445 Ordinary Shares. In addition, 32,818,464 ordinary share equivalents were issuable in exchange for outstanding preferred shares as of February 23, 2018, for a total of 325,137,195 ordinary shares and ordinary share equivalents outstanding as of February 23, 2018.

**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; interpretation of court decisions; expectation on determinations and policy positions of the United States Food and Drug Administration, or FDA; the expected timing of enrollment, interim results and final results of our REDUCE-IT study; 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 2 Pembroke House, Upper Pembroke Street 28-32, 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 1430 Route 206, Bedminster, NJ 07921, 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 biopharmaceutical company with expertise in lipid science focused on the commercialization and development of therapeutics to improve cardiovascular health.

Our lead product, Vascepa® (icosapent ethyl) capsules, is approved by the U.S. Food and Drug Administration, or FDA, for use as an adjunct to diet to reduce triglyceride levels in adult patients with severe (TG  $\geq$ 500 mg/dL) hypertriglyceridemia. This FDA-approved indication for Vascepa, known as the MARINE indication, is based primarily on the successful results from the MARINE study of Vascepa in this approved patient population. In considering this approval, FDA also reviewed the successful results from our study of Vascepa in patients with high triglyceride levels (TG  $\geq$ 200 mg/dL and  $<$ 500 mg/dL) who are also on statin therapy for elevated low-density lipoprotein cholesterol, or LDL-C, levels which condition we refer to as mixed dyslipidemia or persistently high triglycerides. This study is known as the ANCHOR study. Safety data from both the MARINE and ANCHOR studies are reflected in FDA-approved labeling for Vascepa. In January 2013, we began selling and marketing Vascepa in the United States based on the FDA-approved MARINE indication. In August 2015, we began communicating promotional information beyond the MARINE indication to healthcare professionals in the United States based on the federal court declaration described below. In March 2016, we reached agreement with the FDA and U.S. government under which they agreed to be bound by the terms of the August 2015 judicial declaration. Vascepa is available in the United States by prescription only.

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. We market Vascepa in the United States through our direct sales force. In March 2014, we entered into a co-promotion agreement in the United States with Kowa Pharmaceuticals America, Inc. under which Kowa Pharmaceuticals America, Inc. began to co-promote Vascepa in conjunction with its promotion of its primary product, a branded statin for patients with high cholesterol, which commenced in May 2014 and is scheduled to end at the end of 2018. Our direct sales force has, for the past few years through late 2017, consisted of approximately 150 sales professionals, including sales representatives and their managers. During the fourth quarter of 2017, we added approximately 15 sales representatives, bringing our direct sales force in the United States to approximately 165 sales professionals. We anticipate increasing our direct sales force to approximately 400 to 500 sales professionals after REDUCE-IT results, assuming success. We also intend to expand medical education and market awareness initiatives, including, in advance of REDUCE-IT results being known, pilot testing of new promotional initiatives for potential broader applications following REDUCE-IT results.

In February 2015, we entered into an exclusive agreement with Eddingpharm (Asia) Macao Commercial Offshore Limited, or Eddingpharm, to develop and commercialize Vascepa capsules in Mainland China, Hong Kong, Macau and Taiwan, or the China Territory. In March 2016, we entered into an agreement with Biologix FZCo, or Biologix, to register and commercialize Vascepa in countries within the Middle East and North Africa. In September 2017, we entered into an agreement with HLS Therapeutics Inc., or HLS, to register, commercialize and distribute Vascepa in Canada. We continue to assess other partnership opportunities for licensing Vascepa to partners outside of the United States.

Triglycerides are the main constituent of body fat in humans. Hypertriglyceridemia refers to a condition in which patients have high levels of triglycerides in the bloodstream. It is estimated that approximately 70 million adults in the United States have elevated triglyceride levels (TG  $\geq$ 150 mg/dL), approximately 40 million adults in the United States have high triglyceride levels (TG  $\geq$ 200 mg/dL), and approximately 3 to 4 million adults in the United States have severely high triglyceride levels (TG  $\geq$ 500 mg/dL), commonly known as very high triglyceride levels. Many patients with high triglyceride levels also have diabetes and other lipid level abnormalities such as high cholesterol. The patient condition of having more than one lipid level abnormality is referred to as mixed dyslipidemia. According to *The American Heart Association Scientific Statement on Triglycerides and Cardiovascular Disease* (2011), triglycerides provide important information as a marker associated with the risk for heart disease and stroke, especially when an individual also has low high-density lipoprotein cholesterol, or HDL-C (often referred to as “good” cholesterol), and elevated levels of LDL-C (often referred to as “bad” cholesterol). Guidelines for the management of very high triglyceride levels suggest that reducing triglyceride levels is the primary goal in patients to reduce the risk of acute pancreatitis. The effect of Vascepa on cardiovascular mortality and morbidity, or the risk for pancreatitis, in patients with hypertriglyceridemia has not been determined.

We are currently focused on completing the ongoing REDUCE-IT (Reduction of Cardiovascular Events with EPA—Intervention Trial) cardiovascular outcomes study of Vascepa, which we started in December 2011. REDUCE-IT, a multinational, prospective, randomized, double-blind, placebo-controlled study, is the first prospective cardiovascular outcomes study of any drug in a population of patients who, despite stable statin therapy, have elevated triglyceride levels. Based on the results of REDUCE-IT, we plan to seek additional indicated uses for Vascepa. In REDUCE-IT, cardiovascular event rates for patients on stable statin therapy plus 4 grams per day of Vascepa will be compared to cardiovascular event rates for patients on stable statin therapy plus placebo.

In 2016, we completed patient enrollment and randomization of 8,175 individual patients into the REDUCE-IT study, exceeding the 8,000 patients targeted for the trial. The REDUCE-IT study is designed to be completed after reaching 1,612 aggregate primary cardiovascular events. Based on projected event rates, we estimate the onset of the target aggregate number of primary cardiovascular events to be reached near the end of the first quarter of 2018 with study results then expected to be available and made public before the end of the third quarter of 2018, followed by publication of the results. Between reaching the estimated onset of the target 1,612 aggregate primary cardiovascular events and study data being unblinded and disclosed, vital data will be collected from all remaining living patients in the study and data in the study will be rolled-up for evaluation by the independent data monitoring committee, or DMC, and creation of a final study report. We have instructed clinical sites to schedule patients enrolled in the study for their final site visits commencing March 1, 2018.

The REDUCE-IT study, since its inception in 2011, has been conducted under a special protocol assessment, or SPA, agreement with the FDA. This SPA, as amended, provides for periodic safety reviews by the study's DMC. In addition, the SPA, as amended, provided for interim efficacy and safety analyses by the study's DMC at approximately 60% and at approximately 80% of the target aggregate number of primary cardiovascular events. The periodic safety reviews and interim efficacy and safety analyses were conducted confidentially by the study's DMC. We remain blinded to all data from the study. Until the study is completed or the study is halted due to a patient safety concern (not expected), Amarin personnel will remain blinded to the efficacy and safety data from the REDUCE-IT study. Since patient enrollment commenced in 2011, over 33,000 patient years of study experience have been accumulated in the REDUCE-IT study. Following each periodic review of safety data to date, which have occurred quarterly since 2013, and following each of two interim efficacy and safety analyses, the DMC has communicated to us that we should continue the study as planned. The p-value used to assess the primary endpoint in REDUCE-IT at completion, assuming 1,612 aggregate primary cardiovascular events, is  $p < 0.0436$ . In January 2018, we announced that more than 90% of the 1,612 targeted aggregate number of primary cardiovascular events have been reported and documented.

In the successful Phase 3 MARINE and ANCHOR clinical trials, Vascepa was studied at a daily dose of 2 grams and 4 grams. We sought approval of Vascepa at the more efficacious 4-gram dose for use in each patient population. These trials demonstrated favorable results in their respective patient populations, particularly with the 4-gram dose of Vascepa, in reducing triglyceride levels without increasing LDL-C levels in the MARINE trial and with a statistically significant decrease in LDL-C levels in the ANCHOR trial, in each case, relative to placebo. These trials also showed favorable results, particularly with the 4-gram dose of Vascepa, in other important lipid and inflammation biomarkers, including apolipoprotein B (apo B), non-high-density lipoprotein cholesterol (non-HDL-C), total-cholesterol (TC), very low-density lipoprotein cholesterol (VLDL-C), lipoprotein-associated phospholipase A2 (Lp-PLA2), and high sensitivity C-reactive protein (hs-CRP). In these 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).

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 special protocol assessment, or 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 and the FDA has encouraged us to complete the REDUCE-IT outcomes study. Based on our communications with the FDA, we expect that final positive results from the REDUCE-IT outcomes study will be required for label expansion for Vascepa.

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 reflects recognized medical practice but is not covered by 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 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. 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.

## *Commercialization—United States*

We commenced the commercial launch of 1-gram size Vascepa capsules in the United States in January 2013. We commenced sales and shipments of Vascepa at that time to our network of U.S.-based wholesalers. We currently market Vascepa in the United States through our direct sales force of approximately 165 sales professionals, including sales representatives and their managers. We anticipate increasing our sales force to a total of approximately 400 to 500 sales professionals after REDUCE-IT results, assuming success. Commencing in May 2014, in addition to Vascepa promotion by our sales representatives, Kowa Pharmaceuticals America, Inc. began co-promoting Vascepa in conjunction with its promotion of its primary product, a branded statin for patients with high cholesterol. We also employ various medical affairs and marketing personnel to support our commercialization of Vascepa. We intend to expand medical education and market awareness initiatives, including, in advance of REDUCE-IT results being known, pilot testing of new promotional initiatives for potential broader applications following REDUCE-IT results.

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 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.

Under our co-promotion agreement with Kowa Pharmaceuticals America, Inc., both parties have agreed to use commercially reasonable efforts to promote, detail and optimize sales of Vascepa in the United States and have agreed to specific performance requirements detailed in the related agreement. The performance requirements include a negotiated minimum number of sales details to be delivered by each party in the first and second position, the use of a negotiated number of minimum sales representatives from each party, and the achievement of minimum levels of Vascepa revenue in 2015 and beyond. First position refers to when a sales representative's primary purpose in detailing is related to Vascepa, while second position refers to when a sales representative's primary purpose in detailing is to promote another product, but they also devote time in the same sales call to promote Vascepa. Kowa Pharmaceuticals America, Inc. has also agreed to bear the costs incurred for its sales force associated with the commercialization of Vascepa and to pay for certain incremental costs associated with the use of its sales force, such as sample costs and costs for promotional and marketing materials. We will continue to recognize all revenue from sales of Vascepa. In exchange for Kowa Pharmaceuticals America, Inc.'s co-promotional services, Kowa Pharmaceuticals America, Inc. is entitled to a quarterly co-promotion fee based on a percentage of aggregate Vascepa gross margin that varies during the term. The percentage of aggregate Vascepa gross margin earned by Kowa Pharmaceuticals America, Inc. was, as amended, approximately eighteen percent (18%) in 2017, partially offset by certain other refinements. During 2018, which is the last year of the agreement, as amended, we anticipate incurring expense for both the annual co-promotion fee, which in 2018 will again be calculated as a percentage of Vascepa gross margin at a modestly higher rate than in 2017, plus accrual for co-promotion tail payments. Assuming Kowa Pharmaceuticals America, Inc. fulfills its obligations in accordance with the terms of the agreement, as amended, after expiration of the agreement, Kowa Pharmaceuticals America, Inc. is eligible to receive up to three years of co-promotion tail payments equal to declining percentages of the co-promotion fee amount earned in the final year of the agreement with the sum of the three years of co-promotion tail payments totaling less than the co-promotion fee amount earned in the final year of the agreement.

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, 2017 was approximately 394,000 compared to 374,000, 344,000, 305,000, and 286,000 in the three months ended September 30, 2017, June 30, 2017, March 31, 2017, and December 31, 2016, respectively. According to data from another third party, IQVIA (formerly QuintilesIMS), the estimated number of normalized total Vascepa prescriptions for the three months ended December 31, 2017 was approximately 406,000 compared to 372,000, 344,000, 307,000, and 289,000 in the three months ended September 30, 2017, June 30, 2017, March 31, 2017, and December 31, 2016, 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.

The data reported above is based on information made available to us from third-party resources and may be subject to adjustment and may overstate or understate actual prescriptions. 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.*”

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 are being made pursuant to the August 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 and presentation of the current state of scientific research related to the potential of Vascepa to reduce the risk of cardiovascular disease including through use of peer-reviewed scientific publications of available data.

#### *Commercialization—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 based on the MARINE, ANCHOR and ongoing REDUCE-IT clinical trials of Vascepa.

Under the agreement, Eddingpharm is responsible for development and commercialization activities in the China Territory and associated expenses. We will provide development assistance and be responsible for supplying the product. Terms of the agreement include up-front and milestone payments to us of up to \$169.0 million, including a non-refundable \$15.0 million up-front payment received at closing, a non-refundable milestone payment of \$1.0 million received upon successful submission of a clinical trial application, or CTA, with respect to the MARINE indication for Vascepa to the Chinese regulatory authority in March 2016. 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. We are also entitled to receive future regulatory and sales-based milestone payments of up to an additional \$153.0 million. 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 \$1.0 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. Eddingpharm will also pay us tiered double-digit percentage royalties on net sales of Vascepa in the China Territory escalating to the high teens. We will supply finished product to Eddingpharm under negotiated terms.

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. Upon closing of the agreement, we 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. We receive all payments based on total product sales and pay 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 September 2017, we entered into an agreement with HLS to register, commercialize and distribute Vascepa in Canada. Under the agreement, HLS will be responsible for regulatory and commercialization activities and associated costs. We will be 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. Terms of the agreement include up-front and milestone payments to us of up to \$65.0 million. These payments include a non-refundable \$5.0 million up-front payment to be received in two equal installments, the first of which was received at closing with the second to be received upon the six-month anniversary of the closing. In addition to the non-refundable, up-front payment, we are entitled to receive certain regulatory and sales-based milestone payments of up to an additional \$60.0 million, the timing and achievability of which cannot be determined at least until discussions with Canadian regulatory authorities have commenced, as well as tiered double-digit royalties on net sales of Vascepa in Canada.

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

#### *Research and Development*

REDUCE-IT is the first prospective cardiovascular outcomes study of any drug in a population of patients who, despite stable statin therapy, have elevated triglyceride levels. REDUCE-IT is a multinational, prospective, randomized, double-blind, placebo-controlled study designed to assess the cumulative effect on the rate of cardiovascular events for patients treated with Vascepa as an

add-on to statin therapy compared to the corresponding rate of cardiovascular events for patients treated with placebo on top of statin therapy. REDUCE-IT is not designed to demonstrate that lowering triglycerides alone in the study population is sufficient to lower the rate of major adverse cardiovascular events compared to placebo. Rather, it is designed to test the hypothesis that the clinical effects of Vascepa, including its impact on triglyceride lowering, are effective in lowering the rate of major adverse cardiovascular events compared to placebo in patients who despite statin therapy have risk factors for cardiovascular disease, including elevated triglyceride levels. Based on the results of REDUCE-IT, we may seek additional indications for Vascepa beyond the indications studied in the ANCHOR or MARINE trials.

In 2016, we completed patient enrollment and randomization of 8,175 individual patients into the REDUCE-IT study, exceeding the 8,000 patients targeted for the trial. The REDUCE-IT study is designed to be completed after reaching 1,612 aggregate primary cardiovascular events. Based on projected event rates, we estimate the onset of the target aggregate number of primary cardiovascular events to be reached near the end of the first quarter of 2018 with study results then expected to be available and made public before the end of the third quarter of 2018, followed by publication of the results. Between reaching the estimated onset of the target 1,612 aggregate primary cardiovascular events and study data being unblinded and disclosed, vital data will be collected from all remaining living patients in the study and data in the study will be rolled-up for evaluation by the DMC and creation of a final study report. We have instructed clinical sites to schedule patients enrolled in the study for their final site visits commencing March 1, 2018.

The REDUCE-IT study, since its inception in 2011, has been conducted under a SPA agreement with the FDA. This SPA, as amended, provides for periodic safety reviews by the study's DMC. In addition, the SPA, as amended, provided for interim efficacy and safety analyses by the study's DMC at approximately 60% and at approximately 80% of the target aggregate number of primary cardiovascular events. The periodic safety reviews and interim efficacy and safety analyses were conducted confidentially by the study's DMC. We remain blinded to all data from the study. Until the study is completed or the study is halted due to a patient safety concern (not expected), Amarin personnel will remain blinded to the efficacy and safety data from the REDUCE-IT study. Since patient enrollment commenced in 2011, over 33,000 patient years of study experience have been accumulated in the REDUCE-IT study. Following each periodic review of safety data to date, which have occurred quarterly since 2013, and following each of two interim efficacy and safety analyses, the DMC has communicated to us that we should continue the study as planned. The p-value used to assess the primary endpoint in REDUCE-IT at completion, assuming 1,612 aggregate primary cardiovascular events, is  $p < 0.0436$ . In January 2018, we announced that more than 90% of the 1,612 targeted aggregate number of primary cardiovascular events have been reported and documented.

Our scientific rationale for the REDUCE-IT study is supported by (i) epidemiological data that suggests elevated triglyceride levels correlate with increased cardiovascular disease risk, (ii) genetic data that suggests triglyceride and/or triglyceride-rich lipoproteins (as well as low-density lipoprotein cholesterol (LDL cholesterol), 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. Our scientific rationale for the REDUCE-IT study is also supported by research on the putative cardioprotective effects of EPA as presented in scientific literature. It is possible that the effects of EPA may be due not 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. The REDUCE-IT study is needed to determine the clinical benefit, if any, of EPA therapy in statin-treated patients with elevated triglyceride levels.

#### *Commercial Supply*

Prior to 2015, all of our active pharmaceutical ingredient, or API, that has been utilized in product sold was manufactured by two suppliers: Nisshin Pharma, Inc., or Nisshin, and Chemport, Inc., or Chemport. During 2015, we began purchasing API from a third supplier, Finorga SAS, or Novasep. 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 Position*

In February 2018, we received approximately \$65.0 million of net proceeds from a registered offering of our American Depositary Shares (ADSs). We believe that our cash and cash equivalents of \$73.6 million as of December 31, 2017, together with the approximately \$65.0 million received in February 2018, will be sufficient to fund our projected operations through results of the REDUCE-IT study, which we anticipate will be available before the end of the third quarter of 2018 and, assuming positive results of the REDUCE-IT study, through subsequent public presentation of such results at a medical congress before the end of 2018. Depending on the level of cash generated from operations, additional capital may be required to expand promotion of Vascepa as contemplated following anticipated successful results of the REDUCE-IT study. If additional capital is required and we are unable to obtain additional capital, we may be forced to delay, limit or eliminate all or a portion of the expanded promotional activities planned following successful results of the REDUCE-IT study. We anticipate that quarterly net cash outflows in future periods will be variable.



## 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—2018 Update* from the American Heart Association, more than 1 out of every 3 adults in the United States (approximately 92 million) currently lives with one or more types of cardiovascular disease; an estimated 1 million new or recurrent coronary events and 795,000 new or recurrent strokes occur each year; an estimated 29 million adults  $\geq 20$  years of age have high total serum cholesterol levels ( $\geq 240$  mg/dL), and an estimated 71 million adults  $\geq 20$  years of age have borderline high or high low-density lipoprotein (“bad”) cholesterol, or LDL-C, levels ( $\geq 130$  mg/dL).

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 an independent risk factor for cardiovascular disease. Triglyceride levels provide important information as a marker associated with the risk for heart disease and stroke, especially when an individual also has low high-density lipoprotein cholesterol (HDL-C; often called “good” cholesterol) and elevated levels of LDL-C. The effect of Vascepa on cardiovascular mortality and morbidity in patients with hypertriglyceridemia has not been determined.

Guidelines for the management of very high triglyceride levels ( $\geq 500$  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 (apo B), non-HDL-C, and very low-density lipoprotein cholesterol (VLDL-C). The effect of Vascepa on the risk for pancreatitis in patients with hypertriglyceridemia has not been determined.

It is estimated that over 40 million adults in the United States have elevated triglyceride levels  $\geq 200$  mg/dL and that approximately 70 million adults in the United States have elevated triglyceride levels  $\geq 150$  mg/dL. Additionally, approximately 3 to 4 million adults in the United States have very high triglyceride levels ( $\geq 500$  mg/dL). Since 1976, mean triglyceride levels have increased, in concert 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

It is estimated that approximately 4% or less of U.S. adults with triglyceride levels  $\geq 200$  mg/dL are currently receiving prescription medication for lowering triglycerides. Many of these patients are taking statin therapy directed primarily at lowering their LDL-C levels.

The leading prescription treatments to lower triglyceride levels are fibrates (fenofibrate and gemfibrozil), statins and generic forms of an omega-3 fatty acid mixture known as Lovaza® in the United States and as Omacor® in Europe. The use of fenofibrates can lead to abnormal liver function tests (an increase in ALT (alanine transaminase) or AST (aspartate transaminase), which are liver enzymes, and are commonly measured clinically as a part of a diagnostic liver function test to determine liver health), especially when used with statins. The use of gemfibrozil can lead to rhabdomyolysis (severe breakdown of muscles), especially when used with a statin. Lovaza is comprised of omega-3 ethyl esters, which the FDA has described as a complex mixture of eicosapentaenoic acid, or EPA, docosahexaenoic acid, or DHA, and other fatty acids. We believe that DHA may increase LDL-C levels and thereby partially offset one of the typically desired benefits of lipid-lowering therapies, which is lowering LDL-C. Also, in 2012, the FDA required an update to Lovaza product labeling to reflect the risk that Lovaza may increase the frequency of a heart rhythm problem known as atrial fibrillation, or heart flutter. Also, in 2015, the FDA updated the Trilipix® (a fenofibrate) product labeling and removed combination use with statin therapy in mixed dyslipidemia patients as an indication due to a failed outcomes trial.

## Potential Benefits and Market Opportunity for Vascepa

Vascepa is comprised of not less than 96% pure 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 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 MARINE trial and Vascepa's EPA only/DHA-free composition suggest that Vascepa has the potential to become a "best-in-class" triglyceride-lowering agent in the United States and the European Union. If the REDUCE-IT cardiovascular outcomes study is successful, Vascepa could be the first omega-3 based therapy approved for prevention of cardiovascular events as an add-on to statin therapy in this population.

We believe the potential market for Vascepa is large and growing globally. According to Symphony Health data, we estimate that drug treatment for hypercholesterolemia patients exceeds \$69 billion per year in the United States, with sales dominated by statin therapies. U.S. sales of fibrates as a class of products were approximately \$2.8 billion in 2017 with generic fenofibrate and gemfibrozil leading the class. U.S. gross sales of prescription omega-3 therapies in 2017 were over \$1.2 billion with generic Lovaza leading the class.

## Clinical Trials

### *The MARINE Trial (basis for currently 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 ( $\geq 500$  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 special protocol assessment, or SPA, agreement with the FDA.

In November 2010, we reported top-line 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  $p = \text{NS}$ ]). 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 ( $\geq 200$  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 top-line 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 (non-HDL-C), apolipoprotein B (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 (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 current 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 special protocol assessment, or 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 and the FDA has encouraged us to complete the REDUCE-IT outcomes study. Based on our communications with the FDA, we expect that final positive results from the REDUCE-IT outcomes study will be required for label expansion for Vascepa.

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 reflects recognized medical practice but is not covered by 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 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. 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.

### ***Observed Efficacy of Ethyl-EPA***

In Japan, ethyl-EPA is marketed under the product name of Epanel by Mochida Pharmaceutical Co. 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, Epanel, 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  $\geq 150$  mg/dL (median of 272 mg/dL at entry) and HDL-C  $< 40$  mg/dL. Epanel has been approved and available by prescription in Japan for over a decade. In 2013, the Japan Ministry of Health approved Epanel for over-the-counter sales. JELIS provides 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. Further study is needed, such as the REDUCE-IT study, to determine the clinical benefit, if any, of EPA therapy in statin-treated patients with elevated triglyceride levels.

### ***Observed Clinical Safety of Vascepa***

Prior to commencing the 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 both 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.

In addition to the 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.

### ***The REDUCE-IT Study (currently ongoing cardiovascular outcomes study)***

In August 2011, we reached agreement with the FDA on a SPA for the design of the REDUCE-IT (Reduction of Cardiovascular Events with EPA—Intervention Trial) 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. Moreover, any change to a study protocol can invalidate a SPA.

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.

The REDUCE-IT study is designed to evaluate the efficacy of Vascepa in reducing major cardiovascular events in an at-risk patient population also receiving statin therapy. REDUCE-IT is 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 is comprised of patients on optimized statin therapy plus placebo. The active arm of the study is comprised of patients on optimized statin therapy plus Vascepa. All subjects enrolled in the study will have elevated triglyceride levels and either coronary heart disease or risk factors for coronary heart disease. This study is being conducted internationally.

In 2016, we completed patient enrollment and randomization of 8,175 individual patients into the REDUCE-IT study, exceeding the 8,000 patients targeted for the trial. The REDUCE-IT study is designed to be completed after reaching 1,612 aggregate primary cardiovascular events. Based on projected event rates, we estimate the onset of the target aggregate number of primary cardiovascular events to be reached near the end of the first quarter of 2018 with study results then expected to be available and made public before the end of the third quarter of 2018, followed by publication of the results. Between reaching the estimated onset of the target 1,612 aggregate primary cardiovascular events and study data being unblinded and disclosed, vital data will be collected from all remaining living patients in the study and data in the study will be rolled-up for evaluation by the DMC and creation of a final study report. We have instructed clinical sites to schedule patients enrolled in the study for their final site visits commencing March 1, 2018.

The REDUCE-IT study, since its inception in 2011, has been conducted under a SPA agreement with the FDA. This SPA, as amended, provides for periodic safety reviews by the study's DMC. In addition, the SPA, as amended, provided for interim efficacy and safety analyses by the study's DMC at approximately 60% and at approximately 80% of the target aggregate number of primary cardiovascular events. The periodic safety reviews and interim efficacy and safety analyses were conducted confidentially by the study's DMC. We remain blinded to all data from the study. Until the study is completed or the study is halted due to a patient safety concern (not expected), Amarin personnel will remain blinded to the efficacy and safety data from the REDUCE-IT study. Since patient enrollment commenced in 2011, over 33,000 patient years of study experience have been accumulated in the REDUCE-IT study. Following each periodic review of safety data to date, which have occurred quarterly since 2013, and following each of two interim efficacy and safety analyses, the DMC has communicated to us that we should continue the study as planned. The p-value used to assess the primary endpoint in REDUCE-IT at completion, assuming 1,612 aggregate primary cardiovascular events, is  $p < 0.0436$ . In January 2018, we announced that more than 90% of the 1,612 targeted aggregate number of primary cardiovascular events have been reported and documented.

Our scientific rationale for the REDUCE-IT study is supported by (i) epidemiological data that suggests elevated triglyceride levels correlate with increased cardiovascular disease risk, (ii) genetic data that suggests triglyceride and/or triglyceride-rich lipoproteins (as well as low-density lipoprotein cholesterol (LDL cholesterol), 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. Our scientific rationale for the REDUCE-IT study is also supported by research on the putative cardioprotective effects of EPA as presented in scientific literature. It is possible that the effects of EPA may be due not 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. The REDUCE-IT study is needed to determine the clinical benefit, if any, of EPA therapy in statin-treated patients with elevated triglyceride levels.

We currently expect that final positive results of the REDUCE-IT study will be required for FDA label expansion of Vascepa. Based on the results of REDUCE-IT, we may seek additional indications for Vascepa beyond the indications studied in the ANCHOR and MARINE trials such as potential indicated uses for prevention of cardiovascular events, although there can be no assurance as to whether the results of the study will support any such indication.

#### ***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 pending FDA approval of label expansion of Vascepa, anticipated to occur no sooner than after FDA review of the results from the REDUCE-IT study.

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 currently use third-party manufacturers to manufacture the clinical and commercial active pharmaceutical ingredient, or API, within Vascepa, and to encapsulate and package Vascepa. The FDA approval of Vascepa in July 2012 included the approval of one API manufacturer, Nisshin Pharma, Inc., or Nisshin, and one API encapsulator, Patheon, Inc., or Patheon (formerly Banner Pharmacaps, now part of Thermo Fisher Scientific). Nisshin and Patheon are the API manufacturer and API encapsulator, respectively, with which we have had the longest working relationships. Their facilities were approved by the FDA following successful preapproval inspections and they remain active manufacturers of Vascepa.

We currently rely on Patheon and Capsugel Plöermel SAS (now a Lonza company) for the encapsulation of Vascepa and we have an encapsulation agreement with one other qualified commercial API encapsulator, Catalent Pharma Solutions.

In addition to purchasing API from Nisshin, we have also purchased API from Chemport, Inc., or Chemport. In December 2012, we announced our submissions of two sNDAs to the FDA seeking approval for Chemport and BASF (formerly Equateq Limited) as additional Vascepa API manufacturers. In April 2013, the FDA approved our sNDAs encompassing Chemport and BASF as additional Vascepa API suppliers. On December 30, 2013, we issued a notice of termination of our API agreement to BASF as a result of BASF's non-compliance with the terms of such agreement and the agreement subsequently terminated in the first quarter of 2014. BASF remains an approved API supplier. In December 2012, we announced an agreement with an exclusive consortium of companies led by Slanmhor Pharmaceutical, Inc., or Slanmhor. We submitted a sNDA in August 2013 seeking FDA approval for this supplier to manufacture Vascepa API and in July 2014 the FDA approved our sNDA for Slanmhor as an API supplier. In July 2014, we terminated the supply agreement with Slanmhor and subsequently, in June 2015, entered into a new supply agreement with Finorga SAS, or Novasep. API manufactured by Novasep was previously approved by the FDA in July 2014.

The API material that constitutes ethyl-EPA is a modified, naturally occurring substance which is sourced from qualified producers of specific fish oils. A limited number of other manufacturers have the ability, scale, know-how and suitable 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 conform to pharmaceutical current Good Manufacturing Practice, or cGMP, which 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 may include minimum purchase commitments. During 2017 and 2016, 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 currently market Vascepa in the United States through our direct sales force of approximately 165 sales professionals, including sales representatives and their managers. We currently target clinicians who are top prescribers of lipid-regulating therapies. During the period from January 2013, when Vascepa was commercially launched in the United States, until October 2013, when the FDA notified us that it rescinded the ANCHOR study SPA agreement, our direct sales force was larger, consisting of approximately 275 sales representatives. Since then, through late 2017, the size of our direct sales force has included approximately 130 to 150 sales representatives with focus on select sales territories that we believe have demonstrated the greatest potential for Vascepa sales growth. We anticipate increasing our direct sales force to approximately 400 to 500 sales professionals after REDUCE-IT results, assuming success. Commencing in May 2014, in addition to Vascepa promotion by our sales representatives, Kowa Pharmaceuticals America, Inc. began co-promoting Vascepa in the United States. We also employ various medical affairs and marketing personnel to support our commercialization of Vascepa. We intend to expand medical education and market awareness initiatives, including, in advance of REDUCE-IT results being known, pilot testing of new promotional initiatives for potential broader applications following REDUCE-IT results.

Since commercial launch of Vascepa in January 2013, we have promoted Vascepa based on the MARINE clinical trial data as reflected in the 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 are being 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 and presentation of the current state of scientific research related to the potential of Vascepa to reduce the risk of cardiovascular disease including through use of peer-reviewed scientific publications of available data.

Until results of our cardiovascular outcomes trial, REDUCE-IT, show otherwise, we plan to continue to promote Vascepa based on the effects of Vascepa on surrogate biomarkers as studied in MARINE and ANCHOR and supportive but not conclusive data on the potential of Vascepa to reduce cardiovascular risk in the relevant patient population. After results of REDUCE-IT are available, on the assumption that the study demonstrates that Vascepa is effective in lowering the rate of major adverse cardiovascular events in patients with risk factors similar to those studied in REDUCE-IT, we intend to expand the size of our U.S. direct sales force and seek to expand promotion of Vascepa based on the results of the REDUCE-IT trial.

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 (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 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 may be necessary in this market. Significant commercialization of Vascepa in the China Territory is several years away, if at all. 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. Commercialization across the Middle East and North Africa is several years away, if at all, in the most commercially significant territories and 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 will be responsible for regulatory and commercialization activities and associated costs. We will be 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. Significant commercialization of Vascepa in Canada is several years away, if at all. If HLS Therapeutics is not able to effectively register and 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.

We continue to assess other 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<sup>®</sup>, 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<sup>®</sup> and Trilipix<sup>®</sup> for the treatment of severe hypertriglyceridemia, and Niaspan<sup>®</sup>, 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 use and in off-label uses, such as to beneficially affect lipid levels in patients with persistent high triglyceride levels after statin therapy with the aim of potentially lowering cardiovascular risk beyond 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. Each of these competitors, other than potentially Trygg, has greater resources than we do, including financial, product development, marketing, personnel and other resources.

Results of pending low dose omega-3 and other cardiovascular outcomes studies may negatively affect sales of Vascepa. For example, in 2018, results of both VITamin D and Omega-3 TriaL (VITAL) and A Study of Cardiovascular Events in Diabetes (ASCEND) trials are expected to be released. VITAL is 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 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. ASCEND is a British Heart Foundation funded 2x2 factorial design, randomized study to assess whether aspirin 100 mg daily versus placebo and separately, omega-3 fatty acids 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. Positive results due to the omega-3 component from one or both trials may influence greater utilization of 1 gram daily of dietary supplements or Lovaza in a broad low cardiovascular risk population and in patients with diabetes and may potentially cause an update of AHA recommendation for 1 gram per day of EPA and DHA based on trial results. Negative results from such studies could create misleading impressions about the use of omega-3s generally, including Vascepa, despite the highly-pure EPA active ingredient in Vascepa and its higher dose regimen. Also, AstraZeneca is currently 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, for approximately 3-5 years as determined when the number of major adverse cardiovascular event outcomes is reached. The STRENGTH study estimated completion date is in November 2019, but it could be stopped earlier if, for example, it generates an overwhelming efficacy result. In addition, Kowa Research Institute (a subsidiary of the Japanese company Kowa Co., Ltd) announced in March 2017 that it is initiating 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.

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 Federal Food, Drug, and Cosmetic Act, or FDCA, for its omega-3 prescription drug candidate, CaPre®, 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. Acasti initiated a Phase 3 clinical program to assess the safety and efficacy of CaPre in patients with very high (≥500 mg/dL) triglycerides in the fourth quarter of 2017 and expects to begin dosing patients in the first quarter of 2018. Study completion is expected in 2019. We believe Sancilio & Company, or Sancilio, is also developing potential treatments for hypertriglyceridemia based on omega-3 fatty acids. To our knowledge, 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. 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. is developing an omega-3-based therapeutic (MAT9001) for the treatment of severe hypertriglyceridemia and mixed dyslipidemia. In the fourth quarter of 2014, Matinas BioPharma, Inc. 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 pharmacokinetic and pharmacodynamic study of MAT9001 versus Vascepa. In September 2017, Matinas announced that it will be seeking a partner company to develop and commercialize MAT9001. Akcea Therapeutics/Ionis Pharmaceuticals (formerly Isis Pharmaceuticals), or Akcea/Ionis, in August 2017 announced the submission of an NDA to the FDA for volanesorsen (formerly ISIS-APOCIII<sub>Rx</sub>), a drug candidate administered through weekly subcutaneous injections, for the treatment of familial chylomicronemia syndrome (FCS). The NDA submission was based on positive Phase 3 results from the APPROACH trial in patients with FCS and from the COMPASS trial in patients with severe hypertriglyceridemia. A Phase 3 trial is currently ongoing studying volanesorsen in patients with familial partial lipodystrophy (FPL) (BROADEN trial). Akcea/Ionis expects to file an NDA for FPL in 2019. In January 2017, Akcea/Ionis announced a strategic collaboration and option agreement with Novartis whereby Novartis will help develop (including funding cardiovascular outcomes studies) and commercialize products emerging from this collaboration, including volanesorsen. Gemphire Therapeutics has announced plans to advance gemcabene into Phase 3 trials in 2018. Gemcabene is an oral, once-daily pill, for a number of hypercholesterolemic populations and severe hypertriglyceridemia. Gemphire announced a Phase 2b trial (INDIGO-1) in patients with severe hypertriglyceridemia is ongoing with top-line data expected in the second quarter of 2018. Zydus Cadila is conducting a Phase 2 trial of its lead program, Saroglitazar, in severe hypertriglyceridemia in the United States. The product is approved in India under the name Lipaglyn® for the treatment of hypertriglyceridemia and diabetic dyslipidemia.



Vascepa also faces competition from dietary supplement companies 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. Many of the promoters of such products have greater resources than Amarin and they 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 cannot be sure physicians and pharmacists will view the FDA-approved prescription-only status, EPA-only purity of Vascepa and stringent regulatory oversight as significant advantages versus omega-3 dietary supplements regardless of clinical study results and other scientific data.

In addition, several generic drug companies have sought to challenge the validity and enforceability of our patents and have submitted to FDA applications for approval of generic versions of Vascepa.

## **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 non-clinical development, testing, manufacturing, storage, distribution, import, export, labeling, advertising and marketing of pharmaceutical products and devices. 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 is generated in two distinct development stages: pre-clinical 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 pre-clinical 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, its safety in use, 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 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, 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.

### ***NDA and FDA Review Process***

Following trial completion, trial data is analyzed to determine safety and efficacy. Data is then filed with the FDA in an NDA along with proposed labeling for the product and information about the manufacturing and testing processes and facilities that will be used to ensure product quality. The NDA must contain proof of safety, purity, potency and efficacy, which entails extensive pre-clinical and clinical testing. FDA approval of an NDA must be obtained before first marketing of a drug in the United States.

The FDA will likely re-analyze the clinical trial data, which could result in iterative discussions between the FDA and us during the review process. The review and evaluation of applications by the FDA is extensive and time consuming and may take longer than originally planned to complete. The FDA may conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with current Good Manufacturing Practice, or cGMP, requirements and may also audit data from clinical and pre-clinical trials.

There is no assurance that the FDA will ultimately approve a drug product for marketing in the United States. Even if future indications for Vascepa are approved, the FDA's review will be lengthy, and we may encounter significant difficulties or costs during the review process. After approving 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 standards or if problems occur following initial marketing.

### **Off-label Promotion in the United States**

The FDCA has been interpreted by the FDA 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.

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 patients with mixed dyslipidemia 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 reflects 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 is 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 is already in FDA-approved labeling of Vascepa) or the peer-reviewed research related to Vascepa and the potential for cardiovascular risk reduction.

In connection with this litigation, the FDA sent a detailed letter to us on June 5, 2015 that confirmed the validity of the ANCHOR trial results. The letter also sought to clarify how, in the FDA's view, applicable law and FDA policies apply to the communications proposed in our complaint. The FDA stated in this letter that it did not have concerns with much of the information we proposed to communicate and provided us with guidance on the FDA's view of lawful, but limited paths for the dissemination and communication to healthcare professionals of the effects of Vascepa demonstrated in the ANCHOR clinical trial and use of peer-reviewed scientific publications in the context of appropriate disclaimers.

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.

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. Based on our communications with the FDA, we expect that final positive results from the REDUCE-IT outcomes study will be required for label expansion for Vascepa.

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. 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 of 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***

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, knowingly and willfully offering, paying, soliciting, or receiving remuneration 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. Moreover, there are no safe harbors for many common practices, such as educational and research grants or patient assistance programs. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability. The federal civil False Claims Act 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 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 providing free product to customers with the expectation that the customers would bill federal programs for the product; providing consulting fees, grants, free travel, and other benefits to physicians to induce them to prescribe the company’s products; or causing false claims to be submitted because of the company’s marketing of the product for unapproved, and thus non-reimbursable, uses. 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, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH), 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.

As of August 1, 2013, the federal Physician Payment Sunshine Act, being implemented as the Open Payments Program, requires certain manufacturers of drugs, devices, biologics and medical supplies to engage in extensive tracking of payments and other transfers of value to physicians and teaching hospitals, including physician ownership and investment interests, and public reporting of such data. Pharmaceutical and biological manufacturers with products for which payment is available under Medicare, Medicaid or the State Children’s Health Insurance Program are required to have started tracking such payments on August 1, 2013, and must submit a report on or before the 90th day of each calendar year disclosing reportable payments made in the previous calendar year.

The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer’s products from reimbursement under government programs, criminal fines, and imprisonment. There are also state laws requiring pharmaceutical companies to report gifts and other expenses relating to the marketing and promotion of pharmaceutical products; prohibiting certain marketing-related activities including the provision of gifts, meals, or other items to certain healthcare providers; and/or requiring pharmaceutical companies to implement compliance programs or marketing codes. 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. As a company marketing an FDA-approved product in the United States, our operations may be directly, or indirectly through our customers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal anti-kickback statute. 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 that apply to us 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.

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 (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, or collectively the PPACA, was enacted, which includes measures to significantly change the way healthcare is financed by both governmental and private insurers. Among the provisions of the PPACA 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;
- 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;
- creation of the Independent Payment Advisory Board which, beginning in 2014, will have authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription drugs and those recommendations could have the effect of law even if Congress does not act on the recommendations; 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.

It appears likely that the PPACA 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. Legislative changes to the PPACA remain possible under the Trump Administration.

### ***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.

### ***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. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. In this case, Amarin, as a 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. A drug sponsor could also gain a form of marketing exclusivity under the Hatch-Waxman Amendments if such company can, under certain circumstances, complete a human clinical trial process and obtain regulatory approval of its product. Additional three-year periods of exclusivity can be obtained for studies resulting in approval for new uses of existing drugs that protect the pioneer drug company from approval of ANDA applications made with reference to the new use during the three years from approval.

The FDA typically makes a determination on marketing exclusivity in connection with an NDA approval of a drug for a new indication. FDA marketing exclusivity is separate from, and in addition to, patent protection, trade secrets and manufacturing barriers to entry, which also help protect Vascepa against generic competition.

We applied to the FDA for five-year, NCE marketing exclusivity for Vascepa in connection with the NDA for our MARINE indication, which NDA was approved by the FDA on July 26, 2012. On February 21, 2014, in connection with the July 26, 2012 approval of the MARINE indication, the FDA denied a grant of five-year NCE marketing exclusivity to Vascepa and granted three-year marketing exclusivity. Under applicable regulations, such three-year exclusivity would have extended through July 25, 2015 and would have been supplemented by a 30-month stay triggered by patent litigation that would have extended into September 2016, unless such patent litigation was resolved against us sooner.

On February 27, 2014, we sued the FDA in the U.S. District Court for the District of Columbia to challenge the agency's denial of five-year NCE exclusivity for Vascepa, based on our reading of the relevant statute, our view of FDA's inconsistency with its past actions in this area and the retroactive effect of what we believe is a new policy at FDA as it relates to our situation. On May 28, 2015, the court granted our motion for summary judgment. The decision vacated the FDA's denial of our claim for such exclusivity and remanded to the FDA for proceedings consistent with the decision. On July 22, 2015, Watson Laboratories Inc., the purported first Vascepa ANDA filer, sought to intervene and appeal the court's decision. We and FDA opposed this intervention effort. The applicable courts denied Watson the relief sought and appeal periods have expired.

Based on the May 28, 2015 District of Columbia court order granting our motion for summary judgment in the 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, on July 24, 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 is eligible for five-year, NCE marketing exclusivity. This determination provides 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 30-month stay triggered by patent litigation following generic application submissions permitted on July 26, 2016 would continue until January 26, 2020, seven-and-a-half years from FDA approval, unless such patent litigation was resolved against us sooner.

It is possible that FDA's NCE determination could be challenged by interested parties. If challenged, we plan to vigorously support FDA's determination. Any such challenge could have a negative impact on our company and create uncertainty around the continued benefits associated with a five-year exclusivity status.

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' 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 are now in the process of defending the exclusivity of Vascepa through patent litigation against the ANDA filers. In the related lawsuits, we are seeking, among other remedies, an order enjoining filers from marketing generic versions of Vascepa before the last to expire of the asserted patents in 2030. 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.

If an ANDA filer is ultimately successful in patent litigation against us, it meets the requirements for a generic version of Vascepa to the satisfaction of the FDA under its ANDA (after the applicable regulatory exclusivity period and the litigation-related 30-month stay period ends), and is able to supply the product in significant commercial quantities, the generic company could introduce a generic version of Vascepa. Such a market entry would likely limit our U.S. sales substantially, which would have an 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.

#### **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 62 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 62 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;
- 45 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;
- 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;

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

## **Employees**

At February 23, 2018, we had 241 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 23, 2018, 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 DAC (in liquidation) (formerly Corsicanto Limited)	Ireland	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, Corsicanto DAC (in liquidation) (formerly Corsicanto Limited), Corsicanto II DAC, or Ester Neurosciences Limited.

In January 2012, Amarin, through its wholly-owned subsidiary Corsicanto DAC (in liquidation) (formerly Corsicanto Limited), or Corsicanto, a private designated activity company incorporated under the laws of Ireland, completed a private placement of \$150.0 million in aggregate principal amount of its 3.5% exchangeable senior notes due 2032 (the 2012 Notes), a portion of which were exchanged in May 2014 (the 2014 Notes) and a portion of which were extinguished in 2015 and replaced with new 3.5% exchangeable senior notes due 2032 (the 2015 Notes). In September 2016, the entirety of the 2014 Notes and 2015 Notes were mandatorily exchanged in accordance with their respective terms. In January 2017, approximately \$15.0 million of the 2012 Notes were put to the Company, and, in March 2017, the Company redeemed the entirety of the remaining \$0.1 million in aggregate principal amount of 2012 Notes plus accrued and unpaid interest, such that no 2012 Notes remained outstanding as of December 31, 2017. Refer to Note 8—Debt for further discussion. Corsicanto was formed in November 2011 and was subsequently acquired by Amarin in January 2012 for the sole purpose of facilitating this financing transaction. A liquidator was appointed to Corsicanto on September 7, 2017 pursuant to a resolution of Amarin Corporation plc as sole shareholder.

In January 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 (the “2017 Notes”) at an issue price of 100%. The net proceeds from the offering were \$28.8 million after deducting placement agent fees and offering expenses payable by the Company. The offering of the 2017 Notes closed on January 25, 2017. Refer to Note 8—Debt for further discussion. Corsicanto II has no assets, operations, revenues or cash flows other than those related to the issuance, administration and repayment of the 2017 Notes.

## 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](http://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](http://www.sec.gov), that contains reports and other information regarding issuers that file electronically with the SEC. The public may read and copy any files within the SEC’s Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling 1-800-SEC-0330. 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.

## Financial Information About Segments

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(s), which is our President and Chief Executive Officer, in deciding how to allocate resources and assess performance. Since we currently operate in one business segment, which is the development and commercialization of Vascepa, all required financial segment information can be found in the consolidated financial statements.

### 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 sales of Vascepa in the United States.***

As a result of our reliance on a single product, Vascepa® (icosapent ethyl) capsules, and our primary focus on the U.S. market in the near-term, much of our near-term results and value as a company depends on our ability to execute our commercial strategy for Vascepa in the United States. If commercialization efforts for Vascepa are not successful, our business will be materially and adversely affected.

Even if we are able to successfully develop Vascepa outside the United States or develop additional products from our research and development efforts, the development time cycle for products typically takes several years. This restricts our ability to respond to adverse business conditions for Vascepa. If we are not successful with development, or if there is not adequate demand for Vascepa or the market for such product develops less rapidly than we anticipate, 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.

##### ***The uncertain effect of Vascepa on its ultimate targeted clinical benefits makes it more difficult to achieve a level of market acceptance by physicians, patients, healthcare payors and others in the medical community necessary 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  $\geq$ 500 mg/dL) hypertriglyceridemia. Approximately 3 to 4 million adults in the United States have severely high triglyceride levels (TG  $\geq$ 500 mg/dL), commonly known as very high triglyceride levels. 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 hypertriglyceridemia has not been determined and our FDA-approved labeling and promotional efforts state these facts.

In August 2015, based on a federal court order, we began communicating promotional information beyond the MARINE indication to healthcare professionals in the United States for the treatment of patients with high (TG  $\geq$ 200 mg/dL and  $<$ 500 mg/dL) triglyceride levels who are also on statin therapy for elevated low-density lipoprotein cholesterol, or LDL-C, levels, based on results from the ANCHOR study of Vascepa. It is estimated that approximately 40 million adults in the United States have high triglyceride levels (TG  $\geq$ 200 mg/dL), and many patients with high triglycerides also have other lipid level abnormalities such as high cholesterol and are on statin therapy. FDA did not approve Vascepa for use in this population due to the uncertain effect of pharmaceutically induced triglyceride reduction in this patient population on cardiovascular risk reduction, the ultimate targeted clinical benefits. Our promotional efforts disclose this fact and what we view as truthful and non-misleading information on the current state of research on both triglyceride reduction and the active pharmaceutical ingredient, or API, in Vascepa, EPA, as each relate to the potential of Vascepa to reduce cardiovascular risk.

The uncertainties around the ultimate targeted clinical benefits of Vascepa make it more difficult for Vascepa to gain market acceptance by physicians, patients, healthcare payors and others in the medical community. If Vascepa does not achieve an adequate level of acceptance, we may not generate product revenues sufficient to become profitable. The degree of market acceptance of

Vascepa for the MARINE indication and in ANCHOR patients and in any future approved indications and uses will depend on a number of factors, including:

- the perceived efficacy, safety and potential advantages of Vascepa, as compared to alternative treatments;
- 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 outside of FDA-approved labeling and the related perception thereof;
- sufficient third-party coverage or reimbursement for on-label use, and for permitted off-label use, the third-party coverage or reimbursement for which was not addressed in the scope of the August 2015 court declaration or related settlement;
- natural disasters that can 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 efficacy of the product and the prevalence and severity of any side effects, including any limitations or warnings contained in Vascepa's approved labeling.

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

Our sales team consists of approximately 165 sales professionals, including sales representatives and their managers. This sales team promotes Vascepa to a limited group of physicians and other healthcare professionals in select geographies in the United States. This sales team is not large enough to call upon all physicians. In January 2013, when we initially began selling Vascepa in the United States through our own then newly established sales and marketing teams and through a newly established third-party commercial distribution infrastructure, our sales team was larger.

In May 2014 we began co-promoting Vascepa in the United States with Kowa Pharmaceuticals America, Inc. under a co-promotion agreement we entered into in March 2014, which we amended in July 2017. Under the agreement Kowa Pharmaceuticals America, Inc. co-promotes Vascepa in conjunction with its promotion of its primary product, a branded statin for patients with high cholesterol, along with our sales professionals based on a plan designed to focus on select sales territories that we believe have demonstrated the greatest potential for Vascepa sales growth, increasing both the number of sales targets reached and the frequency of sales calls on existing sales targets. However, the commercialization of pharmaceutical products is a complex undertaking, and we have very limited experience as a company operating in this area and co-promoting a pharmaceutical product with a partner.

If the results of the REDUCE-IT outcomes study are successful, we plan to expand our promotion of Vascepa, including increasing the size of our team. We anticipate increasing our sales force to a total of approximately 400 to 500 sales professionals after REDUCE-IT results, assuming success. If REDUCE-IT is successful, we will again need to overcome challenges associated with rapidly hiring and training personnel and managing larger teams of people. Furthermore, our agreement with Kowa Pharmaceuticals America, Inc. is designed such that its co-promotion of Vascepa ceases at the end of 2018. If we do not extend this co-promotion agreement, enter into a co-promotion agreement with an equally capable company or hire equally capable sales representatives, our sales may be negatively impacted.

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, in particular as it relates to various healthcare regulatory requirements applicable to the marketing and sale of pharmaceutical products and the court declaration that we believe enables us to expand marketing efforts for Vascepa, and our inability to adequately monitor compliance with these requirements;
- the inability of our new sales personnel, working for us as a new market entrant, 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.

***We expect final positive results from the REDUCE-IT outcomes study will be required for FDA-approved label expansion for Vascepa.***

Since January 2013, we have marketed Vascepa for use in the FDA-approved MARINE indication in the United States.

In April 2015, we received a Complete Response Letter, or CRL, from the FDA on our supplemental new drug application, or sNDA, that sought approval for the use of Vascepa in patients with high triglyceride levels (TG  $\geq$ 200 mg/dL and  $<$ 500 mg/dL) who are also on statin therapy, which we refer to as the ANCHOR indication. In regulatory communications, the FDA acknowledged that the results of the ANCHOR trial as we presented them to FDA were valid and truthful in that, for example, Vascepa reduced triglyceride levels compared to placebo in patients treated in the ANCHOR study. The clinical rationale for reducing serum triglycerides with Vascepa and modifying other lipid/lipoprotein parameters shown in ANCHOR among statin-treated patients with triglycerides 200-499 mg/dL is to reduce cardiovascular risk. In not approving our ANCHOR sNDA, the FDA concluded that, for regulatory approval purposes, there were insufficient data to support a drug-induced change in serum triglycerides as a surrogate for reducing cardiovascular risk in the ANCHOR population. 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 August 2015, based on a federal court order, we began communicating promotional information beyond the MARINE indication to healthcare professionals in the United States through use of a set of qualified statements that we believe reflect the state of research related to the use of Vascepa in the ANCHOR population and the supportive but not conclusive research on the use of Vascepa to reduce cardiovascular risk in this population. In March 2016, we settled the litigation related to this court order 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. An FDA-approved indication for this patient population has not been granted. If new clinical information is demonstrated that changes what we understand to be truthful and non-misleading, our promotion of Vascepa will need to be modified to ensure that our promotion remains truthful and non-misleading. Our ability to reach full potential in the commercialization of Vascepa in the United States is dependent upon marketing claims associated with Vascepa that are granted with the approval of an indication statement by the FDA.

Based on our communications with the FDA, we expect that final positive results from the REDUCE-IT outcomes study will be required for FDA approval of a new indication or other label expansion for Vascepa. Any delay in obtaining, or an inability to obtain, further expansion of our marketing approval rights with an FDA approval could prevent us from growing revenue at all or greater than our current pace and could therefore have a material adverse effect on our operations and financial condition, including our ability to reach profitability. Even if we obtain additional regulatory approvals for Vascepa, the timing or scope of any approvals may prohibit or reduce our ability to commercialize the product successfully. For example, if the approval process for any expanded indication takes too long, we may miss market opportunities and give other companies the ability to develop competing products or establish market dominance. If the FDA does not approve any expanded indication at all, it could have a material impact on our future results of operations and financial condition. Additionally, the terms of any approvals beyond the approval received from the FDA in July 2012 for the MARINE indication may prove to not have the scope or breadth needed for us to successfully commercialize Vascepa or become profitable.

***Our 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 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.

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 reflects 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 is 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 is already in FDA-approved labeling of Vascepa) or the peer-reviewed research related to Vascepa and the potential for cardiovascular risk reduction.

In connection with this litigation, the FDA sent a detailed letter to us on June 5, 2015 that confirmed the validity of the ANCHOR trial results. The letter also sought to clarify how, in the FDA's view, applicable law and FDA policies apply to the communications proposed in our complaint. The FDA stated in this letter that it did not have concerns with much of the information we proposed to communicate and provided us with guidance on the FDA's view of lawful, but limited paths for the dissemination and communication to healthcare professionals of the effects of Vascepa demonstrated in the ANCHOR clinical trial and use of peer-reviewed scientific publications in the context of appropriate disclaimers.

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.

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. Based on our communications with the FDA, we expect that final positive results from the REDUCE-IT outcomes study will be required for label expansion for Vascepa.

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. Data arising from studies of drug products are complex, such as the many studies that we believe show supportive but not conclusive research on the potential connection between the effects of EPA, the active ingredient in Vascepa, and cardiovascular risk reduction (e.g., the JELIS trial of a highly-pure EPA product in Japan and the ongoing REDUCE-IT study of Vascepa). We, the FDA, our competitors and other interested parties may not agree on the truthfulness and non-misleading nature of our promotional materials with respect to the outcome of these trials or other direct or indirect claims we make about Vascepa. 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 use and in off-label uses, such as to beneficially affect lipid levels in patients with persistent high triglyceride levels after statin therapy with the aim of potentially lowering cardiovascular risk beyond 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. Each of these competitors, other than potentially Trygg, has greater resources than we do, including financial, product development, marketing, personnel and other resources.

Results of pending low dose omega-3 and other cardiovascular outcomes studies may negatively affect sales of Vascepa. For example, in 2018, results of both VITamin D and Omega-3 TriaL (VITAL) and A Study of Cardiovascular Events iN Diabetes (ASCEND) trials are expected to be released. VITAL is 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 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. ASCEND is a British Heart Foundation funded 2x2 factorial design, randomized study to assess whether aspirin 100 mg daily versus placebo and separately, omega-3 fatty acids 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. Positive results due to the omega-3 component from one or both trials may influence greater utilization of 1 gram daily of dietary supplements or Lovaza in a broad low cardiovascular risk population and in patients with diabetes and may potentially cause an update of AHA recommendation for 1 gram per day of EPA and DHA based on trial results. Negative results from such studies could create misleading impressions about the use of omega-3s generally, including Vascepa, despite the highly-pure EPA active ingredient in Vascepa and its higher dose regimen. Also, AstraZeneca is currently 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, for approximately 3-5 years as determined when the number of major adverse cardiovascular event outcomes is reached. The STRENGTH study estimated completion date is in November 2019, but it could be stopped earlier if, for example, it generates an overwhelming efficacy result. In addition, Kowa Research Institute (a subsidiary of the Japanese company Kowa Co., Ltd) announced in March 2017 that it is initiating 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.

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®, 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. Acasti initiated a Phase 3 clinical program to assess the safety and efficacy of CaPre in patients with very high ( $\geq 500$  mg/dL) triglycerides in the fourth quarter of 2017 and expects to begin dosing patients in the first quarter of 2018. Study completion is expected in 2019. We believe Sancilio & Company, or Sancilio, is also developing potential treatments for hypertriglyceridemia based on omega-3 fatty acids. To our knowledge, 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. 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. is developing an omega-3-based therapeutic (MAT9001) for the treatment of severe hypertriglyceridemia and mixed dyslipidemia. In the fourth quarter of 2014, Matinas BioPharma, Inc. filed an IND with the FDA to conduct a human study in the treatment of severe hypertriglyceridemia and, in June 2015, the company announced top-line results for its head-to-head comparative pharmacokinetic and pharmacodynamic study of MAT9001 versus Vascepa. In September 2017, Matinas announced that it will be seeking a partner company to develop and

commercialize MAT9001. Akcea Therapeutics/Ionis Pharmaceuticals (formerly Isis Pharmaceuticals), or Akcea/Ionis, in August 2017 announced the submission of an NDA to the FDA for volanesorsen (formerly ISIS-APOCIIIIRx), a drug candidate administered through weekly subcutaneous injections, for the treatment of familial chylomicronemia syndrome (FCS). The NDA submission was based on positive Phase 3 results from the APPROACH trial in patients with FCS and from the COMPASS trial in patients with severe hypertriglyceridemia. A Phase 3 trial is currently ongoing studying volanesorsen in patients with familial partial lipodystrophy (FPL) (BROADEN trial). Akcea/Ionis expects to file an NDA for FPL in 2019. In January 2017, Akcea/Ionis announced a strategic collaboration and option agreement with Novartis whereby Novartis will help develop (including funding cardiovascular outcomes studies) and commercialize products emerging from this collaboration, including volanesorsen. Gemphire Therapeutics has announced plans to advance gemcabene into Phase 3 trials in 2018. Gemcabene is an oral, once-daily pill, for a number of hypercholesterolemic populations and severe hypertriglyceridemia. Gemphire announced a Phase 2b trial (INDIGO-1) in patients with severe hypertriglyceridemia is ongoing with top-line data expected in the second quarter of 2018. Zydus Cadila is conducting a Phase 2 trial of its lead program, Saroglitazar, in severe hypertriglyceridemia in the United States. The product is approved in India under the name Lipaglyn® for the treatment of hypertriglyceridemia and diabetic dyslipidemia.

***Generic company competitors are seeking FDA approval of generic versions of Vascepa. We are now engaged in related patent litigation and could face other challenges to our exclusivity.***

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 is eligible for five-year, NCE marketing exclusivity. This determination provides 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. We believe the statutory NCE-related 30-month stay triggered by the 1-gram dose patent litigation following generic application submissions permitted on July 26, 2016 is scheduled to continue until January 26, 2020, seven-and-a-half years from FDA approval, unless such patent litigation is resolved against us sooner.

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 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, 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 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, we are seeking, 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. This new lawsuit against Teva has been consolidated with the pending lawsuits against Teva, West-Ward, and DRL referenced above based on the 1-gram dose strength, and all four lawsuits will proceed on the same schedule.

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 US 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 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. 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 any exclusivity protections, such as a 30-month stay, have expired. As a result of the statutory stays associated with the filing of these lawsuits under the Hatch-Waxman Amendments, we believe the FDA cannot grant final approval to West-Ward, DRL, or Teva's respective ANDAs for the 1-gram strength of Vascepa before January 26, 2020, unless there is an earlier court decision holding that the subject patents are not infringed and/or are invalid.

In addition, we believe the FDA cannot grant final approval to Teva's ANDA for the 0.5-gram strength Vascepa before the beginning of March 2020, unless there is an earlier court decision holding that the subject patents are not infringed and/or are invalid. If final approval is granted and an ANDA filer is able to supply the product in significant commercial quantities, the generic company could introduce a generic version of Vascepa. Any such introduction of a generic version of Vascepa would also be subject to current patent infringement claims including those being litigated in the above-detailed patent litigations, and any court order we may seek and be granted to prevent any such launch based on our patent claims prior to any adverse court judgment or PTAB finding against us.

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's five-year, NCE and related exclusivity benefits could be challenged by companies seeking to introduce generic versions of Vascepa.***

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. In May 2016, after significant litigation, FDA determined that Vascepa is eligible for NCE marketing exclusivity. Accordingly, we believe a related 30-month stay is currently in place with respect to our 1-gram dose strength of Vascepa that is scheduled to continue until January 26, 2020, seven-and-a-half years from FDA approval of Vascepa, unless related patent litigation is resolved against us sooner. We believe we are entitled to a separate 30-month stay with respect to our 0.5-gram dose product and the related Teva paragraph IV certification that would expire at the beginning of March 2020, 30 months after the related August 29, 2017 paragraph IV notice was received by us.

The FDA typically makes a determination on marketing exclusivity in connection with an NDA approval of a drug for a new indication. FDA marketing exclusivity is separate from, and in addition to, patent protection, trade secrets and manufacturing barriers to entry which could also help protect Vascepa against generic competition.

We applied to the FDA for five-year, NCE marketing exclusivity for Vascepa in connection with the NDA for our MARINE indication, which NDA was approved by the FDA on July 26, 2012. On February 21, 2014, in connection with the July 26, 2012 approval of the MARINE indication, the FDA denied a grant of five-year NCE marketing exclusivity to Vascepa and granted three-year marketing exclusivity. Under applicable regulations, such three-year exclusivity would have extended through July 25, 2015 and would have been supplemented by a 30-month stay triggered by patent litigation that would have extended into September 2016, unless such patent litigation was resolved against us sooner.

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. A drug sponsor could also gain a form of marketing exclusivity under the Hatch-Waxman Amendments if such company can, under certain circumstances, complete a human clinical trial process and obtain regulatory approval of its product.

In contrast, 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 expect to receive three-year exclusivity in connection with any future regulatory approvals of Vascepa, such as an approval sought based on positive 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.

On February 27, 2014, we sued the FDA in the U.S. District Court for the District of Columbia to challenge the agency's denial of five-year NCE exclusivity for Vascepa, based on our reading of the relevant statute, our view of FDA's inconsistency with its past actions in this area and the retroactive effect of what we believe is a new policy at FDA as it relates to our situation. On May 28, 2015, the court granted our motion for summary judgment. The decision vacated the FDA's denial of our claim for such exclusivity and remanded to the FDA for proceedings consistent with the decision. On July 22, 2015, Watson Laboratories Inc., the purported first Vascepa ANDA filer, sought to intervene and appeal the court's decision. We and FDA opposed this intervention effort. The applicable courts denied Watson the relief sought and appeal periods have expired.

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 is eligible for five-year, NCE marketing exclusivity. We believe this determination provides 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. We believe the statutory NCE-related 30-month stay triggered by the 1-gram dose patent litigation following generic application submissions permitted on July 26, 2016 is scheduled to continue until January 26, 2020, seven-and-a-half years from FDA approval, unless such patent litigation is resolved against us sooner. We also believe we are entitled to a separate 30-month stay with respect to our 0.5-gram dose product and the related Teva paragraph IV certification that would expire at the beginning of March 2020, 30 months after the related August 29, 2017 paragraph IV notice was received by us.

It is possible that FDA's NCE determination and related 30-month stays could be challenged by interested parties. If challenged, we plan to vigorously defend exclusivity for Vascepa. Any such challenge could have a negative impact on our company and create

uncertainty around the continued benefits associated with exclusivity that we believe are applicable to us under the Hatch-Waxman Amendments.

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

***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 tested 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.

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. As a result of our First Amendment litigation and settlement, we may now make this claim to healthcare professionals subject to certain qualifications.

These factors enable dietary supplements to effectively compete with Vascepa. 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 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, 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. On October 27, 2017, the ITC determined to not institute our requested investigation. We are currently appealing this determination in federal court and plan to pursue it vigorously. 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.

***We may not be successful in our Vascepa co-promotion effort with Kowa Pharmaceuticals America, Inc. or in replacing this co-promotion effort after it expires at the end of 2018.***

In March 2014, we entered into a co-promotion agreement with Kowa Pharmaceuticals America, Inc. to co-promote Vascepa in the United States under which Kowa Pharmaceuticals America, Inc. co-promotes Vascepa in conjunction with its promotion of its primary product, a branded statin for patients with high cholesterol. Co-promotion under the agreement commenced in May 2014 based on a plan designed to substantially increase both the number of sales targets reached and the frequency of sales calls on existing sales targets. While our agreement provides for minimum performance criteria, we have little control over Kowa Pharmaceuticals America, Inc., and it may fail to devote the necessary resources and attention to promote Vascepa effectively. If that were to occur for an extended period of time, depending on Vascepa revenues, we may have to increase our planned expenditures and undertake additional development or commercialization activities at our own expense. Or, we may seek to terminate the agreement and search for another commercialization partner. If we elect to increase our expenditures to fund development or commercialization activities on our own, depending on Vascepa's revenues, we may need to obtain additional capital, which may not be available to us on acceptable terms, or at all, or which may not be possible due to our other financing arrangements. If we do not generate sufficient funds from the sale of Vascepa or, to the extent needed to supplement funds generated from product revenue, cannot raise sufficient funds, we may not be able to devote resources sufficient to market and sell Vascepa on our own in a manner required to realize the full market potential of Vascepa.

Furthermore, our agreement with Kowa Pharmaceuticals America, Inc. is designed such that its co-promotion of Vascepa ceases at the end of 2018. If we do not extend this co-promotion agreement, enter into a co-promotion agreement with an equally capable company or hire equally capable sales representatives, our sales may be negatively impacted.

***The commercial value to us of current and sought marketing rights may be smaller than we anticipate.***

There can be no assurance as to the adequacy for commercial success of the scope and breadth of the marketing rights we currently have or, if approved, an indication based on a successful outcome of the REDUCE-IT study. Even if we obtain marketing approval for additional indications, the FDA 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, the number of actual patients with conditions within the scope of our marketing efforts may be smaller than we anticipate. If any such marketing right or approved indication is narrower than we anticipate, the market potential for our product would suffer.

***Our special protocol assessment, or SPA, agreement for ANCHOR was rescinded and our SPA agreement for REDUCE-IT is not a guarantee of FDA approval of Vascepa for the proposed REDUCE-IT indication.***

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 of the drug product candidate with respect to effectiveness for the indication studied. The MARINE and ANCHOR trials were, and the REDUCE-IT trial is, being conducted under a SPA agreement with the FDA. In each case, the FDA agreed that, based on the information we submitted to the agency, the design and planned analysis of the trial is adequate to support use of the conducted study as the primary basis for approval with respect to effectiveness. A SPA agreement is not a guarantee of approval. A SPA agreement is generally binding upon the FDA except in limited circumstances, such as if the FDA identifies a substantial scientific issue essential to determining safety or efficacy after the study begins, or if the study sponsor fails to follow the protocol that was agreed upon with the FDA. The FDA reserves the right of final determinations for approval based on its review of the entire data presented in a marketing application.

In October 2013, the FDA notified us that it rescinded the ANCHOR study SPA agreement because the FDA determined that a substantial scientific issue essential to determining the effectiveness of Vascepa in the studied population was identified after testing began. In April 2015, we received a CRL from the FDA stating that the FDA determined not to approve label expansion reflecting the ANCHOR clinical trial efficacy data at this time.

Thus, even though we have received regulatory approval of Vascepa for the MARINE indication under a SPA agreement, our ANCHOR SPA agreement was rescinded. There is no assurance that the FDA will not rescind our REDUCE-IT SPA agreement.

In August 2016, we announced an amendment to our REDUCE-IT SPA agreement with FDA that reaffirmed FDA concurrence on key elements of the study, defined details of the statistical analysis plan for the study, expanded to greater than 30 the pre-specified secondary and tertiary endpoints in the study, and added a second interim efficacy and safety analysis by the independent data monitoring committee (DMC) at approximately 80% of the target aggregate number of primary cardiovascular events. In this amended REDUCE-IT SPA agreement, FDA agreed that, based on the information submitted to the agency, the critical elements of the revised REDUCE-IT protocol and analysis plans adequately address the objectives necessary to support a regulatory submission. However, secondary and/or tertiary endpoints, their ordering in the statistical hierarchy, their clinical significance, or whether any would yield results appropriate for labeling are considered review issues and are not intended to be a binding component of the REDUCE-IT SPA agreement. Further, matters such as endpoint adjudication procedures (including potential endpoint ascertainment, adjudication process, and detailed definitions) were specified by FDA as issues to be reviewed by the agency as part of a drug approval application. Consistent with the May 2016 FDA SPA draft guidance, FDA stated that the SPA agreement does not necessarily indicate the agency's agreement with every detail of a protocol; instead, such an agreement indicates FDA's concurrence with the elements critical to ensuring that the trial conducted under the protocol would have the potential to form the primary basis of an efficacy claim in a marketing application.

The inability to obtain marketing approval in the ANCHOR or REDUCE-IT indications has prevented, and would continue to prevent, us from growing revenue more significantly, and it has had, and could continue to have, a material adverse effect on our operations and financial condition, including our ability to reach profitability.

***The REDUCE-IT cardiovascular outcomes trial may fail to show that Vascepa can reduce major cardiovascular events in an at-risk patient population on statin therapy, and the long-term clinical results of Vascepa may not be consistent with the clinical results we observed in our Phase 3 clinical trials, in which case our sales of Vascepa may then suffer.***

In accordance with the SPA agreements for our MARINE and ANCHOR trials, efficacy was evaluated in these trials compared to placebo at twelve weeks. No placebo-controlled studies have been conducted regarding the long-term effect of Vascepa on lipids, and no outcomes study has been conducted evaluating Vascepa. The REDUCE-IT study, which commenced in 2011 and completed patient enrollment and randomization of 8,175 individual patients in 2016, is designed to evaluate the efficacy of Vascepa in reducing major cardiovascular events in an at-risk patient population with high triglyceride levels despite being on statin therapy. Based on projected event rates, we estimate the onset of the target aggregate number of primary cardiovascular events to be reached near the end of the first quarter of 2018 with study results then expected to be available and made public before the end of the third quarter of 2018, followed by publication of the results. We have instructed clinical sites to schedule patients enrolled in the study for their final site

visits commencing March 1, 2018. In January 2018, we announced that more than 90% of the targeted events have been reported and documented.

Outcomes studies of certain other lipid-modifying therapies have failed to achieve the endpoints of such studies, even though they reduced triglyceride levels and showed other favorable effects on parameters relevant to cardiovascular health in studied patients, such as inflammation. For example, in 2010, the results of the ACCORD-Lipid trial were published. This trial studied the effect of adding fenofibrate onto open-label simvastatin therapy on cardiovascular outcomes. The addition of fenofibrate did not show any treatment benefit on cardiovascular outcomes over simvastatin monotherapy in this study. In 2011, the results of the AIM-HIGH trial were published. This trial studied the effect of adding a second lipid-altering agent, extended-release niacin, to simvastatin therapy on cardiovascular outcomes in people at high risk for cardiovascular events. Niacin, for example, has also been shown to have favorable effects on inflammation parameters. No significant incremental treatment benefit with extended-release niacin was observed.

Outcomes studies of certain other lipid-modifying therapies included results which, after review of information not fully available to the sponsors during the conduct of the trials, modified initial reports of the trial results. Two examples are the AIM-HIGH trial and the IMPROVE-IT trial. When the AIM-HIGH trial was stopped, there were initial reports of certain safety concerns which, upon further and more detailed subsequent review, were concluded to not be associated with the study therapy. After the IMPROVE-IT trial was completed, initial reports on the effect of adding ezetimibe to statin therapy in subjects with acute coronary syndrome suggested greater benefit on cardiovascular outcomes than was considered to be the case after later reassessment and further evaluation of study data. In 2015, the results of the IMPROVE-IT trial were published. Based on the published results, the addition of ezetimibe showed incremental lowering of LDL-C levels and improved cardiovascular outcomes. This result was statistically significant but less than ten percent. Further evaluation of the IMPROVE-IT results suggested that the outcomes benefit may have been lower after factoring in and making certain assumptions regarding complicating factors such as a high number of patients who discontinued the study drug, withdrew consent, or were lost to follow-up. FDA approval of a new indication for ezetimibe based on the IMPROVE-IT results was denied after a negative FDA advisory committee recommendation that followed examination of the study results.

In addition, in September 2012, researchers published in the *Journal of the American Medical Association*, or *JAMA*, the results of a retrospective meta-analysis of twenty previously conducted studies regarding the use of omega-3 supplements across various patient populations. This meta-analysis suggested that the use of such supplements was not associated with a lower risk of all-cause death, cardiac death, sudden death, heart attack, or stroke. In January 2018, *JAMA Cardiology* published an update to prior meta-analyses and again concluded no benefit for low dose omega-3 supplements (all but one trial included both EPA and DHA) to prevent fatal coronary heart disease or any cardiovascular disease in people who have or are at high risk of developing cardiovascular disease. Previous meta-analyses of trials of omega-3 supplementation appeared to suggest a significant beneficial association of omega-3s with fatal coronary heart disease but not nonfatal coronary heart disease. However, the previous meta-analyses were limited as they included trials of dietary advice to eat fish or excluded trials that did not include a placebo-controlled arm. The *JAMA Cardiology* analysis does not support the recent AHA recommendation that 1 gram of an omega-3 dietary supplementation may be useful in patients with a history of coronary heart disease. These facts illustrate categories of challenges faced in demonstrating favorable results in complex clinical studies like REDUCE-IT and, assuming positive results of the REDUCE-IT study, in seeking to apply those results in support of regulatory approvals.

Data from clinical trials are invariably complex. It is also not typically possible to reliably extrapolate results from one trial to predict results from another as many factors differ between trials. For instance, unlike REDUCE-IT, the outcomes studies for fenofibrates and niacin were conducted in patient populations in which the majority of patients studied had triglycerides below 200 mg/dL and fenofibrates and niacin are believed to work differently than Vascepa in the body and do not have as favorable a side-effect profile. Of all the studies included in both the *JAMA* and *JAMA Cardiology* meta-analyses, all but one trial involved the use of omega-3 supplements containing a mixture of EPA and DHA or EPA and another omega fatty acid, and most were evaluated at relatively lower doses. Vascepa is comprised of highly-pure ethyl-EPA, and has been approved by the FDA for use in adult patients with severe hypertriglyceridemia at a higher dose of 4 grams per day and is being studied in REDUCE-IT at that 4 grams per day dose.

The only other outcomes study involving the use of a highly-pure formulation of ethyl-EPA, called the Japan EPA Lipid Intervention Study (JELIS), suggested that use of a highly-pure formulation of ethyl-EPA in Japan, when used in conjunction with statins, reduced cardiovascular events by 19% compared to the use of statins alone. However, there are several limitations to comparing the JELIS study to REDUCE-IT. First, the patient population was exclusively Japanese, the majority of the participants were women, and at baseline patients had much higher LDL-C levels, limiting its generalizability to the intended target population. Also, a low dose of statins was used. It is unknown whether the positive treatment effects would have persisted if these patients had been optimally treated with statins using contemporary LDL-C targets in the United States. In addition, JELIS was an open-label trial, which could influence patient and physician behavior and reporting of symptoms, decisions regarding hospitalization, and referral of events for adjudication. This may be particularly relevant since hospitalization for unstable angina was a primary contributor of the overall positive result, and is considered a softer endpoint than fatal cardiovascular events.

Further, FDA determined that JELIS results could not be used as support for or against the use of triglyceride levels as a surrogate for cardiovascular risk reduction. Patients treated with EPA and statin in JELIS achieved triglyceride levels that were only 5% lower, on average, than those achieved among patients treated with statin alone; however, the reduction in cardiovascular risk in the primary endpoint analysis was 19%. Likewise, within the primary and secondary prevention sub-analyses, triglyceride levels were lowered only 5% on average in the EPA plus statin group compared with the statin alone group; however, the relative risk reduction was 53% in the primary prevention population with elevated triglyceride ( $\geq 150$  mg/dL) and low HDL-C ( $\leq 40$  mg/dL) levels and 23% in the secondary prevention population with established coronary artery disease. These large differences in magnitude between triglyceride reduction and risk reduction in JELIS suggest that the effects of EPA on triglyceride levels alone may not be responsible for, or predict, the observed differences in cardiovascular events between treatment groups in JELIS. JELIS was not designed to evaluate primary and secondary prevention populations. It is possible that the putative cardioprotective effects of EPA observed in JELIS are due not to a single mode of action, such as triglyceride lowering, but rather to multiple mechanisms working together, such as purported beneficial effects on multiple atherosclerosis processes, including endothelial function, oxidative stress, foam cell formation, inflammation/cytokines, plaque formation/progression, platelet aggregation, thrombus formation, and plaque rupture. The REDUCE-IT study is needed to determine the clinical benefit, if any, of EPA therapy in statin-treated patients with elevated triglyceride levels.

In addition, the independent data monitoring committee for REDUCE-IT, or the DMC, has multiple times per year assessed safety data generated in the ongoing study and has thus far recommended to continue the study as planned. Thus, multiple safety reviews to date have not warranted study stoppage. Nevertheless, the study may be stopped at any time based on recommendations of the DMC due to safety concerns identified by the DMC during its ongoing and regularly scheduled safety data assessments.

There can be no assurance that the REDUCE-IT study will be completed successfully, that the endpoints of the REDUCE-IT cardiovascular outcomes study will be achieved, that, like the IMPROVE-IT trial, patients who discontinue the study drug, withdrew consent, or were lost to follow-up will not negatively affect REDUCE-IT results, that the results will support regulatory approvals, or that the lipid-modifying effects of Vascepa in REDUCE-IT or any other study of Vascepa will not be subject to variation beyond twelve weeks. If the REDUCE-IT trial is not successful or if the results of this long-term study are not consistent with the 12-week clinical results, it could prevent us from expanding the labeled approval of Vascepa or even call into question the currently understood efficacy and safety profile of Vascepa. In any such case, the market potential for Vascepa would suffer and our business would be materially affected.

***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 (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 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. Significant commercialization of Vascepa in the China Territory is several years away, if at all. 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. Commercialization across the Middle East and North Africa is several years away, if at all, in the most commercially significant territories and 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. Significant commercialization of Vascepa in Canada is several years away, if at all. If HLS Therapeutics is not able to effectively register and 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.

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.

***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 and Eddingpharm obtain marketing approval in countries within 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. 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. 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 such approved indication is narrower than we anticipate, the market potential in these countries 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 including direct-to-healthcare provider and direct-to-consumer advertising and promotional activities involving the internet, 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 new federal transparency requirements under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the PPACA, 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. If 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, we will be 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. For example, in September 2014, we participated in a routine inspection from the FDA in which the FDA made observations on perceived deficiencies related to our processes for collection and processing of adverse events. We have responded to FDA with respect to these observations and continue to work with FDA to show that we have improved related systems and, given we received communication from the FDA that it considers this matter to be closed, we believe that we have demonstrated to FDA that we have adequately responded to these observations. 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 these 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 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. 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, we will need to rely on third parties, such as Eddingpharm in China, 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 proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the PPACA, enacted in March 2010, substantially changes the way healthcare is financed by both governmental and private insurers. Among other cost-containment measures, PPACA 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;
- a new formula that increases the rebates a manufacturer must pay under the Medicaid Drug Rebate Program; and
- new policies or laws affecting Vascepa sales, such as state and federal efforts to affect drug pricing and provide healthcare coverage that includes reimbursement for prescription drugs.

We expect further federal and state proposals and healthcare reforms to continue to be proposed by legislators, which could limit the prices that can be charged for the products we develop and may limit our commercial opportunity. It appears likely that the Affordable Care Act will continue the pressure on pharmaceutical pricing, especially under the Medicare and Medicaid programs, and may also increase our regulatory burdens and operating costs. Legislative changes to the Affordable Care Act remain possible under the Trump Administration.

The continuing efforts of government and other third-party payors to further contain or reduce the costs of healthcare through various means may limit our commercial opportunity. For example, the State of California recently 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. These and other measures at the federal and state levels, to the extent applicable to us, could negatively affect our revenue and results from operations.

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 PPACA 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.

In some foreign countries, including major markets in the European Union and Japan, 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.



***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 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 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 or marketing future products if we cannot meet the extensive regulatory requirements of the FDA and other regulatory agencies for quality, safety and efficacy.***

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;
- government or regulatory delays or "clinical holds" requiring suspension or termination of a trial; and

- political instability affecting our clinical trial sites, such as the potential for political unrest affecting our REDUCE-IT clinical trial sites in the Ukraine and Russia.

Even if we obtain positive results from early stage preclinical studies or clinical trials, we may not achieve the same success in future trials. 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, the efficacy results of our Vascepa Phase 3 clinical trials for the treatment of Huntington's disease were negative. As a result, we stopped development of that product candidate, revised our clinical strategy and shifted our focus to develop Vascepa for use in the treatment of cardiovascular disease. Questions can also arise on the quality of study data or its reliability. For example, during the public advisory committee meeting held by FDA as part of its review of our ANCHOR sNDA, a discussion regarding observed, nominally statistically significant changes from baseline in an adverse direction, while on background statin therapy, in certain lipid parameters, including triglycerides, in the placebo group, raised questions about the possibility that the mineral oil placebo used in the ANCHOR trial (and 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 in the ANCHOR trial. Ultimately, 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. The FDA, early on in the course of the REDUCE-IT trial, directed the DMC for REDUCE-IT to periodically review unblinded lipid data to monitor for signals that the placebo might not be inert. After each such quarterly unblinded safety analysis and review meeting to date, the DMC has recommended to continue the REDUCE-IT study as planned. Each of these ongoing DMC recommendations has been shared with FDA. Amarin and FDA remain blinded to such study data. Despite the currently positive disposition of this matter, it illustrates that concerns such as this may arise in the future that could affect our product development, regulatory review or the public perception of our products and our future prospects.

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 past or 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. We have a relatively small sales organization consisting of approximately 165 sales professionals, including sales representatives and their managers. We anticipate increasing our sales force to a total of approximately 400 to 500 sales professionals after REDUCE-IT results, assuming success. 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 key 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 any manufacturer 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, 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 initially purchased all of our supply of the bulk compound (ethyl-EPA), or Vascepa API, from a single supplier, Nisshin Pharma, Inc., or Nisshin, located in Japan. Nisshin was approved by the FDA as a Vascepa API supplier as part of our FDA NDA for the MARINE indication in July 2012. In April 2013, we announced the approval by the FDA of an NDA supplement for Chemport, Inc. and BASF (formerly Equateq Limited) as additional Vascepa API suppliers. We terminated our agreement with BASF due to its inability to meet the agreement requirements, may enter into a new development and supply agreement with BASF, and may purchase API from BASF as it remains an NDA-approved supplier. In 2014, we obtained sNDA approval for a fourth supplier of API, which includes the manufacturing facility of Finorga SAS (Novasep). We currently purchase and use commercial supply from Novasep, Chemport, and Nisshin. Each of the API manufacturers obtains supply of the key raw material to manufacture API from other qualified third-parties.

While we have contractual freedom to source the API for Vascepa and have entered into supply agreements with multiple suppliers who also rely on other third-party suppliers to manufacture the API for Vascepa, Novasep, Nisshin and Chemport currently supply all of our API for Vascepa. Our strategy in adding API 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. For example, Chemport, which was approved as one of our API suppliers in April 2013, is a privately-held company and their commitment to Vascepa supply has required them to seek additional resources. 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 qualification of our API 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.

We currently have encapsulation agreements with three commercial API encapsulators for the encapsulation of Vascepa: Patheon, Inc. (formerly Banner Pharmacaps, now part of Thermo Fisher Scientific), Catalent Pharma Solutions, and Capsugel Plöermel SAS (now a Lonza company). These companies have qualified and validated their manufacturing processes and are capable of manufacturing Vascepa. There can be no guarantee that additional other suppliers with which we have contracted to encapsulate API will be qualified to manufacture the product to our specifications or that these and any future suppliers will have the manufacturing capacity to meeting 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.

***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 pharmaceutical 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 and International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, or ICH, regulations who 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, 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 which could significantly and adversely affect our business.

***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 assure 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 62 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 62 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;
- 45 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;
- 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;
- 1 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 a formulation of EPA/DHA and uses thereof with a term that expires in 2030;
- 1 additional patent related to the use of Vascepa to treat obesity with a term that expires in 2030;
- 2 additional patents covering a pharmaceutical composition comprised of EPA and a hydroxyl compound with a term that expires in 2034; and
- 3 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 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. 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 expected launch of Epanova, a product that is expected to compete with Vascepa in the United States. The patent covers methods of lowering triglycerides by administering a pharmaceutical composition that includes amounts of EPA as free acid, and no more than about 30% DHA. In November 2014, based on a representation from AstraZeneca Pharmaceuticals LP 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. We intend to pursue this litigation vigorously and aggressively protect its intellectual property rights. However, 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 and ANCHOR trials. If granted, many of the resulting granted patents would expire in 2030 or beyond. However, no assurance can be given that these additional MARINE and ANCHOR patents or any of our pending patent applications intended to cover an indication based on future 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 2018, we issued financial and business guidance, including expected fiscal year 2018 total net revenue and expectations regarding improved cash flow from commercial operations and timing of the REDUCE-IT outcomes trial. All such

guidance is 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 2018 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 or other expectations about our business, our stock price could decline in value.

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

We are engaged in the biopharmaceutical 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.

***We are subject to potential product liability.***

Following the commercial launch of Vascepa, we will be 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.

***We may become subject to liability in connection with the wind-down of our EN101 program.***

In 2007, we purchased Ester Neurosciences Limited, or Ester, an Israeli pharmaceutical company, and its lead product candidate, EN101, an AChE-R mRNA inhibitor for the treatment of myasthenia gravis, or MG, a debilitating neuromuscular disease. In connection with the acquisition, we assumed a license to certain intellectual property assets related to EN101 from the Yisum Research Development Company of The Hebrew University of Jerusalem, or Yisum. In keeping with our 2009 decision to re-focus our efforts on developing improved treatments for cardiovascular disease and cease development of all product candidates outside of our cardiovascular disease focus, we amended the terms of our acquisition agreement with the original shareholders of Ester.

Following our decision to cease development of EN101, Yisum terminated its license agreement with us. In June 2011, Yisum announced that it had entered into a license agreement with BiolineRX Ltd for the development of EN101 in a different indication, inflammatory bowel disease.

In 2011 and early 2012, but not after, we received several communications on behalf of the former shareholders of Ester asserting that we are in breach of our agreement with them as it relates to alleged rights to share in the value of EN101 due to the fact that Yisum terminated its license. We do not believe the circumstances presented constitute a breach of the agreement. If the dispute arises again, we plan to defend our position vigorously, but there can be no assurance as to the outcome of this dispute.

***A change in our tax residence could have a negative effect on our future profitability.***

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. Where a company is 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 Convention between the UK and Ireland provides that such enterprise shall be treated as resident only in the jurisdiction in which its place of effective management is situated. We have sought to conduct our affairs in such a way so as to be resident only in Ireland for tax purposes by virtue of having our place of effective management situated in Ireland. Trading income of an Irish company is generally taxable at the Irish corporation tax rate of 12.5%. Non-trading income of an Irish company (e.g., interest income, rental income or other passive income) is taxable at a rate of 25%.

However, we cannot assure you that we are or will continue to be resident only 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. Our and our subsidiaries' income tax returns are periodically examined by various tax authorities. We are currently undergoing federal and state tax audits, including audit by the United States Internal Revenue Service (IRS) for the years 2013 to 2014. Although the outcome of tax audits is always uncertain and could result in significant cash tax payments, we do not believe the outcome of these audits will have a material adverse effect on our consolidated financial position or results of operations. The ultimate resolution may result in a payment that is materially different from our current estimate of the tax liabilities. Should we cease to be an Irish tax resident, we may be subject to a charge to Irish capital gains tax on our assets. Similarly, if the tax residency of any of our subsidiaries were to change

from their current jurisdiction for any of the reasons listed above, we may be subject to a charge to local capital gains tax charge on the assets.

***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 33%, 28%, and 27%, respectively, of gross product sales for the year ended December 31, 2017 and represented 21%, 41%, and 27%, respectively, of the gross accounts receivable balance as of December 31, 2017. Customers A, B, and C accounted for 37%, 30%, and 28%, respectively, of gross product sales for the year ended December 31, 2016 and represented 33%, 16%, and 47%, respectively, of the gross accounts receivable balance as of December 31, 2016. There can be no guarantee that we will be able to sustain our accounts receivable or gross sales levels from our key customers. If, for any reason, we were to lose, or experience a decrease in the amount of business with our largest customers, whether directly or through our distributor relationships, our financial condition and results of operations could be negatively affected.

**Risks Related to our Financial Position and Capital Requirements**

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

We have not yet reached profitability. For the fiscal years ended December 31, 2017, 2016, and 2015, we reported losses of approximately \$67.9 million, \$86.4 million, and \$149.1 million, respectively, and we had an accumulated deficit as of December 31, 2017 of \$1.3 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 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 attain 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 in the MARINE indication, it may not gain market acceptance or achieve commercial success and it may never be approved for the ANCHOR indication or any other indication. In addition, we anticipate continuing to incur significant costs associated with commercializing Vascepa. We may not achieve profitability in the near term due to high costs associated with our REDUCE-IT study and commercialization efforts, for example. If we are unable to continue to generate robust product revenues, we will not become profitable in the near term, if ever, and may be unable to continue operations without continued funding.

***Our historical financial results do not form an accurate basis for assessing our current business.***

As a consequence of the many years developing Vascepa for commercialization and the commercial launch of Vascepa in 2013 in the United States, our historical financial results do not form an accurate basis upon which investors should base their assessment of our business and prospects. In addition, we expect that our costs will increase substantially as we continue to commercialize Vascepa in the MARINE indication and with ANCHOR data and seek to obtain additional regulatory approval of Vascepa from continuation of



the REDUCE-IT cardiovascular outcomes study. Accordingly, our historical financial results reflect a substantially different business from that currently being conducted and from that expected in the future. In addition, we have a limited history of obtaining regulatory approval for, and no demonstrated ability to successfully commercialize, a product candidate. Consequently, any predictions about our future performance may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.

***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 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;
- the timing, cost and level of investment in our sales and marketing efforts to support Vascepa sales and the resulting effectiveness of those efforts with our co-promotion partner, Kowa Pharmaceuticals America, Inc.;
- the timing and ability of commercialization partners outside the United States, to develop, register and commercialize Vascepa in the China Territory, several Middle Eastern and North African countries, and Canada, for example, including obtaining necessary regulatory approvals and establishing marketing channels;
- additional developments regarding our intellectual property portfolio and regulatory exclusivity protections, if any;
- the timing and nature of results of the REDUCE-IT study or post-approval studies for Vascepa;
- outcomes of litigation and other legal proceedings; and
- our regulatory dialogue on the REDUCE-IT study.

***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. In February 2018, we received approximately \$65.0 million of net proceeds from a registered offering of our ADSs. We believe that our cash and cash equivalents balance of \$73.6 million as of December 31, 2017, together with the approximately \$65.0 million received in February 2018, will be sufficient to fund our projected operations through the results of the REDUCE-IT study, which we anticipate will be available before the end of the third quarter of 2018 and, assuming positive results of the REDUCE-IT study, through subsequent public presentation of such results at a medical congress before the end of 2018. Depending on the level of cash generated from operations, additional capital may be required to expand promotion of Vascepa as contemplated following anticipated successful results of the REDUCE-IT study. If additional capital is required and we are unable to obtain additional capital, we may be forced to delay, limit or eliminate all or a portion of the expanded promotional activities planned following successful results of the REDUCE-IT study. 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. We may also need additional capital to fully complete our REDUCE-IT cardiovascular outcomes trial.

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 indications in the United States and in jurisdictions in which we receive regulatory approval, if any, including the cost of sales and marketing capabilities with our co-promotion partner, Kowa Pharmaceuticals America, Inc., and 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;
- the continued cost associated with our REDUCE-IT cardiovascular outcomes study and subsequent publication of REDUCE-IT results;

- continued costs associated with litigation and other legal proceedings;
- the time and costs involved in obtaining additional regulatory approvals for Vascepa after REDUCE-IT results;
- 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, and we may need to delay the advancement of the REDUCE-IT cardiovascular outcomes trial.

***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 developed Vascepa in and from Ireland. 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 to 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. 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 which 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 profitability, if at all. 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 on our future profitability.

***Continued 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 a further 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.

In January 2012, Corsicanto DAC (in liquidation) (formerly Corsicanto Limited), or Corsicanto, issued \$150.0 million in aggregate principal amount of 3.5% exchangeable senior notes due 2032, or the 2012 Notes. In May 2014, we entered into separate, privately negotiated exchange agreements with certain holders of the 2012 Notes pursuant to which Corsicanto exchanged \$118.7 million in aggregate principal amount of the existing 2012 Notes for \$118.7 million in aggregate principal amount of new 3.5% May 2014 exchangeable senior notes due 2032, or the 2014 Notes. In November 2015, we issued \$31.3 million in aggregate principal amount of 3.5% exchangeable senior notes due 2032, or the 2015 Notes, and used \$16.2 million of the proceeds to repay a portion of the 2012 Notes, such that \$15.1 million of 2012 Notes remained outstanding. In September 2016, we mandatorily exchanged the entirety of the 2014 Notes and 2015 Notes, in accordance with their respective terms, into 60,311,188 ADSs. In January 2017, approximately \$15.0 million of the 2012 Notes were put to us and, in March 2017, we redeemed the entirety of the remaining \$0.1 million of outstanding principal amount of 2012 Notes plus accrued but unpaid interest, such that no 2012 Notes remain outstanding. A liquidator was appointed to Corsicanto on September 7, 2017 pursuant to a resolution of Amarin Corporation plc as sole shareholder.

In January 2017, Corsicanto II DAC, or Corsicanto II, issued \$30.0 million in aggregate principal amount of 3.5% exchangeable senior notes due 2047, or the 2017 Notes. In the event of physical settlement, the 2017 Notes would be exchangeable into a total of 7,716,048 ADSs.

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. For example, in March 2014, we entered into a co-promotion agreement with Kowa Pharmaceuticals America, Inc. related to the commercialization of Vascepa in the United States. 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 23, 2018, we had 292,318,731 common shares outstanding including 291,318,286 shares held as ADSs and 1,000,445 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.

***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 the three months ended June 30, 2015, 62,833,330 preferred shares were converted, resulting in the issuance of 6,283,333 ordinary shares. The consolidation and redesignation of the Series A Preference Shares currently outstanding would result in an additional 32,818,464 ordinary shares outstanding, resulting in substantial dilution to shareholders who held our ordinary shares or ADSs representing such ordinary shares prior to the private placement. 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 offer to certain investors party to that agreement an opportunity to participate in future equity and debt financings we may conduct from time to time, and 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.

***A share price of less than \$1.00 may impact our NASDAQ listing.***

If our closing bid price is less than \$1.00 for 30 consecutive trading days, we would receive a NASDAQ staff deficiency letter indicating that we are not in compliance with the minimum bid price requirement for continued listing. Such a letter would trigger an automatic 180 calendar day period within which the company could regain compliance. Compliance is regained at any time during this period if the Amarin closing bid price is \$1.00 per share or more for a minimum of 10 consecutive trading days. If we do not regain compliance during this period, our ADSs could be delisted from The NASDAQ Global Market, transferred to a listing on The NASDAQ Capital Market, or delisted from the NASDAQ markets altogether. The failure to maintain our listing on The NASDAQ Global Market could harm the liquidity of our ADSs and could have an adverse effect on the market price of our ADSs.

***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.

***We may be a passive foreign investment company, or PFIC, which would result in adverse U.S. federal tax consequences to U.S. investors.***

Amarin Corporation plc and certain of our subsidiaries may be classified as “passive foreign investment companies,” or PFICs, 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, which are beyond our ability to predict or control, and which may be subject to legal and factual uncertainties.

We believe it is prudent to assume that we were classified as a PFIC in 2012. We do not believe that we were classified as a PFIC in 2013 through 2017. Our status as a PFIC is subject to change in 2018 and future years.

If we are a PFIC, U.S. holders of notes, ordinary shares or ADSs would be subject to adverse U.S. federal income tax consequences, such as ineligibility for any preferred tax rates on capital gains or on actual or deemed dividends, interest charges on certain taxes treated as deferred, and additional reporting requirements under U.S. federal income tax laws and regulations. Whether or not U.S. holders of our ADSs make a timely “QEF election” or “mark-to-market election” may affect the U.S. federal income tax consequences to U.S. holders with respect to the acquisition, ownership and disposition of Amarin ADSs and any distributions such U.S. holders may receive. A QEF election and other elections that may mitigate the effect of our being classified as a PFIC are unavailable with respect to the notes. Investors should consult their own tax advisors regarding all aspects of the application of the PFIC rules to the notes, ordinary shares and ADSs.

***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 existing indebtedness could adversely affect our financial condition.***

Our existing indebtedness consists of \$30.0 million in aggregate principal amount of 3.5% exchangeable senior notes due 2047, or the 2017 Notes. The 2017 Notes contain a provision for such notes to be put to us by the holders for repayment in cash on January 19, 2022.

Our indebtedness and the related annual debt service requirements 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.

***The accounting for convertible debt securities that may be settled in cash, such as our 2017 Notes, could have a material effect on our reported financial results.***

Under the FASB Accounting Standards Codification, or ASC, we are required to separately account for the liability and equity components of the convertible debt instruments that may be settled entirely or partially in cash upon conversion in a manner that reflects the issuer's economic interest cost. The effect of ASC on the accounting for our outstanding convertible notes may be that the equity component is required to be included in the additional paid-in capital section of stockholders' equity on our consolidated balance sheets and the value of the equity component would be treated as original issue discount for purposes of accounting for the debt component of the notes. As a result, we are required to record non-cash interest expense as a result of the amortization of the discounted carrying value of the notes to their face amount over the term of the notes. We may be required to report higher interest expense in our financial results because ASC may require interest to include both the current period's amortization of the debt discount and the instrument's coupon interest, which could adversely affect our reported or future financial results and the trading price of our ADSs.

Servicing our debt may require a significant amount of cash, and we may not have sufficient cash flow from our business to provide the funds sufficient to pay our substantial debt.

Our ability to make scheduled payments of the principal, to pay interest on or to refinance our indebtedness, including the notes, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not continue to generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations, including the notes, and have a material adverse effect on the trading price of our ADSs.

We may be able to incur substantial additional debt in the future, subject to the restrictions contained in our future debt instruments, if any, which would intensify the risks discussed above.

***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.

***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.

***The effect of comprehensive U.S. tax reform legislation on Amarin is uncertain.***

On December 22, 2017, the U.S. government enacted 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” (informally titled 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, such as a one-time tax on earnings of certain foreign subsidiaries that were previously tax deferred and a new minimum tax on foreign earnings. While we recognized a provisional expense during the year ended December 31, 2017 based on what we believe is a reasonable estimate of the income tax effects of the Act, this expense could change materially as we refine our analysis. Other effects of the Tax Cuts and Jobs Act on our company, whether adverse or favorable, are also uncertain, and may not become evident for some period of time, but could have a material adverse effect on our business, financial position or results from operations.

**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 23, 2018:

Location	Use	Ownership	Size (sq. ft.)
Dublin, Ireland	Offices	Leased	270
Bedminster, New Jersey, USA	Offices	Leased	21,963

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 terminates on October 31, 2018 and may be renewed annually.

Effective July 1, 2011, we leased 9,747 square feet of office space in Bedminster, New Jersey. The lease, as amended, terminates on April 30, 2019, and may also be terminated with six months prior notice. On December 6, 2011 we leased an additional 2,142 square feet of space in the same location. On December 15, 2012 and May 8, 2013, we leased an additional 2,601 and 10,883 square feet of space, respectively, in the same location. In January 2014 and April 2014, we entered into separate transactions with the landlord of this property to vacate approximately 2,142 and 2,000 square feet of space in exchange for discounts on contractual future rent payments. In January 2015, we signed an agreement to sublease approximately 4,700 square feet of this property to a third party, effective April 1, 2015. This sublease agreement has been terminated as of September 30, 2017. Additionally, in June 2015, we executed an agreement to sublease approximately 2,500 square feet of this property to a separate third party, effective June 16, 2015. On December 15, 2016, we leased an additional 732 square feet of space in the same location, effective January 1, 2017.

We believe our existing facilities are adequate for our current needs and that additional space will be available in the future on commercially reasonable terms as needed.

**Item 3. *Legal Proceedings***

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, we 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. We intend to pursue this matter vigorously.



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 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. ("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.

We introduced to the market our 0.5-gram dose strength of Vascepa in October 2016. 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 abbreviated new drug application, or 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. 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 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, we are seeking, 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. This new lawsuit against Teva has been consolidated with the pending lawsuits against Teva, West-Ward, and DRL referenced above based on the 1-gram dose strength of Vascepa, and all four lawsuits will proceed on the same schedule.

On April 26, 2016, the U.S. District Court for the District of New Jersey granted our motion to dismiss the putative consolidated class action lawsuit captioned *In re Amarin Corporation plc, Securities Litigation*, No. 3:13-cv-06663 (D.N.J. Nov. 1, 2013). The class action was dismissed without prejudice with leave for plaintiffs to file an amended complaint. The lawsuit sought unspecified monetary damages and attorneys' fees and costs alleging that we and certain of our current and former officers and directors made misstatements and omissions regarding the FDA's willingness to approve Vascepa's ANCHOR indication and related contributing factors and the potential relevance of data from the ongoing REDUCE-IT trial to that potential approval. The April 2016 dismissal was the second motion to dismiss granted in favor of Amarin and related defendants in this litigation. The first motion to dismiss in this litigation was granted in June 2015 in response to the original complaint and related amendment. On May 26, 2016, plaintiffs appealed the most recent dismissal to the Third Circuit Court of Appeals. On May 23, 2017, the Third Circuit Court of Appeals affirmed the judgment of the U.S. District Court for the District of New Jersey that granted our motion to dismiss the putative consolidated class action lawsuit (Case No. 16-2640). Plaintiffs sought a rehearing and *en banc* review of such affirmation, each of which were denied. The appeal period for this matter has expired. We consider this matter closed.

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.

	Common Stock Price			
	Fiscal 2017		Fiscal 2016	
	High	Low	High	Low
First Quarter	\$ 3.58	\$ 2.81	\$ 1.88	\$ 1.24
Second Quarter	\$ 4.10	\$ 2.85	\$ 2.35	\$ 1.45
Third Quarter	\$ 4.47	\$ 2.97	\$ 3.46	\$ 2.11
Fourth Quarter	\$ 4.24	\$ 3.04	\$ 3.65	\$ 2.75

#### Shareholders

As of January 31, 2018, there were approximately 375 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.

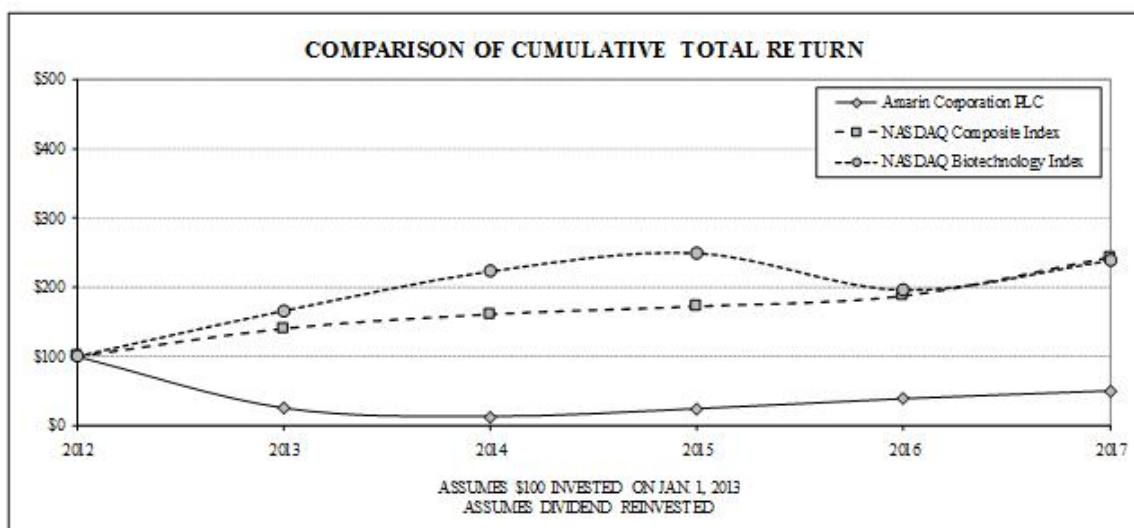
Under our Purchase and Sale Agreement with CPPIB Credit Europe S.à r.l., or CPPIB, as successor in interest to BioPharma Secured Debt Fund II Holdings Cayman LP, we are restricted from paying a dividend on our common shares, unless we have cash and cash equivalents in excess of a specified amount after 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, 2013 and its relative performance is tracked through December 31, 2017.

Included in this 5-year time period is the substantial negative impact on the price of Amarin's ADSs in 2013 when the FDA notified us that it rescinded the ANCHOR study SPA agreement because the FDA determined that a substantial scientific issue essential to determining the effectiveness of Vascepa in the studied population was identified after testing began in the ANCHOR trial. The FDA expressed that this scientific issue arose based on data from the study of other drugs by other companies related to lipid modification. This FDA notification was followed in 2013 by a reduction in force by Amarin and retargeting of the commercial targets for promotion of Vascepa. More recently, over the 3-year time period through December 31, 2017, cumulative total return for Amarin's ADSs exceeded both the NASDAQ Composite Index and NASDAQ Biotechnology Index. In particular, the total return for Amarin's ADSs well exceeded the cumulative returns for the NASDAQ Composite Index and NASDAQ Biotechnology Index in each of the past two calendar years.

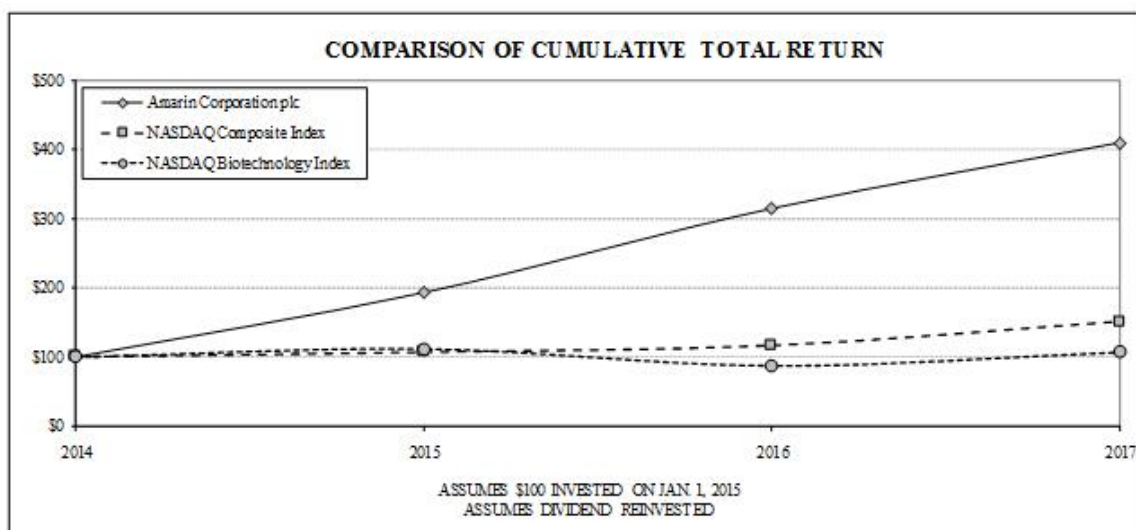


Company/Market/Peer Company	12/31/2013	12/31/2014	12/31/2015	12/31/2016	12/31/2017
Amarin Corporation PLC	\$ 24.35	\$ 12.11	\$ 23.36	\$ 38.07	\$ 49.57
NASDAQ Composite Index	\$ 140.12	\$ 160.78	\$ 171.97	\$ 187.22	\$ 242.71
NASDAQ Biotechnology Index	\$ 166.02	\$ 223.13	\$ 249.39	\$ 196.15	\$ 238.64

#### 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, 2015 and its relative performance is tracked through December 31, 2017.



Company/Market/Peer Company	12/31/2015	12/31/2016	12/31/2017
Amarin Corporation PLC	\$ 192.86	\$ 314.29	\$ 409.18
NASDAQ Composite Index	\$ 106.96	\$ 116.45	\$ 150.96
NASDAQ Biotechnology Index	\$ 111.77	\$ 87.91	\$ 106.95

### 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 2017 are as follows:

Period	Total Number of Shares Purchased (1)	Average Price Paid per Share
October 1 – 31, 2017	—	\$ —
November 1 – 30, 2017	—	—
December 1 – 31, 2017	43,617	4.01
Total	43,617	\$ 4.01

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

## UNITED KINGDOM TAXATION

### 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 common shares or ADSs unless the common shares or ADSs are held in connection with your trade carried on in the UK through a branch or agency and the common 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 common 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 common 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 common shares or ADSs 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 common share or ADS is part of the business property of your UK permanent establishment.

Where the common 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 common shares or ADSs will not generally be subject to UK inheritance tax.

### Stamp Duty and Stamp Duty Reserve Tax

#### *Transfer of ADSs*

No UK stamp duty will be payable on an instrument transferring an ADS or on a written agreement to transfer an ADS provided that the instrument of transfer or the agreement to transfer is executed and remains at all times outside the UK. Where these conditions are not met, the transfer of, or agreement to transfer, an ADS could, depending on the circumstances, attract a charge to ad valorem stamp duty at the rate of 0.5% of the value of the consideration.

No stamp duty reserve tax will be payable in respect of an agreement to transfer an ADS, whether made in or outside the UK.

#### *Issuance and Transfer of Common Shares*

The issuance of common shares by Amarin will not give rise to a charge to UK stamp duty or stamp duty reserve tax under current UK and European Union law; it is not currently known whether this position will continue for UK stamp duty reserve tax in relation to the issuance of common shares in return for an issuance of ADSs after the United Kingdom leaves the European Union. In the event of a change in this position resulting in the issuance of common shares by Amarin giving rise to a charge to UK stamp duty or stamp duty reserve tax, Amarin would be responsible for any such UK stamp duty reserve tax payable on the issuance of common shares in return for the issuance of ADSs.

Transfers of common shares, as opposed to ADSs, will attract ad valorem stamp duty at the rate of 0.5% of the amount or value of the consideration. A charge to stamp duty reserve tax, at the rate of 0.5% of the amount or value of the consideration, will arise on an agreement to transfer common 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 common shares or ADSs.

**Item 6. Selected Financial Data**

The selected financial data set forth below as of and for the years ended December 31, 2017, 2016, 2015, 2014, and 2013 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,				
	2017	2016	2015	2014	2013
(In thousands, except per share amounts)					
<b>Consolidated Statements of Operations Data:</b>					
Product revenue, net	\$ 179,825	\$ 128,966	\$ 80,987	\$ 54,202	\$ 26,351
Licensing revenue	1,279	1,118	769	—	—
Total revenue, net	181,104	130,084	81,756	54,202	26,351
Less: Cost of goods sold	44,952	34,363	27,875	20,485	11,912
Gross margin	136,152	95,721	53,881	33,717	14,439
Operating expenses:					
Selling, general and administrative (1)	134,549	111,372	101,041	79,346	123,795
Research and development	47,158	49,975	51,062	50,326	72,750
Total operating expenses	181,707	161,347	152,103	129,672	196,545
Operating loss	(45,555)	(65,626)	(98,222)	(95,955)	(182,106)
Gain (loss) on change in fair value of derivative liabilities (2)	—	8,170	(1,106)	13,472	47,710
Gain on extinguishment of debt	—	—	1,314	38,034	—
Interest expense	(9,766)	(18,677)	(20,180)	(18,575)	(34,179)
Interest income	429	234	132	96	343
Other income (expense), net	74	(482)	(228)	3,727	(1,189)
Loss from operations before taxes	(54,818)	(76,381)	(118,290)	(59,201)	(169,421)
(Provision for) benefit from income taxes (5)	(13,047)	(9,969)	3,086	2,837	3,194
Net loss	(67,865)	(86,350)	(115,204)	(56,364)	(166,227)
Preferred stock purchase option	—	—	(868)	—	—
Preferred stock beneficial conversion features	—	—	(32,987)	—	—
Net loss applicable to common shareholders	(67,865)	(86,350)	(149,059)	(56,364)	(166,227)
Loss per share:					
Basic	\$ (0.25)	\$ (0.41)	\$ (0.83)	\$ (0.32)	\$ (1.03)
Diluted	\$ (0.25)	\$ (0.41)	\$ (0.83)	\$ (0.36)	\$ (1.28)
Weighted average shares:					
Basic	270,652	211,874	180,654	173,719	161,022
Diluted	270,652	211,874	180,654	173,824	167,070

	As of December 31,				
	2017	2016	2015	2014	2013
(In thousands)					
<b>Consolidated Balance Sheet Data:</b>					
Cash and cash equivalents	\$ 73,637	\$ 98,251	\$ 106,961	\$ 119,539	\$ 191,514
Total assets (3) (4)	161,598	166,999	173,230	168,886	252,476
Long-term liabilities (3)	118,168	99,808	250,059	217,028	248,792
Stockholders’ deficit (4)	(65,100)	(9,058)	(127,552)	(88,448)	(33,856)

- (1) Includes non-cash warrant-related compensation income in 2013, 2014 and 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. See further discussion in Notes 2 and 7 of the Notes to the Consolidated Financial Statements.

- (2) Includes non-cash charges resulting from changes in the fair value of derivative liabilities. See further discussion in Notes 2, 7 and 8 of the Notes to the Consolidated Financial Statements.
- (3) Reflects reclassification of \$1.9 million and \$2.2 million as of December 31, 2015 and 2014, respectively, 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 (“ASU”) No. 2015-03, *Interest—Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs*, adopted in January 2016. No such adjustment was needed as of December 31, 2013 as debt issuance costs were already presented as a deduction from debt in that year.
- (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. See further discussion in Notes 2 and 10 of the Notes to the Consolidated Financial Statements.
- (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 expected timing of enrollment, interim results and final results of our REDUCE-IT study; 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, 2017.*

### **Overview**

We are a biopharmaceutical company with expertise in lipid science focused on the commercialization and development of therapeutics to improve cardiovascular health.

Our lead product, Vascepa® (icosapent ethyl) capsules, is approved by the U.S. Food and Drug Administration, or FDA, for use as an adjunct to diet to reduce triglyceride levels in adult patients with severe (TG ≥500 mg/dL) hypertriglyceridemia. This FDA-approved indication for Vascepa, known as the MARINE indication, is based primarily on the successful results from the MARINE study of Vascepa in this approved patient population. In considering this approval, FDA also reviewed the successful results from our study of Vascepa in patients with high triglyceride levels (TG ≥200 mg/dL and <500 mg/dL) who are also on statin therapy for elevated low-density lipoprotein cholesterol, or LDL-C, levels which condition we refer to as mixed dyslipidemia or persistently high triglycerides. This study is known as the ANCHOR study. Safety data from both the MARINE and ANCHOR studies are reflected in FDA-approved labeling for Vascepa. In January 2013, we began selling and marketing Vascepa in the United States based on the FDA-approved MARINE indication. In August 2015, we began communicating promotional information beyond the MARINE indication to healthcare professionals in the United States based on the federal court declaration described below. In March 2016, we reached agreement with the FDA and U.S. government under which they agreed to be bound by the terms of the August 2015 judicial declaration. Vascepa is available in the United States by prescription only.

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. We market Vascepa in the United States through our direct sales force. In March 2014, we entered into a co-promotion agreement in the United States with Kowa Pharmaceuticals America, Inc. under which Kowa



Pharmaceuticals America, Inc. began to co-promote Vascepa in conjunction with its promotion of its primary product, a branded statin for patients with high cholesterol, which commenced in May 2014 and is scheduled to end at the end of 2018. Our direct sales force has, for the past few years through late 2017, consisted of approximately 150 sales professionals, including sales representatives and their managers. During the fourth quarter of 2017, we added approximately 15 sales representatives, bringing our direct sales force in the United States to approximately 165 sales professionals. We anticipate increasing our direct sales force to approximately 400 to 500 sales professionals after REDUCE-IT results, assuming success. We also intend to expand medical education and market awareness initiatives, including, in advance of REDUCE-IT results being known, pilot testing of new promotional initiatives for potential broader applications following REDUCE-IT results.

In February 2015, we entered into an exclusive agreement with Eddingpharm (Asia) Macao Commercial Offshore Limited, or Eddingpharm, to develop and commercialize Vascepa capsules in Mainland China, Hong Kong, Macau and Taiwan, or the China Territory. In March 2016, we entered into an agreement with Biologix FZCo, or Biologix, to register and commercialize Vascepa in countries within the Middle East and North Africa. In September 2017, we entered into an agreement with HLS Therapeutics Inc., or HLS, to register, commercialize and distribute Vascepa in Canada. We continue to assess other partnership opportunities for licensing Vascepa to partners outside of the United States.

Triglycerides are the main constituent of body fat in humans. Hypertriglyceridemia refers to a condition in which patients have high levels of triglycerides in the bloodstream. It is estimated that over 70 million adults in the United States have elevated triglyceride levels ( $TG \geq 150$  mg/dL), approximately 40 million adults in the United States have high triglyceride levels ( $TG \geq 200$  mg/dL), and approximately 3 to 4 million adults in the United States have severely high triglyceride levels ( $TG \geq 500$  mg/dL), commonly known as very high triglyceride levels. Many patients with high triglyceride levels also have diabetes and other lipid level abnormalities such as high cholesterol. The patient condition of having more than one lipid level abnormality is referred to as mixed dyslipidemia. According to *The American Heart Association Scientific Statement on Triglycerides and Cardiovascular Disease* (2011), triglycerides provide important information as a marker associated with the risk for heart disease and stroke, especially when an individual also has low high-density lipoprotein cholesterol, or HDL-C (often referred to as “good” cholesterol), and elevated levels of LDL-C (often referred to as “bad” cholesterol). Guidelines for the management of very high triglyceride levels suggest that reducing triglyceride levels is the primary goal in patients to reduce the risk of acute pancreatitis. The effect of Vascepa on cardiovascular mortality and morbidity, or the risk for pancreatitis, in patients with hypertriglyceridemia has not been determined.

We are currently focused on completing the ongoing REDUCE-IT (Reduction of Cardiovascular Events with EPA—Intervention Trial) cardiovascular outcomes study of Vascepa, which we started in December 2011. REDUCE-IT, a multinational, prospective, randomized, double-blind, placebo-controlled study, is the first prospective cardiovascular outcomes study of any drug in a population of patients who, despite stable statin therapy, have elevated triglyceride levels. Based on the results of REDUCE-IT, we plan to seek additional indicated uses for Vascepa. In REDUCE-IT, cardiovascular event rates for patients on stable statin therapy plus 4 grams per day of Vascepa will be compared to cardiovascular event rates for patients on stable statin therapy plus placebo.

In 2016, we completed patient enrollment and randomization of 8,175 individual patients into the REDUCE-IT study, exceeding the 8,000 patients targeted for the trial. The REDUCE-IT study is designed to be completed after reaching 1,612 aggregate primary cardiovascular events. Based on projected event rates, we estimate the onset of the target aggregate number of primary cardiovascular events to be reached near the end of the first quarter of 2018 with study results then expected to be available and made public before the end of the third quarter of 2018, followed by publication of the results. Between reaching the estimated onset of the target 1,612 aggregate primary cardiovascular events and study data being unblinded and disclosed, vital data will be collected from all remaining living patients in the study and data in the study will be rolled-up for evaluation by the independent data monitoring committee, or DMC, and creation of a final study report. We have instructed clinical sites to schedule patients enrolled in the study for their final site visits commencing March 1, 2018.

The REDUCE-IT study, since its inception in 2011, has been conducted under a special protocol assessment, or SPA, agreement with the FDA. This SPA, as amended, provides for periodic safety reviews by the study’s DMC. In addition, the SPA, as amended, provided for interim efficacy and safety analyses by the study’s DMC at approximately 60% and at approximately 80% of the target aggregate number of primary cardiovascular events. The periodic safety reviews and interim efficacy and safety analyses were conducted confidentially by the study’s DMC. We remain blinded to all data from the study. Until the study is completed or the study is halted due to a patient safety concern (not expected), Amarin personnel will remain blinded to the efficacy and safety data from the REDUCE-IT study. Since patient enrollment commenced in 2011, over 33,000 patient years of study experience have been accumulated in the REDUCE-IT study. Following each periodic review of safety data to date, which have occurred quarterly since 2013, and following each of two interim efficacy and safety analyses, the DMC has communicated to us that we should continue the study as planned. The p-value used to assess the primary endpoint in REDUCE-IT at completion, assuming 1,612 aggregate primary cardiovascular events, is  $p < 0.0436$ . In January 2018, we announced that more than 90% of the 1,612 targeted aggregate number of primary cardiovascular events have been reported and documented.

Our scientific rationale for the REDUCE-IT study is supported by (i) epidemiological data that suggests elevated triglyceride levels correlate with increased cardiovascular disease risk, (ii) genetic data that suggests triglyceride and/or triglyceride-rich lipoproteins (as well as low-density lipoprotein cholesterol (LDL cholesterol), 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. Our scientific rationale for the REDUCE-IT study is also supported by research on the putative cardioprotective effects of EPA as presented in scientific literature. It is possible that the effects of EPA may be due not 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. The REDUCE-IT study is needed to determine the clinical benefit, if any, of EPA therapy in statin-treated patients with elevated triglyceride levels.

In the successful Phase 3 MARINE and ANCHOR clinical trials, Vascepa was studied at a daily dose of 2 grams and 4 grams. We sought approval of Vascepa at the more efficacious 4-gram dose for use in each patient population. These trials demonstrated favorable results in their respective patient populations, particularly with the 4-gram dose of Vascepa, in reducing triglyceride levels without increasing LDL-C levels in the MARINE trial and with a statistically significant decrease in LDL-C levels in the ANCHOR trial, in each case, relative to placebo. These trials also showed favorable results, particularly with the 4-gram dose of Vascepa, in other important lipid and inflammation biomarkers, including apolipoprotein B (apo B), non-high-density lipoprotein cholesterol (non-HDL-C), total-cholesterol (TC), very low-density lipoprotein cholesterol (VLDL-C), lipoprotein-associated phospholipase A2 (Lp-PLA2), and high sensitivity C-reactive protein (hs-CRP). In these 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).

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 special protocol assessment, or 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 and the FDA has encouraged us to complete the REDUCE-IT outcomes study. Based on our communications with the FDA, we expect that final positive results from the REDUCE-IT outcomes study will be required for label expansion for Vascepa.

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 reflects recognized medical practice but is not covered by 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 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. 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.

#### *Commercialization—United States*

We commenced the commercial launch of 1-gram size Vascepa capsules in the United States in January 2013. We commenced sales and shipments of Vascepa at that time to our network of U.S.-based wholesalers. We currently market Vascepa in the United States through our direct sales force of approximately 165 sales professionals, including sales representatives and their managers. We anticipate increasing our sales force to a total of approximately 400 to 500 sales professionals after REDUCE-IT results, assuming success. Commencing in May 2014, in addition to Vascepa promotion by our sales representatives, Kowa Pharmaceuticals America, Inc. began co-promoting Vascepa in conjunction with its promotion of its primary product, a branded statin for patients with high

cholesterol. We also employ various medical affairs and marketing personnel to support our commercialization of Vascepa. We intend to expand medical education and market awareness initiatives, including, in advance of REDUCE-IT results being known, pilot testing of new promotional initiatives for potential broader applications following REDUCE-IT results.

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 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.

Under our co-promotion agreement with Kowa Pharmaceuticals America, Inc., both parties have agreed to use commercially reasonable efforts to promote, detail and optimize sales of Vascepa in the United States and have agreed to specific performance requirements detailed in the related agreement. The performance requirements include a negotiated minimum number of sales details to be delivered by each party in the first and second position, the use of a negotiated number of minimum sales representatives from each party, and the achievement of minimum levels of Vascepa revenue in 2015 and beyond. First position refers to when a sales representative's primary purpose in detailing is related to Vascepa, while second position refers to when a sales representative's primary purpose in detailing is to promote another product, but they also devote time in the same sales call to promote Vascepa. Kowa Pharmaceuticals America, Inc. has also agreed to bear the costs incurred for its sales force associated with the commercialization of Vascepa and to pay for certain incremental costs associated with the use of its sales force, such as sample costs and costs for promotional and marketing materials. We will continue to recognize all revenue from sales of Vascepa. In exchange for Kowa Pharmaceuticals America, Inc.'s co-promotional services, Kowa Pharmaceuticals America, Inc. is entitled to a quarterly co-promotion fee based on a percentage of aggregate Vascepa gross margin that varies during the term. The percentage of aggregate Vascepa gross margin earned by Kowa Pharmaceuticals America, Inc. was, as amended, approximately eighteen percent (18%) in 2017, partially offset by certain other refinements. During 2018, which is the last year of the agreement, as amended, we anticipate incurring expense for both the annual co-promotion fee, which in 2018 will again be calculated as a percentage of Vascepa gross margin at a modestly higher rate than in 2017, plus accrual for co-promotion tail payments. Assuming Kowa Pharmaceuticals America, Inc. fulfills its obligations in accordance with the terms of the agreement, as amended, after expiration of the agreement, Kowa Pharmaceuticals America, Inc. is eligible to receive up to three years of co-promotion tail payments equal to declining percentages of the co-promotion fee amount earned in the final year of the agreement with the sum of the three years of co-promotion tail payments totaling less than the co-promotion fee amount earned in the final year of the agreement.

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, 2017 was approximately 394,000 compared to 374,000, 344,000, 305,000, and 286,000 in the three months ended September 30, 2017, June 30, 2017, March 31, 2017, and December 31, 2016, respectively. According to data from another third party, IQVIA (formerly QuintilesIMS), the estimated number of normalized total Vascepa prescriptions for the three months ended December 31, 2017 was approximately 406,000 compared to 372,000, 344,000, 307,000, and 289,000 in the three months ended September 30, 2017, June 30, 2017, March 31, 2017, and December 31, 2016, 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.

The data reported above is based on information made available to us from third-party resources and may be subject to adjustment and may overstate or understate actual prescriptions. 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.*"

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 are being made pursuant to the August 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 and presentation of the current state of scientific research related to the potential of Vascepa to reduce the risk of cardiovascular disease including through use of peer-reviewed scientific publications of available data.

#### *Commercialization—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 based on the MARINE, ANCHOR and ongoing REDUCE-IT clinical trials of Vascepa.

Under the agreement, Eddingpharm is responsible for development and commercialization activities in the China Territory and associated expenses. We will provide development assistance and be responsible for supplying the product. Terms of the agreement include up-front and milestone payments to us of up to \$169.0 million, including a non-refundable \$15.0 million up-front payment received at closing, a non-refundable milestone payment of \$1.0 million received upon successful submission of a clinical trial application, or CTA, with respect to the MARINE indication for Vascepa to the Chinese regulatory authority in March 2016. 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. We are also entitled to receive future regulatory and sales-based milestone payments of up to an additional \$153.0 million. 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 \$1.0 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. Eddingpharm will also pay us tiered double-digit percentage royalties on net sales of Vascepa in the China Territory escalating to the high teens. We will supply finished product to Eddingpharm under negotiated terms.

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. Upon closing of the agreement, we 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. We receive all payments based on total product sales and pay 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 September 2017, we entered into an agreement with HLS to register, commercialize and distribute Vascepa in Canada. Under the agreement, HLS will be responsible for regulatory and commercialization activities and associated costs. We will be 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. Terms of the agreement include up-front and milestone payments to us of up to \$65.0 million. These payments include a non-refundable \$5.0 million up-front payment to be received in two equal installments, the first of which was received at closing with the second to be received upon the six-month anniversary of the closing. In addition to the non-refundable, up-front payment, we are entitled to receive certain regulatory and sales-based milestone payments of up to an additional \$60.0 million, the timing and achievability of which cannot be determined at least until discussions with Canadian regulatory authorities have commenced, as well as tiered double-digit royalties on net sales of Vascepa in Canada.

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

#### *Research and Development*

REDUCE-IT is the first prospective cardiovascular outcomes study of any drug in a population of patients who, despite stable statin therapy, have elevated triglyceride levels. REDUCE-IT is a multinational, prospective, randomized, double-blind, placebo-controlled study designed to assess the cumulative effect on the rate of cardiovascular events for patients treated with Vascepa as an add-on to statin therapy compared to the corresponding rate of cardiovascular events for patients treated with placebo on top of statin therapy. REDUCE-IT is not designed to demonstrate that lowering triglycerides alone in the study population is sufficient to lower the rate of major adverse cardiovascular events compared to placebo. Rather, it is designed to test the hypothesis that the clinical effects of Vascepa, including its impact on triglyceride lowering, are effective in lowering the rate of major adverse cardiovascular events compared to placebo in patients who despite statin therapy have risk factors for cardiovascular disease, including elevated triglyceride levels. Based on the results of REDUCE-IT, we may seek additional indications for Vascepa beyond the indications studied in the ANCHOR or MARINE trials.

In 2016, we completed patient enrollment and randomization of 8,175 individual patients into the REDUCE-IT study, exceeding the 8,000 patients targeted for the trial. The REDUCE-IT study is designed to be completed after reaching 1,612 aggregate primary cardiovascular events. Based on projected event rates, we estimate the onset of the target aggregate number of primary cardiovascular events to be reached near the end of the first quarter of 2018 with study results then expected to be available and made public before the end of the third quarter of 2018, followed by publication of the results. Between reaching the estimated onset of the target 1,612 aggregate primary cardiovascular events and study data being unblinded and disclosed, vital data will be collected from all remaining living patients in the study and data in the study will be rolled-up for evaluation by the DMC and creation of a final study report. We have instructed clinical sites to schedule patients enrolled in the study for their final site visits commencing March 1, 2018.

The REDUCE-IT study, since its inception in 2011, has been conducted under a SPA agreement with the FDA. This SPA, as amended, provides for periodic safety reviews by the study's DMC. In addition, the SPA, as amended, provided for interim efficacy and safety analyses by the study's DMC at approximately 60% and at approximately 80% of the target aggregate number of primary cardiovascular events. The periodic safety reviews and interim efficacy and safety analyses were conducted confidentially by the study's DMC. We remain blinded to all data from the study. Until the study is completed or the study is halted due to a patient safety concern (not expected), Amarin personnel will remain blinded to the efficacy and safety data from the REDUCE-IT study. Since patient enrollment commenced in 2011, over 33,000 patient years of study experience have been accumulated in the REDUCE-IT study. Following each periodic review of safety data to date, which have occurred quarterly since 2013, and following each of two interim efficacy and safety analyses, the DMC has communicated to us that we should continue the study as planned. The p-value used to assess the primary endpoint in REDUCE-IT at completion, assuming 1,612 aggregate primary cardiovascular events, is  $p < 0.0436$ . In January 2018, we announced that more than 90% of the 1,612 targeted aggregate number of primary cardiovascular events have been reported and documented.

Our scientific rationale for the REDUCE-IT study is supported by (i) epidemiological data that suggests elevated triglyceride levels correlate with increased cardiovascular disease risk, (ii) genetic data that suggests triglyceride and/or triglyceride-rich lipoproteins (as well as low-density lipoprotein cholesterol (LDL cholesterol), 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. Our scientific rationale for the REDUCE-IT study is also supported by research on the putative cardioprotective effects of EPA as presented in scientific literature. It is possible that the effects of EPA may be due not 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. The REDUCE-IT study is needed to determine the clinical benefit, if any, of EPA therapy in statin-treated patients with elevated triglyceride levels.

#### *Commercial Supply*

Prior to 2015, all of our active pharmaceutical ingredient, or API, that has been utilized in product sold was manufactured by two suppliers: Nisshin Pharma, Inc., or Nisshin, and Chemport, Inc., or Chemport. During 2015, we began purchasing API from a third supplier, Finorga SAS, or Novasep. 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 Position*

In February 2018, we received approximately \$65.0 million of net proceeds from a registered offering of our American Depositary Shares (ADSs). We believe that our cash and cash equivalents of \$73.6 million as of December 31, 2017, together with the approximately \$65.0 million received in February 2018, will be sufficient to fund our projected operations through results of the REDUCE-IT study, which we anticipate will be available before the end of the third quarter of 2018 and, assuming positive results of the REDUCE-IT study, through subsequent public presentation of such results at a medical congress before the end of 2018. Depending on the level of cash generated from operations, additional capital may be required to expand promotion of Vascepa as contemplated following anticipated successful results of the REDUCE-IT study. If additional capital is required and we are unable to obtain additional capital, we may be forced to delay, limit or eliminate all or a portion of the expanded promotional activities planned following successful results of the REDUCE-IT study. We anticipate that quarterly net cash outflows in future periods will be variable.

#### **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. In accordance with U.S. Generally Accepted Accounting Principles, or GAAP, during 2013, before we had the ability to reliably estimate returns of Vascepa from our Distributors, revenue was recognized based on the resale of Vascepa for the purposes of filling patient prescriptions, and not based on our sales to such Distributors. In 2014, we concluded that we had developed sufficient history such that we can reliably estimate returns and as a result, began to recognize revenue based on sales to our Distributors.

*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. Up-front and milestone payments under such agreements are typically recognized as licensing revenue over the estimated period in which we are required to provide regulatory and development support and clinical and commercial supply pursuant to 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 co-promotion fees payable to Kowa Pharmaceuticals America, Inc. 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 as well as costs of product supply received from suppliers when such receipt by us is prior to regulatory approval of the supplier. We expense research and development costs as incurred.

*Gain (Loss) on Change in Fair Value of Derivative Liabilities.* Gain (loss) on change in fair value of derivative liabilities is comprised of: (i) the change in fair value of the derivative liability related to the change in control provision associated with the December 2012 royalty-bearing instrument, (ii) the change in fair value of the derivative liabilities related to the change in control provisions associated with the May 2014 and November 2015 exchangeable senior notes, and in 2015 included (iii) the change in fair value of the warrant derivative liability, and (iv) the change in fair value of the derivative liability related to the preferred stock purchase option.

*Interest and Other Income (Expense), Net.* Interest expense consists of interest incurred under lease obligations, interest incurred under our December 2012 royalty-bearing instrument financing arrangement, and interest incurred under our 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 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 income (expense), net, consists primarily of foreign exchange losses and gains.

*(Provision for) Benefit from Income Taxes.* (Provision for) benefit from 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. The change in the effective tax rate was primarily driven by our evaluation of available evidence which resulted in the recording of non-cash provisions for income taxes against certain of the deferred tax assets of our U.S. subsidiary for the years ended December 31, 2017 and 2016.

## **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, including those related to derivative financial liabilities. 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 significant accounting policies is contained in Note 2 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K. A summary of our critical accounting policies, significant judgments and estimates used in the preparation of our consolidated financial statements.

*Revenue Recognition*—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. In accordance with GAAP, our revenue recognition policy requires that: (i) there is persuasive evidence that an arrangement exists between us and the Distributor, (ii) delivery has occurred, (iii) collectability is reasonably assured and (iv) the price is fixed or determinable.

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. We sell Vascepa to Distributors. In accordance with GAAP, during 2013, before we had the ability to reliably estimate returns of Vascepa from our Distributors, revenue was recognized based on the resale of Vascepa for the purposes of filling patient prescriptions, and not based on our sales to such Distributors. In 2014, we concluded that we had developed sufficient history such that we can reliably estimate returns and as a result, began to recognize revenue based on sales to our Distributors. Consequently, we recognized net product revenues of \$179.8 million and \$129.0 million based on sales to Distributors during the years ended December 31, 2017 and 2016, respectively.

We have written contracts with our Distributors, and delivery occurs when a Distributor receives Vascepa. 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. In order to conclude that the price is fixed or determinable, we must be able to (i) calculate our gross product revenues from the sales to Distributors and (ii) reasonably estimate our net product revenues. We calculate gross product revenues based on the wholesale acquisition cost that we charge our Distributors for Vascepa. We estimate our net product revenues 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 (formerly QuintilesIMS) 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, 2017 and 2016.

When evaluating multiple-element arrangements, we identify the deliverables included within the agreement and evaluate which deliverables represent separate units of accounting based on whether the delivered element has stand-alone value to the collaborator or if the arrangement includes a general right of return for delivered items. We may receive up-front, non-refundable payments when licensing our intellectual property in conjunction with research and development agreements. In determining the units of accounting, we evaluate whether the license has stand-alone value from the undelivered elements to the collaborative partner based on the consideration of the relevant facts and circumstances for each arrangement. Factors considered in this 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 independently.

When we believe a license to our intellectual property does not have stand-alone value from the other deliverables to be provided in the arrangement, we generally recognize revenue attributable to the license over the contractual or estimated performance period. Any unrecognized portion of license revenue is classified within deferred revenue in the accompanying consolidated balance sheets. When we believe a license to our intellectual property has stand-alone value, we recognize revenue attributed to the license upon delivery. The periods over which revenue is recognized is subject to estimates and may change over the course of the agreement. Such a change could have a material impact on the amount of revenue we record in future periods.

*Derivative Financial Liabilities*—Derivative financial liabilities are initially recorded at fair value. They are subsequently held at fair value, with gains and losses arising for changes in fair value recognized in the statement of operations. The fair value of derivative financial liabilities is determined using various valuation techniques. We use our judgment to select a variety of methods and make assumptions that are mainly based on market conditions existing at each balance sheet date, which include our projections for future estimated revenues, management estimates of the probability of a change in control occurring, and the terms of debt issues of similar companies. Fluctuations in the assumptions used in the valuation model would result in adjustments to the fair value of the derivative liabilities reflected on our balance sheet and, therefore, our statement of operations. If we issue 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. For options and warrants treated as derivative financial liabilities, at settlement date the carrying value of the options and warrants are transferred to equity. The cash proceeds received from shareholders for additional shares are recorded in common stock and additional paid-in capital. We have recorded financial derivatives related to certain outstanding warrants (extinguished during the first quarter of 2015), the change in control provision associated with our December 2012 royalty-bearing instrument, the change in control provisions associated with our May 2014 and November 2015 exchangeable senior notes (both derecognized upon exchange of the debt hosts into equity during the third quarter of 2016), and a preferred stock purchase option (subsequently reclassified to permanent equity).

**Inventory**—We capitalize purchases of saleable inventory of Vascepa from suppliers that have been qualified by the FDA. The API purchased for Vascepa was sourced from three API suppliers in 2017, 2016, and 2015. If we add a new API supplier, all Vascepa API purchased from such supplier is included as a component of research and development expense until the new API supplier is approved. Upon sNDA approval of each additional supplier, we capitalize subsequent Vascepa API purchases from such supplier as inventory. In April 2016, we adopted Accounting Standards Update (“ASU”) No. 2015-11, *Inventory (Topic 330)—Simplifying the Measurement of Inventory*, and as such, began to state inventories at the lower of cost or net realizable market value (previously, we stated inventories at the lower of cost or market value). Cost is determined based on actual cost using the average cost method. 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, quantities in excess of expected demand, changes in price levels or other causes, then we 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. We expense inventory identified for use as marketing samples when they are packaged. The average cost reflects the actual purchase price of Vascepa API. Additionally, the determination of the classification of our inventory requires the use of estimates in order to determine the portion of inventories anticipated to be utilized within twelve months of the balance sheet date.

**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, 2017, 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 and current year 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 recorded U.S. net deferred tax assets of \$8.7 million are not more likely than not to be realizable as of December 31, 2017. Any changes in the available evidence used to assess realizability of our U.S. deferred tax assets could result in a material change to the carrying value of such deferred tax assets in future periods. The majority of our deferred tax assets are held outside of the United States, for which a full valuation allowance has been previously recorded. 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, 2017 and December 31, 2016***

**Product Revenue, net.** We recorded net product revenue of \$179.8 million and \$129.0 million during the years ended December 31, 2017 and 2016, respectively, an increase of \$50.9 million, or 39%. This increase in revenue was driven primarily by an increase in estimated normalized total Vascepa prescriptions. Based on data provided by Symphony Health and IQVIA (formerly QuintilesIMS), estimated normalized total Vascepa prescriptions increased by approximately 441,000 and 425,000, respectively, over



the year ended December 31, 2016, representing growth of 45% and 42%, respectively. During 2017, overall wholesaler inventory levels decreased from year-end 2016 levels calculated based on estimated days of Vascepa sales on hand. We believe that changes in channel inventory at these independent wholesalers and retail pharmacies are common and are impacted by numerous factors, including holiday timing and recent order trends. We also believe, based on information available to us, that channel inventory levels at the end of both 2017 and 2016 were within ordinary ranges.

All of our product revenue in the years ended December 31, 2017 and 2016 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 (formerly QuintilesIMS) may differ from period to period.

During the years ended December 31, 2017 and 2016, our net product revenue included an 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, 2017 and 2016 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, 2017 and 2016 was \$1.3 million and \$1.1 million, respectively, an increase of \$0.2 million, or 14%. Licensing revenue relates to the amortization of a \$15.0 million up-front payment received in February 2015 and a \$1.0 million milestone payment achieved in March 2016, both associated with a Vascepa licensing agreement for the China Territory. Licensing revenue also includes amortization of a \$5.0 million up-front amount associated with a Vascepa licensing agreement for Canada, which was reached in September 2017. The up-front and milestone payments are being recognized over the estimated period in which we are required to provide regulatory and development support and clinical and commercial supply under the agreements. The amount of licensing revenue recorded may be variable 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 2018.

*Cost of Goods Sold.* Cost of goods sold during the years ended December 31, 2017 and 2016 was \$45.0 million and \$34.4 million, respectively, an increase of \$10.6 million, or 31%. 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, 2017 and 2016 was sourced from three 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 2018 to be similar to 2017. 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, 2017 and 2016 was 75% and 73%, respectively. This improvement was primarily driven by lower unit cost API purchases.

**Selling, General and Administrative Expense.** Selling, general and administrative expense for the years ended December 31, 2017 and 2016 was \$134.5 million and \$111.4 million, respectively, an increase of \$23.2 million, or 21%. Selling, general and administrative expenses for the years ended December 31, 2017 and 2016 are summarized in the table below:

<i>In thousands</i>	<b>Year Ended December 31,</b>	
	<b>2017</b>	<b>2016</b>
Selling, general and administrative expense (1)	\$ 100,204	\$ 82,042
Co-promotion fees (2)	22,507	17,969
Non-cash stock-based compensation expense (3)	11,838	11,361
Total selling, general and administrative expense	<u>\$ 134,549</u>	<u>\$ 111,372</u>

- (1) Selling, general and administrative expense, excluding co-promotion fees and non-cash compensation charges for stock compensation, for the years ended December 31, 2017 and 2016 was \$100.2 million and \$82.0 million, respectively, an increase of \$18.2 million, or 22%. This increase is due primarily to increased promotional activities, including commercial spend for anticipated expansion following successful REDUCE-IT results, and increased legal costs, which are subject to quarterly variability.
- (2) Co-promotion fees payable to Kowa Pharmaceuticals America, Inc. were \$22.5 million and \$18.0 million in the years ended December 31, 2017 and 2016, respectively, an increase of \$4.5 million, or 25%. The increase is due primarily to an increase in gross margin on product sales for the year ended December 31, 2017 compared to the same period in 2016, offset as a result of amended contract terms in 2017 related to the percentage of aggregate Vascepa gross margin earned by Kowa Pharmaceuticals America, Inc. and certain other refinements.
- (3) Non-cash stock-based compensation expense for the years ended December 31, 2017 and 2016 was \$11.8 million and \$11.4 million, respectively, an increase of \$0.5 million, or 4%.

We anticipate increasing our direct sales force to approximately 400 to 500 sales professionals after REDUCE-IT results, assuming success. We also intend to expand medical education and market awareness initiatives, including, in advance of REDUCE-IT results being known, pilot testing of new promotional initiatives for potential broader applications following REDUCE-IT results. During 2018, which is the last year of the agreement, as amended, with Kowa Pharmaceuticals America, Inc., we anticipate incurring expense for both the annual co-promotion fee, which in 2018 will again be calculated as a percentage of Vascepa gross margin at a modestly higher rate than in 2017, plus accrual for co-promotion tail payments. Assuming Kowa Pharmaceuticals America, Inc. fulfills its obligations in accordance with the terms of the agreement, as amended, after expiration of the agreement, Kowa Pharmaceuticals America, Inc. is eligible to receive up to three years of co-promotion tail payments equal to declining percentages of the co-promotion fee amount earned in the final year of the agreement with the sum of the three years of co-promotion tail payments totaling less than the co-promotion fee amount earned in the final year of the agreement.

**Research and Development Expense.** Research and development expense for the years ended December 31, 2017 and 2016 was \$47.2 million and \$50.0 million, respectively, a decrease of \$2.8 million, or 6%. Research and development expenses for the years ended December 31, 2017 and 2016 are summarized in the table below:

<i>In thousands</i>	<b>Year Ended December 31,</b>	
	<b>2017</b>	<b>2016</b>
REDUCE-IT study (1)	\$ 34,886	\$ 36,989
Regulatory filing fees and expenses (2)	1,011	1,735
Internal staffing, overhead and other (3)	9,139	8,999
Research and development expense, excluding non-cash expense	45,036	47,723
Non-cash stock-based compensation expense (4)	2,122	2,252
Total research and development expense	<u>\$ 47,158</u>	<u>\$ 49,975</u>

The decrease in research and development expenses for the year ended December 31, 2017, as compared to the prior year period, is primarily due to timing of REDUCE-IT and related costs.

- (1) In December 2011, we announced commencement of patient dosing in our cardiovascular outcomes study of Vascepa, titled REDUCE-IT, which is designed to evaluate the efficacy of Vascepa, including its impact on triglyceride lowering and its other clinical effects, in reducing major adverse cardiovascular events compared to placebo in patients who despite statin therapy have risk factors for cardiovascular disease, including elevated triglyceride levels. In 2016, we completed patient enrollment and randomization of 8,175 individual patients into the REDUCE-IT study, exceeding the 8,000 patients targeted for the trial. We manage the study through a contract research organization (CRO) through which all costs for this outcomes study are incurred with the exception of costs for clinical trial material (CTM) and costs for internal management. Our internal personnel are responsible for managing multiple projects and their costs are not specifically allocated to REDUCE-IT or any other individual project. For the years ended December 31, 2017 and 2016, we incurred expenses through our CRO in connection with this trial

of approximately \$29.9 million and \$28.8 million, respectively. Inclusive of CTM costs, the combined CRO and CTM costs during the years ended December 31, 2017 and 2016 for REDUCE-IT were approximately \$34.9 million and \$37.0 million, respectively. The decrease in expenses in 2017 as compared to 2016 is primarily the result of timing variability for REDUCE-IT costs. We expense costs for CTM when allocated to clinical research. We currently estimate that we will incur \$10 million to \$15 million in quarterly costs through study completion and initial publication of the trial results. We anticipate that the rate at which we incur such costs will vary from quarter to quarter. We estimate that the study will be completed with top-line study results becoming available and made public before the end of the third quarter of 2018, followed by publication of the results. We anticipate that our costs for this outcomes study will continue to represent the most significant component of our research and development expenditures until the results of this study are published.

- (2) The regulatory filing fees in each of the years ended December 31, 2017 and 2016 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. We anticipate these costs to increase 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. The amount and timing of such increases will depend on the results of the currently ongoing REDUCE-IT trial.
- (4) Non-cash stock-based compensation expense represents the costs associated with equity awards issued to internal staff supporting our research and development and regulatory functions.

*Gain (Loss) on Change in Fair Value of Derivative Liabilities.* Gain (loss) on change in fair value of derivative liabilities for the year ended December 31, 2017 was nil versus a gain of \$8.2 million in the prior year period. Gain (loss) on change in fair value of derivative liabilities for the years ended December 31, 2017 and 2016 is comprised of (i) the change in fair value of the derivative liability related to the change in control provision associated with the December 2012 royalty-bearing instrument, and (ii) the change in fair value of the derivative liabilities related to the change in control provisions associated with the May 2014 and November 2015 exchangeable senior notes.

Our December 2012 royalty-bearing instrument financing arrangement with CPPIB Credit Europe S.à r.l., or CPPIB, as successor in interest to BioPharma Secured Debt Fund II Holdings Cayman LP, contains a redemption feature whereby, upon a change of control, we would be required to repay \$150.0 million, less any previously repaid amount, which net remaining unpaid amount as of December 31, 2017 was \$109.1 million. Unless this early redemption feature is triggered, the remaining amount, without additional interest accumulation, is anticipated to be paid based on the royalty provisions of the agreement. The fair value of the derivative liability is recalculated at each reporting period using a probability-weighted model incorporating management estimates for 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 fair values of the debt was determined to be the fair value of the embedded derivative. No gain or loss on change in fair value of derivative liability was recognized for the year ended December 31, 2017 as the fair value of the derivative was determined to be nil based on underlying assumptions as of both December 31, 2016 and December 31, 2017. As of December 31, 2015, the fair value of the derivative was determined to be \$5.5 million, and as of December 31, 2016, the fair value of the derivative was determined to be nil. As such, we recognized a \$5.5 million gain on change in fair value of derivative liability for the year ended December 31, 2016.

Our 3.5% May 2014 exchangeable senior notes due 2032, or 2014 Notes, contained a redemption feature whereby, upon occurrence of a change in control, we would have been required to repurchase the notes. The fair value of the embedded derivative was calculated using a probability-weighted model incorporating management estimates of the probability of a change in control occurring, 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. In September 2016, we exercised our optional exchange rights upon satisfaction of specified equity conditions set forth in the 2014 Notes indenture to mandatorily exchange the 2014 Notes into ADSs (see Note 8—Debt). As such, the related derivative liability was derecognized at that time and we recognized a \$2.1 million gain on change in fair value of derivative liability for the year ended December 31, 2016. There was no such change in fair value of derivative liability for the year ended December 31, 2017.

Our 3.5% November 2015 exchangeable senior notes due 2032, or 2015 Notes, contained the same redemption feature as the 2014 Notes and the related derivative liability was calculated utilizing the same methodology. In September 2016, we exercised our optional exchange rights upon satisfaction of specified equity conditions consistent with the terms of the 2015 Notes to mandatorily exchange the 2015 Notes into ADSs (see Note 8—Debt). As such, the related derivative liability was derecognized at that time and we recognized a \$0.6 million gain on change in fair value of derivative liability for the year ended December 31, 2016. There was no such change in fair value of derivative liability for the year ended December 31, 2017.

The change in fair value of the derivative liability related to the royalty-bearing instrument is largely related to our projections for future estimated revenues, management estimates of the probability of a change in control occurring, and the terms of debt issues of similar companies. The change in fair value of the derivative liabilities related to the 2014 Notes and 2015 Notes was a result of the exchange of the related debt hosts for the year ended December 31, 2016. Any changes in the assumptions used to value the derivative liabilities could result in a material change to the carrying value of such liabilities.

*Interest Expense, net.* Net interest expense for the years ended December 31, 2017 and 2016 was \$9.3 million and \$18.4 million, respectively, a decrease of \$9.1 million, or 48%. Net interest expense for the years ended December 31, 2017 and 2016 is summarized in the table below:

<i>In thousands</i>	Year ended December 31,	
	2017	2016
Exchangeable senior notes (1):		
Amortization of debt discounts	\$ 200	\$ 5,703
Contractual coupon interest	1,004	4,151
Total exchangeable senior notes interest expense	1,204	9,854
Long-term debt from royalty-bearing instrument (2):		
Cash interest	6,425	6,727
Non-cash interest	2,132	2,081
Total long-term debt from royalty-bearing instrument interest expense	8,557	8,808
Other interest expense	5	15
Total interest expense	9,766	18,677
Interest income (3)	(429)	(234)
Total interest expense, net	\$ 9,337	\$ 18,443

- (1) Cash and non-cash interest expense related to the exchangeable senior notes for the years ended December 31, 2017 and 2016 was \$1.2 million and \$9.9 million, respectively. The decrease in cash and non-cash interest expense is the result of the decrease in principal amount of exchangeable senior notes from \$165.1 million outstanding during the majority of 2016 to \$30.0 million outstanding during 2017.
- (2) Cash and non-cash interest expense related to the December 2012 royalty-bearing instrument for the years ended December 31, 2017 and 2016 was \$8.6 million and \$8.8 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, 2017 and 2016 was \$0.4 million and \$0.2 million, respectively. Interest income represents income earned on cash balances.

*Other Income (Expense), net.* Other income (expense), net, for the year ended December 31, 2017 and 2016 was income of \$0.1 million and expense of \$0.5 million, respectively. Other income (expense), net, in the years ended December 31, 2017 and 2016 primarily consists of gains and losses on foreign exchange transactions.

*(Provision for) Benefit from Income Taxes.* (Provision for) benefit from income taxes for the year ended December 31, 2017 and 2016 was a provision of \$13.0 million and a provision of \$10.0 million, respectively. The provisions recorded relate 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, 2017 and 2016 include \$1.3 million of excess tax benefits and \$0.4 million of excess tax deficiencies, 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, 2016 and December 31, 2015***

***Product Revenue, net.*** We recorded product revenue of \$129.0 million and \$81.0 million during the years ended December 31, 2016 and 2015, respectively, an increase of \$48.0 million, or 59%. This increase in revenue was driven primarily by an increase in estimated normalized total Vascepa prescriptions. Based on data provided by Symphony Health and IQVIA (formerly QuintilesIMS), estimated normalized total Vascepa prescriptions increased by approximately 339,000 and 378,000, respectively, over the year ended December 31, 2015, representing growth of 53% and 56%, respectively. During 2016, predominantly in the second quarter, wholesaler inventory levels increased based on estimated days of inventory on hand. In addition, regional stocking of Vascepa expanded at certain retail pharmacies, likely due to higher volume sales of Vascepa. We estimate that these changes in channel inventory increased net product revenue by approximately \$3.0 million to \$6.0 million during 2016, compared to a \$0.4 million to \$0.7 million decrease in net product revenue due to net inventory level changes during 2015. We believe that changes in channel inventory at these independent wholesalers and retail pharmacies are common and impacted by numerous factors, including holiday timing and recent order trends. We also believe, based on information available to us, that channel inventory levels at the end of both 2015 and 2016 are within ordinary ranges.

All of our product revenue in the years ended December 31, 2016 and 2015 was derived from product sales of Vascepa, net of allowances, discounts, incentives, rebates, chargebacks and returns. Included in 2016 net product revenue are sales of 0.5-gram size Vascepa capsules, which were introduced in October 2016, for the subset of patients who prefer a smaller capsule. Sales of Vascepa 0.5-gram size capsules have not been significant to date. The FDA-approved dosing for Vascepa continues to be 4 grams per day and we expect that the majority of patients taking Vascepa will continue to be prescribed the 1-gram size Vascepa capsules. We also expect that the majority of new patients will be prescribed the 1-gram size Vascepa capsule. Timing of shipments to wholesalers, as used for revenue recognition, and timing of prescriptions as estimated by third-party sources such as Symphony Health Solutions and QuintilesIMS may differ from period to period.

During the years ended December 31, 2016 and 2015, our net product revenue included an 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, 2016 and 2015 was up to \$70 per 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, 2016 and 2015 was \$1.1 million and \$0.8 million, respectively, an increase of \$0.4 million, or 46%. Licensing revenue relates to the amortization of a \$15.0 million up-front payment received in February 2015 and a \$1.0 million milestone payment achieved in March 2016, both associated with a Vascepa licensing agreement for the China Territory. The up-front and milestone payments are being recognized over the estimated period in which we are required to provide regulatory and development support and clinical and commercial supply under the agreement. The amount of licensing revenue recorded may be variable from period to period based on changes in estimates of the timing and level of support required. We do not anticipate significant revenues related to the Biologix agreement in 2017.

***Cost of Goods Sold.*** Cost of goods sold during the years ended December 31, 2016 and 2015 was \$34.4 million and \$27.9 million, respectively, an increase of \$6.5 million, or 23%. 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, 2016 and 2015 was sourced from three API suppliers. The contracted cost of supply from our initial API supplier was higher than the contracted cost from our other API suppliers. In the future, we anticipate making continued purchases from this initial supplier and to make additional lower unit cost purchases of Vascepa API from other API suppliers, with the amount of such purchases dependent on the rate of our revenue growth. 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, 2016 and 2015 was 73% and 66%, respectively. This improvement was primarily driven by lower unit cost API purchases.

**Selling, General and Administrative Expense.** Selling, general and administrative expense for the years ended December 31, 2016 and 2015 was \$111.4 million and \$101.0 million, respectively, an increase of \$10.4 million, or 10%. Selling, general and administrative expenses for the years ended December 31, 2016 and 2015 are summarized in the table below:

<i>In thousands</i>	<b>Year Ended December 31,</b>	
	<b>2016</b>	<b>2015</b>
Selling, general and administrative expense (1)	\$ 82,042	\$ 82,474
Co-promotion fees (2)	17,969	7,967
Non-cash stock-based compensation expense (3)	11,361	10,609
Non-cash warrant related compensation income	—	(9)
<b>Total selling, general and administrative expense</b>	<b>\$ 111,372</b>	<b>\$ 101,041</b>

- (1) Selling, general and administrative expense, excluding co-promotion fees and non-cash compensation charges for stock compensation and warrants, for the years ended December 31, 2016 and 2015 was \$82.0 million and \$82.5 million, respectively, a decrease of \$0.4 million, or 1%. This slight decrease is due primarily to an increase in prior-year sales and marketing costs in support of expanded Vascepa promotion following the favorable federal court declaration on August 7, 2015 and related settlement on March 8, 2016 allowing communication of truthful and non-misleading ANCHOR clinical trial and related data to be communicated to healthcare professionals, more than offset by lower legal costs resulting from the same.
- (2) Co-promotion fees payable to Kowa Pharmaceuticals America, Inc. were \$18.0 million and \$8.0 million in the years ended December 31, 2016 and 2015, respectively, an increase of \$10.0 million, or 126%. The increase is due primarily to an increase in gross margin on product sales for the year ended December 31, 2016 compared to the same period in 2015, coupled with an increase in the percentage of aggregate Vascepa gross margin earned by Kowa Pharmaceuticals America, Inc. from 15% in 2015 to 19% in 2016.
- (3) Stock-based compensation expense for the years ended December 31, 2016 and 2015 was \$11.4 million and \$10.6 million, respectively, an increase of \$0.8 million, or 7%, primarily due to an increase in new stock option and restricted stock awards granted to attract and retain qualified employees.

We anticipate that selling, general and administrative expenses, excluding non-cash costs, will increase by less than 10% in 2017 compared with 2016, with the exception of commercial spending for anticipated expansion following successful REDUCE-IT results and increased co-promotion fees anticipated to be paid to Kowa Pharmaceuticals America, Inc. associated primarily with anticipated increased revenue growth.

**Research and Development Expense.** Research and development expense for the years ended December 31, 2016 and 2015 was \$50.0 million and \$51.1 million, respectively, a decrease of \$1.1 million, or 2%. Research and development expenses for the years ended December 31, 2016 and 2015 are summarized in the table below:

<i>In thousands</i>	<b>Year Ended December 31,</b>	
	<b>2016</b>	<b>2015</b>
REDUCE-IT study (1)	\$ 36,989	\$ 34,706
Regulatory filing fees and expenses (2)	1,735	2,162
Internal staffing, overhead and other (3)	8,999	10,914
Research and development expense, excluding non-cash expense	47,723	47,782
Non-cash stock-based compensation expense (4)	2,252	3,280
<b>Total research and development expense</b>	<b>\$ 49,975</b>	<b>\$ 51,062</b>

The decrease in research and development expenses for the year ended December 31, 2016, as compared to the prior year period, is primarily due to a decrease in overhead costs and non-cash stock-based compensation partially offset by quarterly variability in costs related to the REDUCE-IT study.

- (1) In December 2011, we announced commencement of patient dosing in our cardiovascular outcomes study of Vascepa, titled REDUCE-IT, which is designed to evaluate the efficacy of Vascepa, including its impact on triglyceride lowering and its other clinical effects, in reducing major adverse cardiovascular events compared to placebo in patients who despite statin therapy have risk factors for cardiovascular disease, including elevated triglyceride levels. In 2016, we completed patient enrollment and randomization of 8,175 individual patients into the REDUCE-IT study, exceeding the 8,000 patients targeted for the trial. The study duration is dependent on the rate of clinical events in the study, which rate may be affected by the epidemiology of the patients enrolled in the study and the length of time that the enrolled patients are followed. We manage the study through a contract research organization (CRO) through which all costs for this outcomes study are incurred with the exception of costs for clinical trial material (CTM) and costs for internal management. Our internal personnel are responsible for managing multiple projects and their costs are not specifically allocated to REDUCE-IT or any other individual project. For the years ended December 31, 2016 and 2015, we incurred expenses through our CRO in connection with this trial of approximately

\$28.8 million and \$28.5 million, respectively. Inclusive of CTM costs, the combined CRO and CTM costs during the years ended December 31, 2016 and 2015 for REDUCE-IT were approximately \$37.0 million and \$34.7 million, respectively. The increase in expenses in 2016 as compared to 2015 is primarily the result of timing variability for REDUCE-IT costs. We expense costs for CTM when allocated to clinical research. The aggregate cost of this outcomes study will depend on the rate of clinical events in the study. We currently estimate that we will incur \$30 million to \$40 million in annual costs through study completion and the rate at which we incur such costs will vary from quarter to quarter. The study is designed to be completed after reaching 1,612 aggregate primary cardiovascular events. Based on projected event rates, we estimate the onset of the target aggregate number of primary cardiovascular events to be reached near the end of 2017 with study results then expected to be available and published in 2018. We anticipate that our costs for this outcomes study will continue to represent the most significant component of our research and development expenditures.

- (2) The regulatory filing fees in each of the years ended December 31, 2016 and 2015 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.
- (4) Non-cash stock-based compensation expense represents the costs associated with equity awards issued to internal staff supporting our research and development and regulatory functions.

We anticipate that research and development expenses in 2017, excluding non-cash costs, will remain relatively consistent with 2016 levels, with the majority of such spending devoted to the ongoing REDUCE-IT trial.

*Gain (Loss) on Change in Fair Value of Derivative Liabilities.* Gain (loss) on change in fair value of derivative liabilities for the year ended December 31, 2016 was a gain of \$8.2 million versus a loss of \$1.1 million in the prior year period. Gain (loss) on change in fair value of derivative liabilities for the years ended December 31, 2016 and 2015 is comprised of (i) the change in fair value of the warrant derivative liability, (ii) the change in fair value of the derivative liability related to the change in control provision associated with the December 2012 BioPharma financing, (iii) the change in fair value of the derivative liabilities related to the change in control provisions associated with the May 2014 and November 2015 exchangeable senior notes, and (iv) the change in fair value of the derivative liability related to the preferred stock purchase option.

The warrant derivative liability was related to the change in fair value of warrants issued in conjunction with the October 2009 private placement. In October 2009, we issued 36.1 million warrants at an exercise price of \$1.50 per warrant and recorded a \$48.3 million warrant derivative liability, representing the fair value of the warrants issued. As these warrants were classified as a derivative liability, they were revalued at each reporting period, with changes in fair value recognized in the consolidated statement of operations. Of the 8,087,388 warrants outstanding as of December 31, 2014, 1,844,585 warrants were exercised and the remaining 6,242,803 warrants expired on February 27, 2015. As such, no warrants were outstanding as of December 31, 2015 and the derivative liability was extinguished. The fair value of the warrant derivative liability as of December 31, 2014 was \$0.1 million and we recognized a \$0.1 million gain on change in fair value of derivative liability for the year ended December 31, 2015. There was no such change in fair value of warrant derivative liability for the year ended December 31, 2016.

Our December 2012 financing agreement with BioPharma contains a redemption feature whereby, upon a change of control, we would be required to repay \$150.0 million, less any previously repaid amount, which net remaining unpaid amount as of December 31, 2016 was \$125.6 million. Unless this early redemption feature is triggered, the remaining amount, without additional interest accumulation, is anticipated to be paid based on the royalty provisions of the agreement. The fair value of the derivative liability is recalculated at each reporting period using a probability-weighted model incorporating management estimates for 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 fair values of the debt was determined to be the fair value of the embedded derivative. As of December 31, 2015, the fair value of the derivative was determined to be \$5.5 million, and as of December 31, 2016, the fair value of the derivative was determined to be nil based on current assumptions. As such, we recognized a \$5.5 million gain on change in fair value of derivative liability for the year ended December 31, 2016. As of December 31, 2014, the fair value of the derivative was determined to be \$4.8 million, and as of December 31, 2015, the fair value of the derivative was determined to be \$5.5 million. As such, we recognized a \$0.7 million loss on change in fair value of derivative liability for the year ended December 31, 2015.

Our 2014 Notes, issued in May 2014, contained a redemption feature whereby, upon occurrence of a change in control, we would have been required to repurchase the notes. The fair value of the embedded derivative was calculated using a probability-weighted model incorporating management estimates of the probability of a change in control occurring, 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. In September 2016, we exercised our optional exchange rights upon satisfaction of specified equity conditions set forth in the 2014 Notes indenture to mandatorily exchange the 2014 Notes into ADSs (see Note 8—Debt). As such, the related derivative liability was derecognized and we recognized a \$2.1 million gain on change in fair value of derivative

liability for the year ended December 31, 2016. As of December 31, 2014, the fair value of the derivative was determined to be \$2.6 million, and as of December 31, 2015, the fair value of the derivative was determined to be \$2.1 million. As such, we recognized a \$0.5 million gain on change in fair value of derivative liability for the year ended December 31, 2015.

Our 2015 Notes, issued in November 2015, contained the same redemption feature as the 2014 Notes and the related derivative liability was calculated utilizing the same methodology. In September 2016, we exercised our optional exchange rights upon satisfaction of specified equity conditions consistent with the terms of the 2015 Notes to mandatorily exchange the 2015 Notes into ADSs (see Note 8—Debt). As such, the related derivative liability was derecognized and we recognized a \$0.6 million gain on change in fair value of derivative liability for the year ended December 31, 2016. Upon issuance in November 2015, the fair value of the derivative was determined to be \$0.5 million, and as of December 31, 2015, the fair value of the derivative was determined to be \$0.6 million. As such, we recognized a \$0.1 million loss on change in fair value of derivative liability for the year ended December 31, 2015.

In connection with the closing of a private placement transaction in early March 2015, we recorded a derivative liability pursuant to a pre-existing contractual right. This preferred stock purchase option was determined to be a derivative liability effective March 5, 2015, the date in 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. The liability was charged to accumulated deficit as a deemed non-cash dividend 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. The liability was then marked to fair value through March 30, 2015, the date on which we executed a separate subscription agreement with the investor, resulting in a charge of \$0.9 million through gain (loss) on change in fair value of derivatives in the year ended December 31, 2015. The liability of \$1.8 million was then reclassified to permanent equity on March 30, 2015. There was no such change in fair value of derivative liability for the year ended December 31, 2016.

The change in fair value of the derivative liability related to the BioPharma financing agreement is largely related to our projections for future estimated revenues, management estimates of the probability of a change in control occurring, and the terms of debt issues of similar companies. The change in fair value of the derivative liabilities related to the 2014 Notes and 2015 Notes is a result of the exchange of the related debt hosts for the year ended December 31, 2016 and was largely related to changes in quoted bond prices for the year ended December 31, 2015. Any changes in the assumptions used to value the derivative liabilities could result in a material change to the carrying value of such liabilities.

*Gain on Extinguishment of Debt.* In November 2015, we entered into a privately negotiated subscription agreement with one of our existing investors (the “Investor”), pursuant to which the Investor agreed to purchase approximately \$31.3 million in aggregate principal amount of new 3.5% November 2015 Exchangeable Senior Notes due 2032 (the “2015 Notes”) for approximately \$27.5 million. Concurrent with the issuance of the 2015 Notes, we entered into separate, privately negotiated purchase agreements with certain holders of the 3.5% January 2012 Exchangeable Senior Notes due 2032 (the “2012 Notes”) pursuant to which we purchased approximately \$16.2 million in aggregate principal amount of the 2012 Notes for \$15.9 million (the “2012 Notes Purchase”), which includes accrued but unpaid interest on such 2012 Notes. The 2012 Notes Purchase was funded by the issuance of the 2015 Notes. Following the closing of the 2012 Notes Purchase, we had approximately \$15.1 million in aggregate principal amount of 2012 Notes outstanding. The 2012 Notes Purchase was accounted for as an extinguishment of debt and we recorded a gain of \$1.3 million upon extinguishment for the year ended December 31, 2015, which represents the reacquisition of the conversion option at fair value and a negotiated discount on the purchase of the notes partially offset by legal and transaction advisory costs incurred. There was no such gain on extinguishment of debt for the year ended December 31, 2016.



*Interest Expense, net.* Net interest expense for the years ended December 31, 2016 and 2015 was \$18.4 million and \$20.0 million, respectively, a decrease of \$1.6 million, or 8%. Net interest expense for the years ended December 31, 2016 and 2015 is summarized in the table below:

<i>In thousands</i>	Year ended December 31,	
	2016	2015
Exchangeable senior notes (1):		
Amortization of debt discounts	\$ 5,703	\$ 6,362
Contractual coupon interest	4,151	5,313
Total exchangeable senior notes interest expense	9,854	11,675
Long-term debt from royalty-bearing instrument (2):		
Cash interest—current	6,727	6,483
Cash interest—deferred	—	112
Non-cash interest	2,081	1,895
Total long-term debt from royalty-bearing instrument interest expense	8,808	8,490
Other interest expense	15	15
Total interest expense	18,677	20,180
Interest income (3)	(234)	(132)
Total interest expense, net	\$ 18,443	\$ 20,048

- (1) Cash and non-cash interest expense related to the exchangeable senior notes for the years ended December 31, 2016 and 2015 was \$9.9 million and \$11.7 million, respectively.
- (2) Cash and non-cash interest expense related to the December 2012 royalty-bearing instrument for the years ended December 31, 2016 and 2015, held by BioPharma during such years, was \$8.8 million and \$8.5 million, respectively. These amounts reflect the assumption that our Vascepa net revenue levels will not be high enough to support repayment to BioPharma 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, 2016 and 2015 was \$0.2 million and \$0.1 million, respectively. Interest income represents income earned on cash balances.

*Other Income (Expense), net.* Other income (expense), net, for the year ended December 31, 2016 was expense of \$0.5 million versus expense of \$0.2 million in the prior year period. Other income (expense), net, in the years ended December 31, 2016 and 2015 primarily consists of gains and losses on foreign exchange transactions.

*(Provision for) Benefit from Income Taxes.* (Provision for) benefit from income taxes for the years ended December 31, 2016 and 2015 was a provision of \$10.0 million and a benefit of \$3.1 million, respectively. The current provision relates entirely to the U.S. subsidiary operations. We are profitable in the United States as a result of intercompany transactions between our U.S. subsidiary and our other companies. In April 2016, we adopted 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. 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 provision for income taxes for the year ended December 31, 2016 includes \$0.4 million of excess tax deficiencies arising from share-based payments.

*Preferred Stock Purchase Option.* In connection with the closing of a private placement transaction in early March 2015, we recorded a derivative liability pursuant to a pre-existing contractual right. This preferred stock purchase option was determined to be a derivative liability effective March 5, 2015, the date in 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. The liability was charged to accumulated deficit as a deemed non-cash dividend 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. There was no such adjustment to net loss for the year ended December 31, 2016.

*Preferred Stock Beneficial Conversion Features.* In 2015, we issued Series A preference shares in a private placement transaction executed in two tranches that each contain a conversion feature whereby such shares are convertible into ordinary shares at a fixed rate (see Note 10—Equity). The conversion price on the date of issuance was less than the market price of our ordinary shares on such date. We determined that these discounts represent contingent beneficial conversion features, which were valued based on the difference between the conversion price and the market price of the ordinary shares on the date of issuance. These features are

analogous to preference dividends and were recorded as non-cash returns to preferred shareholders through accumulated deficit, and are therefore reflected as adjustments to net loss applicable to common shareholders for earnings per common share purposes in accordance with GAAP. During the year ended December 31, 2015, we recorded an adjustment to net loss applicable to common shareholders of \$31.3 million upon effectiveness of the related resale Registration Statement on Form S-3 and \$1.6 million upon shareholder approval received at the Company's Annual General Meeting of Shareholders. There was no such adjustment to net loss in the year ended December 31, 2016

## Liquidity and Capital Resources

Our sources of liquidity as of December 31, 2017 include cash and cash equivalents of \$73.6 million. In February 2018, we completed a public offering of 19,178,082 ADSs. The underwriters purchased the ADSs from us at a price of \$3.41 per ADS after commission, resulting in net proceeds to us of approximately \$65.0 million, after deducting estimated offering expenses payable by us. Our projected uses of cash include expansion of medical education and market awareness initiatives, including, in advance of REDUCE-IT results being known, pilot testing of new promotional initiatives for potential broader application following REDUCE-IT results, increasing inventory balances for incremental inventory build prior to REDUCE-IT results, and general corporate and working capital purposes. Our cash flows from operating, investing and financing activities, as reflected in the consolidated statements of cash flows, are summarized in the following table:

In millions	Year Ended December 31,		
	2017	2016	2015
Cash (used in) provided by:			
Operating activities (1)	\$ (32.8)	\$ (71.8)	\$ (84.0)
Investing activities	—	—	—
Financing activities (1)	8.2	63.1	71.4
Decrease in cash and cash equivalents	<u>\$ (24.6)</u>	<u>\$ (8.7)</u>	<u>\$ (12.6)</u>

- (1) Due to the adoption of ASU No. 2016-09, *Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*, and retrospective application of the aspects of the standard that affect cash flow presentation, \$0.7 million of excess tax benefit has been reclassified from cash flows provided by financing activities to cash flows used in operating activities for the year ended December 31, 2015.

Net cash used in operating activities during 2017 compared to 2016 decreased primarily as a result of increased collections due to higher revenues, which resulted in decreased net loss. Increased sales and marketing spending in 2017 in support of expanded Vascepa promotion was more than offset by higher collections from product sales.

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, 2017, the net remaining amount to be repaid to CPPIB is \$109.1 million. To date, our net revenues have been below the contractual threshold amount such that each payment made has reflected the calculated optional reduction amount as opposed to the contractual threshold payments for each quarterly period. As of December 31, 2017, there are no quarterly contractual threshold payments remaining, such that the maximum amount payable is subject only to the calculated threshold limitation based on quarterly Vascepa net revenues. In accordance with the agreement, quarterly differences between the calculated optional reduction amounts and the contractual threshold amounts were rescheduled for payment beginning in the second quarter of 2017 and any such deferred payments will remain subject to continued application of the quarterly ceiling in amounts due established by the calculated threshold for royalty based on quarterly Vascepa net revenues. No additional interest expense or liability is incurred as a result of such deferred repayments. The agreement does not expire until \$150.0 million in aggregate has been repaid. We can prepay an amount equal to \$150.0 million less any previously repaid amount.

In January 2017, 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 investors pursuant to which we issued and sold \$30.0 million in aggregate principal amount of 3.5% exchangeable senior notes due 2047, or the 2017 Notes. The net proceeds we received from the January 2017 offering were approximately \$28.8 million, after deducting placement agent fees and estimated offering expenses.

The 2017 Notes were issued pursuant to an indenture dated as of January 25, 2017, by and among Corsicanto II, us as guarantor, and Wilmington Trust, National Association, as trustee. The 2017 Notes are the senior unsecured obligations of the Issuer and are guaranteed by us. The 2017 Notes bear interest at a rate of 3.5% per annum from, and including, January 25, 2017, payable semi-annually in arrears on January 15 and July 15 of each year, beginning on July 15, 2017. The 2017 Notes will mature on January 15,

2047, unless earlier repurchased, redeemed or exchanged. On or after January 19, 2021, we may redeem for cash all or a portion of the 2017 Notes at a redemption price of 100% of the aggregate principal amount of the 2017 Notes to be redeemed, plus accrued and unpaid interest. On January 19, 2022, holders of the 2017 Notes may require that we repurchase in cash all or any portion of the 2017 Notes at a price equal to 100% of the aggregate principal amount of the 2017 Notes to be repurchased, plus accrued and unpaid interest. At any time prior to January 15, 2047, the holders may exchange their 2017 Notes for ADSs at their option, and we may mandatorily exchange the 2017 Notes if the price of our shares trades above 130% of the exchange price then in effect for 20 VWAP trading days in any 30 consecutive VWAP trading day period (as defined in the indenture). The initial exchange rate for such conversion is 257.2016 ADSs per \$1,000 principal amount of the 2017 Notes (equivalent to an initial exchange price of approximately \$3.89 per ADS), subject to adjustment upon the occurrence of certain events, including the payment of cash dividends. Upon exchange, the 2017 Notes are to be settled in ADSs.

During 2018, we anticipate that inventory balances will grow in proportion to anticipated revenue growth. Additionally, we anticipate incremental inventory increases prior to REDUCE-IT results of up to approximately \$10 million.

As of December 31, 2017, we had cash and cash equivalents of \$73.6 million, a decrease of \$24.6 million from December 31, 2016. The decrease is primarily due to net cash used in operating activities in support of the commercialization of Vascepa and funding of REDUCE-IT, substantially offset by accounts receivable collections and the net effect of financing activities related to the repayment of the 2012 Notes and issuance of the 2017 Notes. We have incurred annual operating losses since our inception and, as a result, we had an accumulated deficit of \$1.3 billion as of December 31, 2017. 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, payments to our Vascepa co-promotion partner, and anticipated expanded Vascepa promotional activities before REDUCE-IT results which, assuming REDUCE-IT success, will increase more pronouncedly after REDUCE-IT results. We believe that our cash and cash equivalents of \$73.6 as of December 31, 2017, together with the approximately \$65.0 million received in February 2018 from the registered offering, will be sufficient to fund our projected operations through the results of the REDUCE-IT study, which we anticipate will be available before the end of the third quarter of 2018 and, assuming positive results of the REDUCE-IT study, through subsequent public presentation of such results at a medical congress before the end of 2018. Depending on the level of cash generated from operations, additional capital may be required to expand promotion of Vascepa as contemplated based on anticipated successful results of the REDUCE-IT study. If additional capital is required and we are unable to obtain additional capital, we may be forced to delay, limit or eliminate all or a portion of the expanded promotional activities planned following successful results of the REDUCE-IT study. We anticipate that quarterly net cash outflows in future periods will be variable.

### Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2017 and the effects such obligations are expected to have on our liquidity and cash flows in future periods:

#### Payments Due by Period

<i>In millions</i>	<u>Total</u>	<u>2018</u>	<u>2019 to 2020</u>	<u>2021 to 2022</u>	<u>After 2022</u>
Contractual obligations:					
Purchase obligations (1)	\$ 40.1	\$ 11.4	\$ 18.0	\$ 10.7	\$ —
Operating lease obligations (2)	0.8	0.6	0.2	—	—
Interest payment obligations—exchangeable debt (3)	4.7	1.0	2.1	1.6	—
Total contractual cash obligations	<u>\$ 45.6</u>	<u>\$ 13.0</u>	<u>\$ 20.3</u>	<u>\$ 12.3</u>	<u>\$ —</u>

- (1) We have Vascepa API supply agreements with three independent companies from which we purchase qualified API supply: Nisshin, Chemport and Finorga SAS, or Novasep. We also have encapsulation agreements with three FDA-approved commercial API encapsulators for Vascepa manufacturing: Patheon, Inc. (formerly Banner Pharmacaps, now part of Thermo Fisher Scientific), Catalent Pharma Solutions, and Capsugel Plöermeel SAS (now a Lonza company), or Capsugel. Our agreements with Chemport, Novasep, and Capsugel 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 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 Bedminster, NJ, net of sublease rental income.
- (3) Represents scheduled interest payments due under the terms of the 2017 Notes, assuming that they have not been exchanged for ADSs prior to January 19, 2022, the put date in the 2017 Notes. The above table does not reflect the repayment of the notes, unless otherwise described, as they may be exchanged for ADSs prior to maturity.

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, 2017, the net remaining amount to be repaid is \$109.1 million. To date, our revenues have been below the contractual threshold amount such that each payment made has reflected the calculated optional reduction amount as opposed to the contractual threshold payments for each quarterly period. As of December 31, 2017, there are no quarterly contractual threshold payments remaining, such that the maximum amount payable is subject only to the calculated threshold limitation based on quarterly Vascepa net revenues. In accordance with the agreement, quarterly differences between the calculated optional reduction amounts and the contractual threshold amounts were rescheduled for payment beginning in the second quarter of 2017 and any such deferred payments will remain subject to continued application of the quarterly ceiling in amounts due established by the calculated threshold based on quarterly Vascepa net revenues. No additional interest expense or liability is incurred as a result of such deferred repayments and no cliff payment of the remaining balance is due except in the event of Company default or Company change of control. The agreement does not expire until \$150.0 million in aggregate has been repaid. We can prepay an amount equal to \$150.0 million less any previously repaid amount.

We have scheduled interest payments due under the terms of the 2017 Notes, assuming that they remain outstanding through January 19, 2022 and have not been exchanged for ADSs.

Under the 2004 share repurchase agreement with Laxdale Limited, or Laxdale, upon approval of Vascepa by the FDA on July 26, 2012, we were required to make a milestone payment to Laxdale of £7.5 million. We made this payment in 2012 and capitalized this Laxdale milestone payment of \$11.6 million as a component of other long-term assets. This long-term asset is being amortized over the estimated useful life of the intellectual property we acquired from Laxdale and we recognized amortization expense of \$0.6 million in each of the years ended December 31, 2017 and 2016. Also under the Laxdale agreement, 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 \$10.1 million as of December 31, 2017). Additionally, upon receipt of a marketing approval in the United States or 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 \$6.7 million as of December 31, 2017) for each of the two potential market approvals (i.e. £10 million maximum, or approximately \$13.5 million as of December 31, 2017).

We do not enter into financial instruments for trading or speculative purposes. As of December 31, 2017 and 2016, 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.

#### **Shelf Registration Statement**

On August 22, 2017, the universal shelf registration statement on Form S-3 (Registration No. 333-197936) that we had filed with the SEC on August 7, 2014 expired. On March 1, 2017, we filed with the SEC a new universal shelf registration statement on Form S-3ASR (Registration No. 333-216385), which provides for the offer, from time to time, of: ordinary shares, which may be represented by American Depositary Shares; preference shares, which may be represented by American Depositary Shares; senior or subordinated debt securities; warrants to purchase any of these securities; and any combination of these securities, individually or as units. The addition of any newly issued equity securities into the market may be dilutive to existing stockholders and new issuances by us or sales by our selling security holders could have an adverse effect on the price of our securities.

#### **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 other than in 2013, we enter into no 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, 2017, the fair value of our cash and cash equivalents maturing in one year or less was \$73.6 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 (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, 2017 (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, 2017. In conducting this evaluation, we used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), in *Internal Control-Integrated Framework (2013)*.

Based upon this evaluation and those criteria, management believes that, as of December 31, 2017, 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, 2017. 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 2017 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, 2017, 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, 2017, 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, 2017 and 2016, the related consolidated statements of operations, stockholders' deficit and cash flows for each of the three years in the period ended December 31, 2017 and the related notes and our report dated February 27, 2018 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 27, 2018

**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. 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. 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 2018 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](http://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., 1430 Route 206, Bedminster, NJ 07921, 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 2018 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 2018 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 2018 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 2018 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	<a href="#">Articles of Association of the Company</a>	Quarterly Report on Form 10-Q, File No. 0-21392, as Exhibit 3.1	August 8, 2013
4.1	<a href="#">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</a>	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	<a href="#">Indenture, dated as of January 9, 2012, by and among Corsicanto Limited, the Company and Wells Fargo Bank, National Association, as trustee</a>	Current Report on Form 8-K dated January 9, 2012, File No. 0-21392, as Exhibit 4.1	January 10, 2012
4.3	<a href="#">Form of Ordinary Share certificate</a>	Annual Report on Form 20-F for the year ended December 31, 2002, File No. 0-21392, as Exhibit 2.4	April 24, 2003
4.4	<a href="#">Form of American Depositary Receipt evidencing ADSs</a>	Annual Report on Form 10-K for the year ended December 31, 2011, File No. 0-21392, as Exhibit 4.4	February 29, 2012
4.5	<a href="#">Form of Series A Preference Share Terms</a>	Current Report on Form 8-K dated March 5, 2015, File No. 0-21392, as Exhibit 4.1	March 11, 2015
4.6	<a href="#">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</a>	Current Report on Form 8-K dated March 30, 2015, File No. 0-21392, as Exhibit 4.1	March 30, 2015
4.7	<a href="#">Form of American Depositary Receipt evidencing restricted ADSs representing Series A Preference Shares</a>	Current Report on Form 8-K dated March 30, 2015, File No. 0-21392, as Exhibit 4.2	March 30, 2015
4.8	<a href="#">Indenture, dated January 25, 2017, by and between Corsicanto II Designated Activity Company, Amarin plc and Wilmington Trust, National Association, as trustee</a>	Current Report on Form 8-K dated January 25, 2017, File No. 0-21392, as Exhibit 4.1	January 25, 2017
4.9	<a href="#">Form of 3.50% January 2017 Exchangeable Senior Notes due 2047</a>	Current Report on Form 8-K dated January 25, 2017, File No. 0-21392, as Exhibit 4.2	January 25, 2017
10.1	<a href="#">The Company 2002 Stock Option Plan*</a>	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	<a href="#">The Company 2011 Stock Option Plan*</a>	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	<a href="#">Amendment No. 1 to 2011 Stock Option Incentive Plan*</a>	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	<a href="#">Amendment No. 2 to 2011 Stock Option Incentive Plan*</a>	Quarterly Report on Form 10-Q for quarterly period ended June 30, 2012, File No. 0-21392, as Exhibit 10.2	August 8, 2008

Exhibit Number	Description	Incorporated by Reference Herein	
		Form	Date
10.5	<a href="#">Amendment No. 3 to 2011 Stock Option and Incentive Plan*</a>	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	<a href="#">Amendment No. 4 to 2011 Stock Option and Incentive Plan*</a>	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	<a href="#">Amendment No. 5 to 2011 Stock Option and Incentive Plan*</a>	Quarterly Report on Form 10-Q for quarterly period ended June 30, 2015, File No. 0-21392, as Exhibit 4.2	August 6, 2015
10.8	<a href="#">Amarin Corporation plc Management Incentive Compensation Plan*</a>	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	<a href="#">Form of Incentive Stock Option Award Agreement</a>	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	<a href="#">Form of Non-Qualified Stock Option Award Agreement</a>	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	<a href="#">Form of Restricted Stock Unit Award Agreement</a>	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	<a href="#">Letter Agreement, dated November 15, 2010, between the Company and John F. Thero*</a>	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	<a href="#">Letter Agreement with Joseph Kennedy, dated December 13, 2011*</a>	Current Report on Form 8-K dated December 23, 2011, File No. 0-21392, as Exhibit 10.5	December 23, 2011
10.14	<a href="#">Letter Agreement with John Thero, dated December 23, 2011*</a>	Current Report on Form 8-K dated December 23, 2011, File No. 0-21392, as Exhibit 10.1	December 23, 2011
10.15	<a href="#">Letter Agreement with Steve Ketchum, dated February 8, 2012*</a>	Current Report on Form 8-K dated February 16, 2012, File No. 0-21392, as Exhibit 10.1	February 16, 2012
10.16	<a href="#">Letter Agreement with John Thero, dated January 10, 2014*</a>	Current Report on Form 8-K dated January 8, 2014, File No. 0-21392, as Exhibit 10.1	January 10, 2014
10.17	<a href="#">Amendment, dated July 6, 2015, to Letter Agreement with Joseph Kennedy, dated December 13, 2011*</a>	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	<a href="#">Amendment, dated July 6, 2015, to Letter Agreement with Steven Ketchum, dated February 8, 2012*</a>	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	<a href="#">Amendment, dated July 6, 2015, to Letter Agreement with John Thero, dated December 23, 2011*</a>	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	<a href="#">2011 Long Term Incentive Award with Joseph Kennedy, dated December 16, 2011*</a>	Form S-8, File No. 333-180180, as Exhibit 4.1	March 16, 2012

Exhibit Number	Description	Incorporated by Reference Herein	
		Form	Date
10.21	<a href="#">2012 Long Term Incentive Award with Steven Ketchum dated March 1, 2012*</a>	Form S-8, File No. 333-180180, as Exhibit 4.2	March 16, 2012
10.22	<a href="#">Employment Agreement dated November 5, 2009 with John F. Thero*</a>	Registration Statement on Form F-1, File No. 333-163704, as Exhibit 4.104	December 14, 2009
10.23	<a href="#">Development and License Agreement dated March 6, 2007 between Amarin Pharmaceuticals Ireland Limited and Elan Pharma International Limited ††</a>	Annual Report on Form 20-F for the year ended December 31, 2007, File No. 0-21392, as Exhibit 4.67	May 19, 2008
10.24	<a href="#">Termination and Assignment Agreement, dated July 21, 2009 between Elan Pharma International Limited and Amarin Pharmaceuticals Ireland Limited ††</a>	Annual Report on Form 20-F for the year ended December 31, 2008, File No. 0-21392, as Exhibit 4.90	October 22, 2009
10.25	<a href="#">Form of Purchase Agreement, dated June 1, 2007, between the Company and the Purchasers named therein</a>	Annual Report on Form 20-F for the year ended December 31, 2007, File No. 0-21392, as Exhibit 4.69	May 19, 2008
10.26	<a href="#">Form of Equity Securities Purchase Agreement for U.S. Purchasers, dated December 4, 2007, between the Company and the Purchasers named therein</a>	Report of Foreign Private Issuer filed on Form 6-K, File No. 0-21392, as Exhibit 99.5	December 17, 2007
10.27	<a href="#">Form of Equity Securities Purchase Agreement for Non-U.S. Purchasers, dated December 4, 2007, between the Company and the Purchasers named therein</a>	Report of Foreign Private Issuer filed on Form 6-K, File No. 0-21392, as Exhibit 99.6	December 17, 2007
10.28	<a href="#">Form of Debt Securities Purchase Agreement, dated December 4, 2007, between the Company and the Purchasers named therein</a>	Report of Foreign Private Issuer filed on Form 6-K, File No. 0-21392, as Exhibit 99.7	December 17, 2007
10.29	<a href="#">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. ††</a>	Report of Foreign Private Issuer filed on Form 6-K, File No. 0-21392, as Exhibit 99.1	January 28, 2008
10.30	<a href="#">Letter Agreement, dated December 6, 2007, between the Company and the Sellers' Representative of the selling shareholders of Ester Neurosciences Limited</a>	Report of Foreign Private Issuer filed on Form 6-K, File No. 0-21392, as Exhibit 99.1	February 1, 2008
10.31	<a href="#">Amendment No. 1 to Stock Purchase Agreement, dated April 7, 2008, between the Company and Medica II Management L.P.</a>	Annual Report on Form 20-F for the year ended December 31, 2007, File No. 0-21392, as Exhibit 4.79	May 19, 2008
10.32	<a href="#">Securities Purchase Agreement, dated May 12, 2008, among the Company and the Purchasers named therein</a>	Annual Report on Form 20-F for the year ended December 31, 2008, File No. 0-21392, as Exhibit 4.80	October 22, 2009
10.33	<a href="#">Form of Securities Purchase Agreement, dated May 13, 2008, between the Company and the Purchasers named therein ††</a>	Annual Report on Form 20-F for the year ended December 31, 2007, File No. 0-21392, as Exhibit 4.81	May 19, 2008
10.34	<a href="#">Amendment and Waiver Agreement, dated May 25, 2009, between Ester Neurosciences Limited, Medica II Management L.P. and the Company††</a>	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

Exhibit Number	Description	Incorporated by Reference Herein	
		Form	Date
10.35	<a href="#"><u>Form of Securities Purchase Agreement dated October 12, 2009 between the Company and the Purchasers named therein</u></a>	Annual Report on Form 20-F for the year ended December 31, 2008, File No. 0-21392, as Exhibit 4.94	October 22, 2009
10.36	<a href="#"><u>Amendment No. 1, dated December 2, 2009, to Securities Purchase Agreement dated October 12, 2009 between the Company and the Purchasers named therein</u></a>	Registration Statement on Form F-1, File No. 333-163704, as Exhibit 4.105	December 14, 2009
10.37	<a href="#"><u>Master Services Agreement, dated September 29, 2009, between Medpace Inc. and Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Limited</u></a>	Annual Report on Form 20-F for the year ended December 31, 2008, File No. 0-21392, as Exhibit 4.92	October 22, 2009
10.38	<a href="#"><u>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</u></a>	Annual Report on Form 20-F for the year ended December 31, 2008, File No. 0-21392, as Exhibit 4.97	October 22, 2009
10.39	<a href="#"><u>Management Rights Deed of Agreement dated October 16, 2009 by and among the Company and Purchasers named therein</u></a>	Annual Report on Form 20-F for the year ended December 31, 2009, File No. 0-21392, as Exhibit 4.100	June 25, 2010
10.40	<a href="#"><u>Supply Agreement, dated November 1, 2010, between Nisshin Pharma Inc. and Amarin Pharmaceuticals Ireland Limited ††</u></a>	Annual Report on Form 10-K for the year ended December 31, 2010, File No. 0-21392, as Exhibit 10.40	March 16, 2011
10.41	<a href="#"><u>API Commercial Supply Agreement, dated May 25, 2011, between Amarin Pharmaceuticals Ireland Ltd. and Chemport Inc. ††</u></a>	Quarterly Report on Form 10-Q for the period ended June 30, 2011, File No. 0-21392, as Exhibit 10.2	August 9, 2011
10.42	<a href="#"><u>Amendment to API Commercial Supply Agreement by and between Amarin Pharmaceuticals Ireland Ltd and Chemport Inc., dated April 4, 2012 ††</u></a>	Quarterly Report on Form 10-Q for quarterly period ended June 30, 2012, File No. 0-21392, as Exhibit 10.6	August 8, 2008
10.43	<a href="#"><u>Second Amendment to API Commercial Supply Agreement by and between Amarin Pharmaceuticals Ireland Ltd. and Chemport Inc., dated July 19, 2012††</u></a>	Quarterly Report on Form 10-Q for quarterly period ended September 30, 2012, File No. 0-21392, as Exhibit 10.1	November 8, 2012
10.44	<a href="#"><u>Irrevocable License Agreement dated as of April 11, 2011, as amended by the First Amendment to Irrevocable License Agreement dated as of May 9, 2011, each by Amarin Pharmaceuticals Ireland Ltd. and Bedminster 2 Funding, LLC</u></a>	Quarterly Report on Form 10-Q for the period ended June 30, 2011, File No. 0-21392, as Exhibit 10.3	August 9, 2011
10.45	<a href="#"><u>Second Amendment to Irrevocable License Agreement, by and between Bedminster 2 Funding, LLC and Amarin Pharmaceuticals Ireland Ltd., dated April 25, 2012</u></a>	Quarterly Report on Form 10-Q for quarterly period ended June 30, 2012, File No. 0-21392, as Exhibit 10.4	August 8, 2008
10.46	<a href="#"><u>Third Amendment to Irrevocable License Agreement by and between Bedminster 2 Funding, LLC and Amarin Pharmaceuticals Ireland Ltd., dated July 17, 2012</u></a>	Quarterly Report on Form 10-Q for quarterly period ended June 30, 2012, File No. 0-21392, as Exhibit 10.5	August 8, 2008

Exhibit Number	Description	Incorporated by Reference Herein	
		Form	Date
10.47	<a href="#">Fourth Amendment to Irrevocable License Agreement by and between Bedminster 2 Funding, LLC and Amarin Pharmaceuticals Ireland Ltd., dated December 15, 2012</a>	Annual Report on Form 10-K for the year ended December 31, 2012, File No. 0-21392, as Exhibit 10.71	February 28, 2012
10.48	<a href="#">Online Office Agreement dated as of September 30, 2011 by Amarin Corporation plc and Regus CME Ireland Ltd.</a>	Quarterly Report on Form 10-Q for the period ended September 30, 2011, File No. 0-21392, as Exhibit 10.2	November 8, 2011
10.49	<a href="#">Lease Agreement, dated January 22, 2007, between the Company, Amarin Pharmaceuticals Ireland Limited and Mr. David Colgan, Mr. Philip Monaghan, Mr. Finian McDonnell and Mr. Patrick Ryan</a>	Annual Report on Form 20-F for the year ended December 31, 2006, File No. 0-21392, as Exhibit 4.71	March 5, 2007
10.50	<a href="#">Lease Agreement dated November 28, 2011, by the Company, 534 East Middle Turnpike, LLC, Peter Jay Alter, as Trustee of the Leon C. Lech Irrevocable Trust under Declaration of Trust dated October 14, 1980 and Ferndale Realty, LLC</a>	Annual Report on Form 10-K for the year ended December 31, 2011, File No. 0-21392, as Exhibit 10.61	February 29, 2012
10.51	<a href="#">Sublease Agreement by and among Advance Realty Management, Inc., Bedminster 2 Funding, LLC and Amarin Pharma Inc., dated April 25, 2012</a>	Quarterly Report on Form 10-Q for quarterly period ended June 30, 2012, File No. 0-21392, as Exhibit 10.3	August 8, 2012
10.52	<a href="#">Lease Agreement dated May 8, 2013, by and between Amarin Pharma, Inc. and Bedminster 2 Funding, LLC.</a>	Quarterly Report on Form 10-Q for the period ended March 31, 2013, File No. 0-21392, as Exhibit 10.1	May 9, 2013
10.53	<a href="#">Second Amendment to Lease Agreement, by and between Amarin Pharma, Inc. and Bedminster 2 Funding, LLC, dated January 23, 2014</a>	Annual Report on Form 10-K for the year ended December 31, 2014, File No. 0-21392, as Exhibit 10.80	March 3, 2015
10.54	<a href="#">Third Amendment to Lease Agreement, by and between Amarin Pharma, Inc. and Bedminster 2 Funding, LLC, dated April 3, 2014</a>	Annual Report on Form 10-K for the year ended December 31, 2014, File No. 0-21392, as Exhibit 10.81	March 3, 2015
10.55	<a href="#">Fourth Amendment to Lease Agreement, by and between Amarin Pharma, Inc. and Bedminster 2 Funding, LLC, dated December 15, 2016</a>	Annual Report on Form 10-K for the year ended December 31, 2016, File No. 0-21392, as Exhibit 10.55	March 1, 2017
10.56	<a href="#">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††</a>	Annual Report on Form 10-K for the year ended December 31, 2012, File No. 0-21392, as Exhibit 10.76	February 28, 2012
10.57	<a href="#">Co-Promotion Agreement dated March 31, 2014, by and among the Company and Kowa Pharmaceuticals America, Inc. ††</a>	Quarterly Report on Form 10-Q for quarterly period ended March 31, 2014, File No. 0-21392, as Exhibit 10.1	May 9, 2014
10.58	<a href="#">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††</a>	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

Exhibit Number	Description	Incorporated by Reference Herein	
		Form	Date
10.59	<a href="#">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</a>	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
10.60	<a href="#">Securities Subscription Agreement dated March 30, 2015, by and between Amarin Corporation plc and Sofinnova Venture Partners VII, L.P.</a>	Current Report on Form 8-K dated March 30, 2015, File No. 0-21392, as Exhibit 10.1	March 30, 2015
10.61	<a href="#">Letter Agreement, dated May 9, 2016, by and between Amarin Corporation plc and Michael Kalb*</a>	Current Report on Form 8-K dated June 30, 2016, File No. 0-21392, as Exhibit 10.1	June 30, 2016
10.62	<a href="#">Form of Private Placement Agreement, dated January 20, 2017, by and among Amarin Corporation plc, Corsicanto II Designated Activity Company and certain investors</a>	Current Report on Form 8-K dated January 20, 2017, File No. 0-21392, as Exhibit 10.1.	January 20, 2017
10.63	<a href="#">Amendment No. 6 to 2011 Stock Incentive Plan*</a>	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
10.64	<a href="#">2017 Employee Stock Purchase Plan*</a>	Filed herewith	
10.65	<a href="#">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. ††</a>	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
10.66	<a href="#">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</a>	Filed herewith	
10.67	<a href="#">Distribution Agreement, dated March 8, 2016, by and among Biologix FZCo, Amarin Pharmaceuticals Ireland Limited and Amarin Pharma, Inc. †</a>	Filed herewith	
10.68	<a href="#">Development, Commercialization and Supply Agreement, dated September 25, 2017, by and among Amarin Pharmaceuticals Ireland Limited, Amarin Pharma, Inc. and HLS Therapeutics Inc. †</a>	Filed herewith	
14.1	<a href="#">Code of Ethics</a>	Registration Statement on Form F-3, File No. 333-170505, November 10, 2010 as Exhibit 99.1	
21.1	<a href="#">List of Subsidiaries</a>	Filed herewith	
23.1	<a href="#">Consent of Independent Registered Public Accounting Firm</a>	Filed herewith	
31.1	<a href="#">Certification of President and Chief Executive Officer (Principal Executive Officer) pursuant to Section 302 of Sarbanes-Oxley Act of 2002</a>	Filed herewith	
31.2	<a href="#">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</a>	Filed herewith	

Exhibit Number	Description	Incorporated by Reference Herein	
		Form	Date
32.1	<a href="#"><u>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</u></a>	Filed herewith	
101	INS XBRL Instance Document		
101	SCH XBRL Taxonomy Extension Schema Document		
101	CAL XBRL Taxonomy Calculation Linkbase Document		
101	DEF XBRL Taxonomy Extension Definition Linkbase Document		
101	LAB XBRL Taxonomy Label Linkbase Document		
101	PRE XBRL Taxonomy Presentation Linkbase Document		
†	Confidential treatment has been requested 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.		
††	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 27, 2018

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
<u>/s/ John F. Thero</u> John F. Thero	Director, President and Chief Executive Officer (Principal Executive Officer)	February 27, 2018
<u>/s/ Michael W. Kalb</u> Michael W. Kalb	Senior Vice President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 27, 2018
<u>/s/ Lars Ekman, M.D., Ph.D.</u> Lars Ekman, M.D., Ph.D.	Director	February 27, 2018
<u>/s/ Patrick O'Sullivan</u> Patrick O'Sullivan	Director	February 27, 2018
<u>/s/ Kristine Peterson</u> Kristine Peterson	Director	February 27, 2018
<u>/s/ David Stack</u> David Stack	Director	February 27, 2018
<u>/s/ Jan van Heek</u> Jan van Heek	Director	February 27, 2018
<u>/s/ Joseph Zakrzewski</u> Joseph Zakrzewski	Director	February 27, 2018

AMARIN CORPORATION PLC  
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Financial Statement Schedules:

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

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## 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, 2017 and 2016, the related consolidated statements of operations, stockholders' deficit and cash flows for each of the three years in the period ended December 31, 2017 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, 2017 and 2016 and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2017, 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, 2017, 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 27, 2018 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.

/s/ Ernst & Young LLP

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

Iselin, New Jersey  
February 27, 2018

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

	As of December 31,	
	2017	2016
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 73,637	\$ 98,251
Restricted cash	600	600
Accounts receivable, net	45,318	19,985
Inventory	30,260	20,507
Prepaid and other current assets	3,455	6,983
Total current assets	153,270	146,326
Property, plant and equipment, net	28	78
Deferred tax assets	—	11,082
Other long-term assets	174	741
Intangible asset, net	8,126	8,772
<b>TOTAL ASSETS</b>	<b>\$ 161,598</b>	<b>\$ 166,999</b>
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
Current Liabilities:		
Accounts payable	\$ 25,155	\$ 6,062
Accrued expenses and other current liabilities	58,902	37,720
Current portion of exchangeable senior notes, net of discount	481	15,351
Current portion of long-term debt from royalty-bearing instrument	22,348	15,944
Deferred revenue, current	1,644	1,172
Total current liabilities	108,530	76,249
Long-Term Liabilities:		
Exchangeable senior notes, net of discount	28,992	—
Long-term debt from royalty-bearing instrument	70,834	85,155
Deferred revenue, long-term	17,192	13,943
Other long-term liabilities	1,150	710
Total liabilities	226,698	176,057
Commitments and contingencies (Note 9)		
Stockholders' Deficit:		
Series A Convertible Preferred Stock, £0.05 par, unlimited authorized; 328,184,640 shares issued and outstanding as of December 31, 2017 and December 31, 2016 (equivalent to 32,818,464 ordinary shares upon future consolidation and redesignation at a 10:1 ratio)	24,364	24,364
Common stock, £0.50 par, unlimited authorized; 272,719,044 issued, 271,022,011 outstanding as of December 31, 2017; 270,183,201 issued, 269,363,696 outstanding as of December 31, 2016	208,768	207,166
Additional paid-in capital	977,866	964,914
Treasury stock; 1,697,033 shares as of December 31, 2017; 819,505 shares as of December 31, 2016	(4,229)	(1,498)
Accumulated deficit	(1,271,869)	(1,204,004)
Total stockholders' deficit	(65,100)	(9,058)
<b>TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT</b>	<b>\$ 161,598</b>	<b>\$ 166,999</b>

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,		
	2017	2016	2015
Product revenue, net	\$ 179,825	\$ 128,966	\$ 80,987
Licensing revenue	1,279	1,118	769
Total revenue, net	181,104	130,084	81,756
Less: Cost of goods sold	44,952	34,363	27,875
Gross margin	136,152	95,721	53,881
Operating expenses:			
Selling, general and administrative	134,549	111,372	101,041
Research and development	47,158	49,975	51,062
Total operating expenses	181,707	161,347	152,103
Operating loss	(45,555)	(65,626)	(98,222)
Gain (loss) on change in fair value of derivative liabilities	—	8,170	(1,106)
Gain on extinguishment of debt	—	—	1,314
Interest expense	(9,766)	(18,677)	(20,180)
Interest income	429	234	132
Other income (expense), net	74	(482)	(228)
Loss from operations before taxes	(54,818)	(76,381)	(118,290)
(Provision for) benefit from income taxes	(13,047)	(9,969)	3,086
Net loss	(67,865)	(86,350)	(115,204)
Preferred stock purchase option	—	—	(868)
Preferred stock beneficial conversion features	—	—	(32,987)
Net loss applicable to common shareholders	<u>\$ (67,865)</u>	<u>\$ (86,350)</u>	<u>\$ (149,059)</u>
Loss per share:			
Basic	\$ (0.25)	\$ (0.41)	\$ (0.83)
Diluted	<u>\$ (0.25)</u>	<u>\$ (0.41)</u>	<u>\$ (0.83)</u>
Weighted average shares outstanding:			
Basic	270,652	211,874	180,654
Diluted	270,652	211,874	180,654

See the notes to the consolidated financial statements.

**AMARIN CORPORATION PLC**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT**  
**YEARS ENDED DECEMBER 31, 2017, 2016 and 2015**  
(in thousands, except share amounts)

	Preferred Shares	Common Shares	Treasury Shares	Preferred Stock	Common Stock	Additional Paid-in Capital	Treasury Stock	Accumulated Deficit	Total
<b>January 1, 2015</b>	—	<b>174,610,451</b>	<b>(20,079)</b>	<b>\$ —</b>	<b>\$ 143,113</b>	<b>\$ 738,890</b>	<b>\$ (217)</b>	<b>\$ (970,234)</b>	<b>\$ (88,448)</b>
Issuance of Series A Convertible Preferred Stock, net	391,017,970	—	—	29,168	—	28,685	—	—	57,853
Conversion of Series A Convertible Preferred Stock, net	(62,833,330)	6,283,333	—	(4,804)	4,804	(187)	—	—	(187)
Preferred stock purchase option	—	—	—	—	—	1,814	—	(868)	946
Preferred stock beneficial conversion features	—	—	—	—	—	32,987	—	(32,987)	—
Exercise of warrants	—	1,844,585	—	—	1,429	1,284	—	—	2,713
Exercise of stock options	—	18,020	—	—	13	18	—	—	31
Vesting of restricted stock units	—	821,376	(154,423)	—	619	(619)	(194)	—	(194)
Reacquisition of conversion option in convertible notes	—	—	—	—	—	(1,300)	—	—	(1,300)
Tax benefits realized from stock-based compensation	—	—	—	—	—	727	—	—	727
Stock-based compensation	—	—	—	—	—	13,872	—	—	13,872
Net loss	—	—	—	—	—	—	—	(115,204)	(115,204)
<b>December 31, 2015</b>	<b><u>328,184,640</u></b>	<b><u>183,577,765</u></b>	<b><u>(174,502)</u></b>	<b><u>\$ 24,364</u></b>	<b><u>\$ 149,978</u></b>	<b><u>\$ 816,171</u></b>	<b><u>\$ (411)</u></b>	<b><u>\$ (1,119,293)</u></b>	<b><u>\$ (129,191)</u></b>
Cumulative-effect adjustment	—	—	—	—	—	—	—	1,639	1,639
<b>January 1, 2016</b>	<b><u>328,184,640</u></b>	<b><u>183,577,765</u></b>	<b><u>(174,502)</u></b>	<b><u>\$ 24,364</u></b>	<b><u>\$ 149,978</u></b>	<b><u>\$ 816,171</u></b>	<b><u>\$ (411)</u></b>	<b><u>\$ (1,117,654)</u></b>	<b><u>\$ (127,552)</u></b>
Issuance of common stock, net of transaction costs	—	24,265,000	—	—	15,712	48,901	—	—	64,613
Exchange of exchangeable senior notes, net of transaction costs	—	60,311,188	—	—	40,062	87,374	—	—	127,436
Exercise of stock options	—	177,146	—	—	119	168	—	—	287
Vesting of restricted stock units	—	1,852,102	(645,003)	—	1,295	(1,302)	(1,087)	—	(1,094)
Stock-based compensation	—	—	—	—	—	13,602	—	—	13,602
Net loss	—	—	—	—	—	—	—	(86,350)	(86,350)
<b>December 31, 2016</b>	<b><u>328,184,640</u></b>	<b><u>270,183,201</u></b>	<b><u>(819,505)</u></b>	<b><u>\$ 24,364</u></b>	<b><u>\$ 207,166</u></b>	<b><u>\$ 964,914</u></b>	<b><u>\$ (1,498)</u></b>	<b><u>\$ (1,204,004)</u></b>	<b><u>\$ (9,058)</u></b>
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)
<b>December 31, 2017</b>	<b><u>328,184,640</u></b>	<b><u>272,719,044</u></b>	<b><u>(1,697,033)</u></b>	<b><u>\$ 24,364</u></b>	<b><u>\$ 208,768</u></b>	<b><u>\$ 977,866</u></b>	<b><u>\$ (4,229)</u></b>	<b><u>\$ (1,271,869)</u></b>	<b><u>\$ (65,100)</u></b>

See the notes to the consolidated financial statements.

**AMARIN CORPORATION PLC**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(in thousands)

	Year Ended December 31,		
	2017	2016	2015
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net loss	\$ (67,865)	\$ (86,350)	\$ (115,204)
Adjustments to reconcile loss to net cash used in operating activities:			
Depreciation and amortization	62	138	166
Loss on sale of fixed assets	—	48	—
Allowance for doubtful accounts	—	12	—
Stock-based compensation	13,960	13,613	13,889
Stock-based compensation—warrants	—	—	(9)
Amortization of debt discount and debt issuance costs	2,332	7,783	8,258
Amortization of intangible asset	646	645	646
Gain (loss) on change in fair value of derivative liabilities	—	(8,170)	1,106
Gain on extinguishment of debt	—	—	(1,314)
Deferred income taxes	11,082	8,798	(4,252)
Changes in assets and liabilities:			
Accounts receivable, net	(25,333)	(6,171)	(5,984)
Inventory	(9,753)	(1,522)	(5,252)
Prepaid and other current assets	6,028	(3,831)	(519)
Other long-term assets	567	(567)	431
Accrued interest payable	(6,491)	(6,205)	(652)
Deferred revenue	1,221	884	14,231
Accounts payable and other current liabilities	40,267	8,705	10,489
Other long-term liabilities	440	375	(51)
Net cash used in operating activities	(32,837)	(71,815)	(84,021)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Purchases of equipment	(12)	(21)	(28)
Net cash used in investing activities	(12)	(21)	(28)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Proceeds from issuance of exchangeable debt	30,000	—	—
Proceeds from issuance of preferred stock, net of transaction costs	—	—	57,666
Proceeds from issuance of common stock, net of transaction costs	—	64,613	—
Proceeds from issuance of convertible debt, net of transaction costs	—	—	27,514
Proceeds from exercise of warrants, net of transaction costs	—	—	2,713
Proceeds from exercise of stock options, net of transaction costs	638	287	31
Payment of debt issuance costs	(1,207)	—	—
Debt issuance costs	—	—	(109)
Repurchase of exchangeable senior notes, including transaction costs	(15,107)	—	(16,145)
Payment on long-term debt from royalty-bearing instrument	(3,322)	—	—
Transaction costs related to exchange of exchangeable senior notes	—	(680)	—
Taxes paid related to stock-based awards	(2,767)	(1,094)	(194)
Payment under capital leases	—	—	(5)
Net cash provided by financing activities	8,235	63,126	71,471
NET DECREASE IN CASH AND CASH EQUIVALENTS	(24,614)	(8,710)	(12,578)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	98,251	106,961	119,539
CASH AND CASH EQUIVALENTS, END OF PERIOD	<u>\$ 73,637</u>	<u>\$ 98,251</u>	<u>\$ 106,961</u>
Supplemental disclosure of cash flow information:			
Cash paid during the year for:			
Interest	<u>\$ 17,241</u>	<u>\$ 17,083</u>	<u>\$ 12,559</u>
Income taxes	<u>\$ 1,753</u>	<u>\$ 1,457</u>	<u>\$ 711</u>
Supplemental disclosure of non-cash transactions:			
Exchange of exchangeable senior notes into common stock	<u>\$ —</u>	<u>\$ 128,115</u>	<u>\$ —</u>
Transfer of preferred stock purchase option derivative liability to equity	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 868</u>
Accretion of preferred stock beneficial conversion features	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 32,987</u>
Conversion of Series A Convertible Preferred Stock into common stock	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 4,804</u>
Reacquisition of conversion option in convertible notes	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 1,300</u>

See the notes to the consolidated financial statements.

AMARIN CORPORATION PLC  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**(1) Nature of Business and Basis of Presentation**

**Nature of Business**

Amarin Corporation plc (“Amarin” or the “Company”) is a biopharmaceutical company with expertise in lipid science focused on the commercialization and development of therapeutics to improve cardiovascular health.

The Company’s lead product, Vascepa® (icosapent ethyl) capsules, is approved by the U.S. Food and Drug Administration, or FDA, for use as an adjunct to diet to reduce triglyceride levels in adult patients with severe (TG  $\geq$ 500 mg/dL) hypertriglyceridemia. Vascepa is available in the United States 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. In August 2015, in addition to marketing Vascepa for severe hypertriglyceridemia, the Company commenced marketing Vascepa for use in adult patients with mixed dyslipidemia, as an adjunct to diet and an add-on to statin therapy in patients who despite statin therapy have high triglycerides (TGs  $\geq$ 200 mg/dL and  $\leq$ 500 mg/dL), which the Company also refers to as persistently high triglycerides. This expanded promotion of Vascepa commenced pursuant to a federal court order and is continuing pursuant to an agreement among the Company, the FDA and the U.S. government.

The Company is also developing Vascepa for FDA approval of potential additional indications for use. In particular, the Company is conducting a cardiovascular outcomes study of Vascepa, titled REDUCE-IT (Reduction of Cardiovascular Events with EPA—Intervention Trial). The REDUCE-IT study, which commenced in 2011 and completed patient enrollment and randomization of 8,175 individual patients in 2016, is designed to evaluate the efficacy of Vascepa in reducing major cardiovascular events in a high-risk patient population on statin therapy. The Company anticipates that results of the REDUCE-IT study will be available and made public before the end of the third quarter of 2018.

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 through its direct sales force of approximately 165 sales professionals, including sales representatives and their managers, and through a co-promotion agreement with Kowa Pharmaceuticals America, Inc. Under this co-promotion agreement, which commenced in May 2014 and is scheduled to end at the end of 2018, Kowa Pharmaceuticals America, Inc. co-promotes Vascepa in conjunction with its promotion of its primary product, a branded statin for patients with high cholesterol. 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 of America (the “U.S.” or 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 (“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, 2017, 2016 and 2015 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 deferred tax assets and liabilities and the provision for income taxes have been reclassified to conform to the current year presentation. These reclassifications do not have a material impact on the Company’s consolidated financial statements.

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, 2017, the Company had current assets of \$153.3 million, including cash and cash equivalents of \$73.6 million. The Company’s consolidated balance sheets also include long-term debt from a royalty-bearing instrument and exchangeable senior notes. In January 2017, the Company issued \$30.0 million in aggregate principal amount of January 2017 3.5% exchangeable senior notes due 2047, or the 2017 Notes. The terms of the 2017 Notes are such that they may be redeemed by the Company for cash on or after January 19, 2021 and may be put back to the Company by the holders on January 19, 2022 for cash equal to 100% of the principal



amount plus any accrued and unpaid interest. The 2017 Notes are exchangeable into American Depositary Shares (“ADSs”) at the option of holders at any time after issuance and prior to maturity and are exchangeable into ADSs at the option of the Company upon satisfaction of certain equity conditions. Accordingly, the exchangeable senior notes do not represent a short-term claim on the liquid assets of the Company as of December 31, 2017. The terms of the Company’s January 2012 3.5% exchangeable senior notes due 2032, or the 2012 Notes, which were repaid in full during the first quarter of 2017, allowed for repurchase in cash by the Company at the option of the holders on January 19, 2017, as well as redemption by the Company for cash of all or part of the 2012 Notes on or after January 19, 2017, both at a price equal to 100% of the principal amount of the 2012 Notes to be repurchased or redeemed, plus accrued and unpaid interest to, but excluding, the repurchase or redemption date. Accordingly, \$15.1 million in principal amount of 2012 Notes represented a short-term claim on the liquid assets of the Company as of December 31, 2016. Refer to Note 8—Debt for further discussion.

In February 2018, the Company received approximately \$65.0 million of net proceeds from a registered offering of its ADSs (refer to Note 18—Subsequent Events for further discussion). The Company believes its cash and cash equivalents will be sufficient to fund its projected operations through the results of the REDUCE-IT study, which we anticipate will be available before the end of the third quarter of 2018 and, assuming positive results of the REDUCE-IT study, through subsequent public presentation of such results at a medical congress before the end of 2018. Depending on the level of cash generated from operations, additional capital may be required to expand promotion of Vascepa as contemplated following anticipated successful results of the REDUCE-IT study. If additional capital is required and the Company is unable to obtain additional capital, the Company may be forced to delay, limit or eliminate all or a portion of the expanded promotional activities planned following successful results of the REDUCE-IT study. The Company anticipates that annual net cash outflows in future periods will be variable.

## **(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 instruments 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**

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. Patients are required to have a prescription in order to purchase Vascepa. In accordance with GAAP, the Company’s revenue recognition policy requires that: (i) there is persuasive evidence that an arrangement exists between the Company and the Distributor, (ii) delivery has occurred, (iii) collectability is reasonably assured and (iv) the price is fixed or determinable.

The Company has contracts with its primary Distributors and delivery generally occurs when a Distributor receives Vascepa. 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. In order to conclude that the price is fixed or determinable, the Company must be able to (i) calculate its gross product revenues from the sales to

Distributors and (ii) reasonably estimate its net product revenues. The Company calculates gross product revenues generally based on the wholesale acquisition cost that the Company charges its Distributors for Vascepa. The Company estimates its net product revenues by deducting from its 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.

*Trade Allowances:* The Company generally provides invoice discounts on Vascepa sales to its Distributors for prompt payment and pays 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 judgment and experience, 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, 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 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.

*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 is three years after it has been 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.

*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 and deducts these estimated amounts from its gross product revenues at the time the revenues are recognized. 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, 2017 and 2016:

<i>In thousands</i>	Trade Allowances	Rebates, Chargebacks and Discounts	Product Returns	Other Incentives	Total
<b>Balance as of January 1, 2016</b>	<b>\$ 4,296</b>	<b>\$ 9,881</b>	<b>\$ 535</b>	<b>\$ 1,084</b>	<b>\$ 15,796</b>
Provision related to current period sales	22,952	69,370	583	11,696	104,601
Provision related to prior period sales	(87)	(450)	—	—	(537)
Credits/payments made for current period sales	(19,213)	(48,719)	—	(9,815)	(77,747)
Credits/payments made for prior period sales	(4,205)	(9,167)	(259)	(1,284)	(14,915)
<b>Balance as of December 31, 2016</b>	<b>3,743</b>	<b>20,915</b>	<b>859</b>	<b>1,681</b>	<b>27,198</b>
Provision related to current period sales	35,067	126,903	1,480	15,081	178,531
Provision related to prior period sales	(323)	(682)	—	(70)	(1,075)
Credits/payments made for current period sales	(23,087)	(96,181)	(344)	(12,773)	(132,385)
Credits/payments made for prior period sales	(3,365)	(18,891)	(108)	(1,812)	(24,176)
<b>Balance as of December 31, 2017</b>	<b>\$ 12,035</b>	<b>\$ 32,064</b>	<b>\$ 1,887</b>	<b>\$ 2,107</b>	<b>\$ 48,093</b>

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.

#### Multiple-Element Arrangements and Licensing Revenue

When evaluating multiple-element arrangements, the Company identifies the deliverables included within the agreement and evaluates which deliverables represent separate units of accounting based on whether the delivered element has stand-alone value to the customer or if the arrangement includes a general right of return for delivered items.

The consideration received is allocated between each of the separable elements in the arrangement using the relative selling price method. The selling price used for each separable element will be based on vendor specific objective evidence (“VSOE”) if available, third-party evidence if VSOE is not available, or estimated selling price if neither VSOE nor third-party evidence is available. Revenue is then recognized as each of the separable elements to which the revenue has been allocated is delivered.

The Company may receive up-front, non-refundable payments when licensing its intellectual property in conjunction with research, development and commercialization agreements. In determining the units of accounting, management evaluates whether the license has stand-alone value from the undelivered elements to the collaborative partner based on the consideration of the relevant facts and circumstances for each arrangement. Factors considered in this 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.

When management believes the license to its intellectual property does not have stand-alone value from the other deliverables to be provided in the arrangement, the Company generally recognizes revenue attributable to the license over the Company’s contractual or estimated performance period. Any unrecognized portion of license revenue is classified within deferred revenue in the accompanying consolidated balance sheets. When management believes the license to its intellectual property has stand-alone value, the Company recognizes revenue attributed to the license upon delivery. The periods over which revenue is recognized is subject to estimates by management and may change over the course of the agreement. Such a change could have a material impact on the amount of revenue the Company records in future periods.

#### Milestones

Contingent consideration from activities that is earned upon the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved. At the inception of each arrangement that includes milestone payments, the Company evaluates whether each milestone is substantive. This evaluation includes an assessment of whether: (a) the consideration is commensurate with either (1) the entity’s performance to achieve the milestone, or (2) the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity’s performance to achieve the milestone, (b) the consideration relates solely to past performance and (c) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. The Company evaluates factors such as the scientific, clinical, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement in making this assessment.

See Note 17—Development, Commercialization and Supply Agreements for further information regarding licensing revenue and milestones.

### **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, 2017 and 2016:

<i>In thousands</i>	<b>December 31, 2017</b>	<b>December 31, 2016</b>
Gross trade accounts receivable	\$ 57,802	\$ 24,127
Trade allowances	(12,035)	(3,743)
Chargebacks	(449)	(387)
Allowance for doubtful accounts	—	(12)
Accounts receivable, net	<u>\$ 45,318</u>	<u>\$ 19,985</u>

### **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.

### **Property, Plant and Equipment**

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. The estimated useful lives, by asset classification, are as follows:

<b>Asset Classification</b>	<b>Useful Lives</b>
Computer equipment and software	3 - 5 years
Furniture and fixtures	5 years
Leasehold improvements	Lesser of useful life or lease term

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.

### **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 a milestone payment paid 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 and is amortized over its estimated useful life on a straight-line basis. See Note 9—Commitments and Contingencies for further information regarding other obligations related to the acquisition of Laxdale Limited.

### **Beneficial Conversion Features**

The Company issued Series A preference shares in a private placement transaction executed in two tranches that each contain a conversion feature whereby such shares are convertible into ordinary shares at a fixed rate. The conversion price on the date of issuance was less than the market price of the Company's ordinary shares. It was determined that these discounts represent contingent beneficial conversion features, which were valued based on the difference between the conversion price and the market price of the ordinary shares on the date of issuance, which is the commitment date. These features are analogous to preference dividends and were each recorded as a non-cash return to preferred shareholders through accumulated deficit upon the earliest possible date of conversion, which occurred in the second quarter of 2015 upon effectiveness of the related resale Registration Statement on Form S-3 and in the third quarter of 2015 upon shareholder approval received at the Company's Annual General Meeting of Shareholders. See Note 10—Equity for further discussion.

### **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 expenses.

### **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.

### **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 payable to Kowa Pharmaceuticals America, Inc.

### **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. 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 or 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.

The Company regularly assesses its ability to realize deferred tax assets. Changes in historical earnings performance, future earnings projections, and changes in tax laws and tax rates, 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.

In April 2016, the Company adopted Accounting Standards Update ("ASU") No. 2016-09, *Compensation—Stock Compensation (Topic 718): Improvements to Employee 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, 2017 and 2016 include \$1.3 million of excess tax benefits and \$0.4 million of excess tax deficiencies, respectively, arising from share-based payments. 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 payable 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 outstanding as of December 31, 2015, with a corresponding cumulative-effect adjustment to accumulated deficit. The standard also amended the presentation of employee share-based payment-related items in the statement of cash flows by requiring that: (i) excess income tax benefits and deficiencies be classified in cash flows from operating activities, and (ii) cash paid to taxing authorities arising from the withholding of shares from employees be classified as cash flows from financing activities. The Company adopted the aspects of the standard affecting cash flow presentation retrospectively and, accordingly, reclassified \$0.7 million of excess tax benefit from cash flows provided by financing activities to cash flows used in operating activities in the consolidated statement of cash flows for the year ended December 31, 2015. The presentation requirement for cash flows related to taxes paid for withheld shares had no impact on the consolidated statements of cash flows since such payments have historically been presented as a financing activity.

The Company's and its subsidiaries' income tax returns are periodically examined by various tax authorities. The Company is currently undergoing federal and state audits, including audit by the United States Internal Revenue Service (IRS) for the years 2013 to 2014. 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 and warrants 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 and warrants are deemed anti-dilutive such that basic net loss per share and diluted net loss per share are equal. However, in certain periods in which there is a gain recorded pursuant to the change in fair value of the warrant derivative liability, for diluted net loss per share purposes, the impact of such gains is reversed and the treasury stock method is used to determine diluted net loss per share.

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, 2017, 2016 and 2015 are as follows:

<i>In thousands</i>	2017	2016	2015
Net loss	\$ (67,865)	\$ (86,350)	\$ (115,204)
Preferred stock purchase option (see Note 10—Equity)	—	—	(868)
Preferred stock beneficial conversion features (see Note 10—Equity)	—	—	(32,987)
Net loss applicable to common shareholders—basic and diluted	(67,865)	(86,350)	(149,059)
Weighted average shares outstanding—basic and diluted	270,652	211,874	180,654
Net loss per share—basic and diluted	\$ (0.25)	\$ (0.41)	\$ (0.83)

For the years ended December 31, 2017, 2016 and 2015, the following potentially dilutive securities were not included in the computation of net loss per share because the effect would be anti-dilutive:

<i>In thousands</i>	2017	2016	2015
Stock options	24,108	21,188	17,818
Restricted stock and restricted stock units	12,006	10,143	10,887
Exchangeable senior notes (if converted)	7,716	1,714	59,407
Preferred stock (if converted)	32,818	32,818	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 income (expense), 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 on the issuance of those shares.

The 2012 Notes could be settled in any combination of ADSs or cash, at the Company's discretion, upon conversion and were therefore accounted for in accordance with ASC 470-20. Under ASC 470-20, the fair value of the liability component of the 2012 Notes was determined and deducted from the initial proceeds to determine the proceeds allocated to the conversion option, which was recorded in equity. The difference between the initial fair value of the liability component and the amount repayable was fully amortized over the expected term of the instrument. The conversion feature in the 2012 Notes qualified for the exception from derivative accounting in accordance with ASC 815-40. The terms of the 2012 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. Consequently, in January 2017, holders of the 2012 Notes exercised their option to put approximately \$15.0 million in aggregate principal amount of 2012 Notes to the Company for cash and, in March 2017, the Company redeemed the entirety of the remaining \$0.1 million in aggregate principal amount of 2012 Notes, such that no 2012 Notes remained outstanding as of December 31, 2017. The carrying value of the conversion option will remain in equity hereafter as a result of the repayment in full of the related debt instrument.

The 2017 Notes can only be settled in ADSs upon conversion. The terms of the 2017 Notes also allow 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 qualifies for the exception from derivative accounting in accordance with ASC 815-40 and is therefore accounted for as part of the debt host. The conversion feature in the 2017 Notes will continue to be evaluated on a quarterly basis to determine if it still receives 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 is being amortized through interest expense over the expected term of the 2017 Notes, through the first optional put date in January 2022.

See Note 8—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 12—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 33%, 28%, and 27%, respectively, of gross product sales for the year ended December 31, 2017 and represented 21%, 41%, and 27%, respectively, of the gross accounts receivable balance as of December 31, 2017. Customers A, B, and C accounted for 37%, 30%, and 28%, respectively, of gross product sales for the year ended December 31, 2016 and represented 33%, 16%, and 47%, respectively, of the gross accounts receivable balance as of December 31, 2016. 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 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 key 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 three FDA-approved commercial API manufacturers and encapsulators for Vascepa manufacturing. Each of these companies has qualified 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 encapsulate API will remain qualified to manufacture the product 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 income (expense), net, in the consolidated statements of operations. For transactions settled during the applicable period, gains and losses are included in other income (expense), net, in the consolidated statements of operations. Certain amounts payable 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, 2017 and 2016 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:

<i>In thousands</i>	December 31, 2017			
	Total	Level 1	Level 2	Level 3
<b>Asset:</b>				
Cash equivalents—money markets	\$ 9,317	\$ 9,317	\$ —	\$ —



<i>In thousands</i> <b>Asset:</b>	December 31, 2016			
	Total	Level 1	Level 2	Level 3
Cash equivalents—money markets	\$ 14,238	\$ 14,238	\$ —	\$ —

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, 2017 and 2016 are as follows:

<i>In thousands</i>	December 31, 2017		December 31, 2016	
	Carrying Value	Estimated Fair Value	Carrying Value	Estimated Fair Value
Current portion of long-term debt from royalty-bearing instrument, net of accrued interest	\$ 21,569		\$ 8,437	
Long-term debt from royalty-bearing instrument	70,834		85,155	
Total long-term debt from royalty-bearing instrument	\$ 92,403	\$ 88,000	\$ 93,592	\$ 90,500
2012 Notes	—	—	15,107	15,174
2017 Notes	28,992	38,200	—	—

The estimated fair value of the long-term debt from royalty-bearing instrument pursuant to the December 2012 financing is calculated utilizing the same Level 3 inputs utilized in valuing the related derivative liability (see Derivative Liabilities below). The estimated fair value of the 2012 Notes and 2017 Notes is calculated based on Level 1 quoted bond prices or, in the absence of quoted bond prices, is calculated using a Level 3 binomial model. The carrying value of the 2012 Notes as of December 31, 2016 did not include a debt discount, as it had been fully amortized as non-cash interest expense over the expected term of the 2012 Notes, which was calculated to be a period of twenty-four months. During the first quarter of 2017, the Company repurchased \$15.0 million in aggregate principal amount of 2012 Notes at the option of holders and redeemed the remaining \$0.1 million in aggregate principal amount at the Company's option, such that no 2012 Notes remained outstanding as of December 31, 2017. The carrying value of the 2017 Notes as of December 31, 2017 includes a debt discount of \$1.0 million, which is being amortized as non-cash interest expense over the expected term of the 2017 Notes, through the first optional put date in January 2022.

#### 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 Features

The Company's December 2012 royalty-bearing instrument financing arrangement (discussed in Note 8—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, 2017, the fair value of the derivative was determined to be nil based on current assumptions, and the debt was valued by comparing debt issues of similar companies with (i) remaining terms of between 2.3 and 4.3 years, (ii) coupon rates of between 5.8% and 10.8% and (iii) market yields of between 10.2% and 18.4%. As of December 31, 2016, 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 2.4 and 5.0 years, (ii) coupon rates of between 8.1% and 11.1% and (iii) market yields of between 11.9% and 18.4%. As such, the Company recognized no gain on change in fair value of derivative liability for the year ended December 31, 2017. The Company recognized a \$5.5 million gain on change in fair value of derivative liability for the year ended December 31, 2016.

The Company's 2014 Notes and 2015 Notes each contained a redemption feature whereby, upon occurrence of a change in control, the Company would have been required to repurchase the notes. The Company determined these redemption features to be embedded derivatives, requiring bifurcation in accordance with ASC 815. The derivatives were carried at fair value and were classified as Level 3 in the fair value hierarchy due to the use of significant unobservable inputs. The fair value of each embedded derivative was calculated using a probability-weighted model incorporating management estimates of the probability of a change in control occurring, 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 these derivative liabilities was remeasured at each reporting period, with changes in fair value recognized in the consolidated statement of operations. These derivative liabilities were derecognized in September 2016, as the related debt hosts were exchanged into equity, and therefore no gain or loss on change in fair value of derivative liability was recognized for the year ended December 31, 2017. The Company recognized a gain on change in fair value of derivative liability for the 2014 Notes and 2015 Notes of \$2.1 million and \$0.6 million, respectively, for the year ended December 31, 2016.

#### *Warrant Derivative Liability*

The Company's warrant derivative liability (discussed in Note 7—Warrants and Warrant Derivative Liability) was carried at fair value and was classified as Level 3 in the fair value hierarchy due to the use of significant unobservable inputs. During the year ended December 31, 2015 of the 8,087,388 warrants outstanding as of December 31, 2014, 1,844,585 warrants were exercised while the remaining 6,242,803 warrants expired and the related derivative liability was extinguished. As such, no warrants were outstanding as of December 31, 2017 and 2016.

#### *Preferred Stock Purchase Option Derivative Liability*

Pursuant to a pre-existing contractual right to participate in certain private placement transactions effected by the Company in connection with the subscription agreement executed on March 5, 2015, the Company determined that such right represented a derivative liability (see Note 10—Equity). This preferred stock purchase option derivative liability was carried at fair value and classified as Level 3 in the fair value hierarchy due to the use of significant unobservable inputs. The fair value of this liability was calculated using a Black-Scholes model and was determined to be \$0.9 million at inception. On March 30, 2015, this right was exercised and the liability was marked to fair value through such date, resulting in a charge of \$0.9 million through gain (loss) on change in fair value of derivatives in the year ended December 31, 2015. The liability was then reclassified to permanent equity on such date.

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

#### *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. The Company also considered the following recent accounting pronouncements which were not yet adopted as of December 31, 2017:

In May 2017, the FASB issued Accounting Standards Update ("ASU") No. 2017-09, *Compensation—Stock Compensation: Scope of Modification Accounting*. The amendments in ASU No. 2017-09 provide guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. The new guidance is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. The Company has evaluated the accounting, transition and disclosure requirements of these standards and does not expect them to have a material impact on the Company's consolidated financial statements.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*, which is intended to reduce diversity in practice regarding how certain cash receipts and cash payments related to eight specific issues are presented and classified in the statement of cash flows. In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash*, which requires that the statement of cash flows explain the change during

the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. For each of these ASUs, the new guidance is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. The Company has evaluated the accounting, transition and disclosure requirements of these standards and does not expect them to have a material impact on the Company's consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-08, *Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net)*, which clarifies that an entity is a principal when it controls the specified good or service before that good or service is transferred to the customer, and is an agent when it does not control the specified good or service before it is transferred to the customer. The new guidance is intended to improve the operability and understandability of the implementation guidance on principal versus agent considerations. In April 2016, the FASB issued ASU No. 2016-10, *Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing*, which clarifies the following two aspects of Topic 606: (a) identifying performance obligations; and (b) the licensing implementation guidance. Further, in May 2016, the FASB issued ASU No. 2016-12, *Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients*, which provides clarifying guidance in certain narrow areas and adds some practical expedients. The amendments do not change the core principles of the guidance in Topic 606 and are effective for the Company's fiscal year beginning January 1, 2018. The Company has evaluated the accounting, transition and disclosure requirements of these standards in connection with its evaluation of ASU 2014-09 as discussed below and does not expect them to have a material impact on the Company's consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*. The new guidance will require lessees to recognize a right-of-use asset and a lease liability for virtually all of their leases (other than leases that meet the definition of a short-term lease). The liability will be equal to the present value of lease payments. The asset will be based on the liability, subject to adjustment, such as for initial direct costs. Under the new guidance, lessor accounting is largely unchanged but certain targeted improvements were made to align, where necessary, lessor accounting with the lessee accounting model and Topic 606, *Revenue from Contracts with Customers*. The new lease guidance also simplified the accounting for sale and leaseback transactions primarily because lessees must recognize lease assets and lease liabilities and therefore, will no longer be provided with a source of off-balance sheet financing. The new guidance is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the accounting, transition and disclosure requirements of the standard and cannot currently estimate the financial statement impact of adoption.

In January 2016, the FASB issued ASU No. 2016-01, *Financial Instruments—Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities*. The new guidance is intended to improve the recognition and measurement of financial instruments by requiring separate presentation of financial assets and financial liabilities by measurement category and form of financial asset (i.e., securities or loans and receivables) within the balance sheet or the accompanying notes to the financial statements, eliminating the requirement for public business entities to disclose the method(s) and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost within the balance sheet, requiring public business entities to use the exit price notion when measuring the fair value of financial instruments for disclosure purposes, requiring equity investments (except those accounted for under the equity method of accounting, or those that result in consolidation of the investee) to be measured at fair value with changes in fair value recognized in net income, and requiring a reporting organization to present separately in other comprehensive income the portion of the total change in the fair value of a liability resulting from a change in the instrument-specific credit risk (also referred to as "own credit") when the organization has elected to measure the liability at fair value in accordance with the fair value option for financial instruments, among others. The new guidance is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. The Company is currently evaluating the accounting, transition and disclosure requirements of the standard and cannot currently estimate the financial statement impact of adoption.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which will replace numerous requirements in U.S. GAAP, including industry-specific requirements. This guidance provides a five-step model to be applied to all contracts with customers, with an underlying principle that an entity will recognize revenue to depict the transfer of goods or services to customers at an amount that the entity expects to be entitled to in exchange for those goods or services. This guidance is effective for annual reporting periods beginning after December 15, 2017 and interim periods therein. An entity can elect to apply the guidance under one of the following two methods: (i) retrospectively to each prior reporting period presented, referred to as the full retrospective method, or (ii) retrospectively with the cumulative effect of initially applying the standard recognized at the date of initial application in retained earnings, referred to as the modified retrospective method. The Company will adopt the new standard effective January 1, 2018 and will apply the modified retrospective method.

The Company has completed its assessment of adopting ASU No. 2014-09 for net product revenues and contract revenues generated by its license agreements. The assessment consisted of a review of a representative sample of contracts, discussions with key stakeholders, and a cataloging of potential impacts on its internal statements, accounting policies, financial control, and operations.

The Company does not expect significant changes in the amounts or timing of revenue recognition for net product revenues which is its primary revenue stream. For contract revenues generated by its license agreements, the Company expects to recognize an immaterial cumulative-effect adjustment to its accumulated deficit. The Company is also evaluating the new disclosures required by the standard to determine what additional information will need to be disclosed.

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 and has an estimated weighted-average remaining useful life of 12.6 years. The carrying value as of December 31, 2017 and 2016 is as follows:

<i>In thousands</i>	<b>December 31, 2017</b>	<b>December 31, 2016</b>
Technology rights	\$ 11,624	\$ 11,624
Accumulated amortization	(3,498)	(2,852)
Intangible asset, net	<u>\$ 8,126</u>	<u>\$ 8,772</u>

Amortization expense for each of the years ended December 31, 2017 and 2016 was \$0.6 million and is included in research and development expense. Estimated future amortization expense, based upon the Company's intangible asset, as of December 31, 2017 is as follows:

<i>In thousands</i>	
<b>Year Ending December 31,</b>	<b>Amount</b>
2018	\$ 646
2019	646
2020	646
2021	646
2022	646
Thereafter	4,896
Total	<u>\$ 8,126</u>

### (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, 2017 and 2016 consist of the following:

<i>In thousands</i>	<b>December 31, 2017</b>	<b>December 31, 2016</b>
Raw materials	\$ 7,044	\$ 4,430
Work in process	10,844	10,716
Finished goods	12,372	5,361
Inventory	<u>\$ 30,260</u>	<u>\$ 20,507</u>

### (5) Property, Plant and Equipment

Property, plant and equipment as of December 31, 2017 and 2016 consist of the following:

<i>In thousands</i>	<b>December 31, 2017</b>	<b>December 31, 2016</b>
Leasehold improvements	\$ 156	\$ 157
Computer equipment	63	63
Furniture and fixtures	66	42
Software	559	559
	<u>844</u>	<u>821</u>
Accumulated depreciation and amortization	(816)	(755)
Construction in progress	—	12
Property, plant and equipment, net	<u>\$ 28</u>	<u>\$ 78</u>

Depreciation expense for each of the years ended December 31, 2017, 2016, and 2015 was \$0.1 million, \$0.1 million and \$0.2 million, respectively.

#### **(6) Accrued Expenses and Other Current Liabilities**

Accrued expenses and other current liabilities consist of the following as of December 31, 2017 and 2016:

<i>In thousands</i>	<b>December 31, 2017</b>	<b>December 31, 2016</b>
Payroll and payroll-related expenses	\$ 8,298	\$ 6,611
Research and development expenses	1,772	293
Sales and marketing accruals	9,230	2,821
Accrued revenue allowances	34,445	22,195
All other	5,157	5,800
Accrued expenses and other current liabilities	<u>\$ 58,902</u>	<u>\$ 37,720</u>

#### **(7) Warrants and Warrant Derivative Liability**

On October 16, 2009, the Company completed a \$70.0 million private placement with both existing and new investors resulting in \$62.3 million in net proceeds and an additional \$3.6 million from bridge notes converted in conjunction with the private placement. In consideration for the \$62.3 million in net cash proceeds Amarin issued 66.4 million units, each unit consisting of (i) one ADS (representing one ordinary share) at a purchase price of \$1.00 and (ii) a warrant with a five-year term to purchase 0.5 (one half) of an ADS at an exercise price of \$1.50 per ADS. In consideration for the conversion of \$3.6 million of convertible bridge notes, Amarin issued 4.0 million units, each unit consisting of (i) one ADS (representing one ordinary share) at a purchase price of \$0.90 and (ii) a warrant with a five-year term to purchase 0.5 (one half) of an ADS at an exercise price of \$1.50 per ADS. The total number of warrants issued in conjunction with the financing was 35.2 million.

In conjunction with the October 2009 financing, the Company issued an additional 0.9 million warrants to three former officers. The warrants issued in connection with the October 2009 financing contained a pricing variability feature which provided for an increase to the exercise price if the exchange rate between the U.S. dollar and British pound adjusts such that the warrants could be exercised at a price less than the £0.5 par value of the common stock—that is, if the exchange rate exceeded U.S. \$3.00 per £1.0 sterling. Due to the potential variable nature of the exercise price, the warrants were not considered to be indexed to the Company's common stock. Accordingly, the warrants did not qualify for the exception to classify the warrants within equity and were classified as a derivative liability.

The fair value of this warrant derivative liability was remeasured at each reporting period, with changes in fair value recognized in the consolidated statement of operations. Upon exercise, the fair value of the warrants exercised was remeasured and reclassified from warrant derivative liability to additional paid-in-capital. Although the warrants contained a pricing variability feature, the number of warrants issuable remained fixed. Therefore, the maximum number of common shares issuable as a result of the October 2009 private placement was 36.1 million.

In October 2014, the Company and the holders of the remaining October 2009 warrants mutually agreed to extend the expiration date of such warrants from October 16, 2014 to February 27, 2015. Of the 8,087,388 warrants outstanding as of December 31, 2014, 1,844,585 warrants were exercised, resulting in net proceeds to the Company of \$2.7 million, and the remaining 6,242,803 warrants expired. The related derivative liability was extinguished and we recognized a \$0.1 million gain on change in fair value of derivative liability for the year ended December 31, 2015. No warrants were outstanding as of December 31, 2017 and 2016.

## **(8) 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, 2017, the remaining amount to be repaid to CPPIB is \$109.1 million. During the year ended December 31, 2017, the Company made repayments under the agreement of \$16.5 million and an additional \$5.3 million is scheduled to be paid in February 2018 for the fourth quarter of 2017. These payments were calculated based on the threshold limitation, as described below, as opposed to the scheduled quarterly repayments. Additional quarterly repayments, subject to the threshold limitation, are scheduled to be paid. All such payments reduce the remainder of the \$150.0 million in aggregate payments to CPPIB.

These quarterly payments are subject to a quarterly threshold amount whereby, if a calculated threshold, based on quarterly Vascepa net revenues, is not achieved, the quarterly payment payable in that quarter can at the Company's election be reduced, with the reduction carried forward without interest for payment in a future period. The payment of any carried forward amount is subject to similarly calculated threshold repayment amounts based on Vascepa net revenue levels. Except upon a change of control in Amarin, the agreement does not expire until \$150.0 million in aggregate has been repaid. Except in the event of the Company's default, there is no compounding of interest and no scheduled cliff payment due under this agreement. Rather, payment will be made, subject to the threshold limitation, until \$150.0 million in aggregate has been repaid, including payments made previously. The Company can prepay an amount equal to \$150.0 million less any previously repaid amount.

For each quarterly period since the inception of the debt, net revenues were below the contractual threshold amount such that cash payments were calculated for each period reflecting the optional reduction amount as opposed to the contractual threshold payment due for each quarterly period. In accordance with the agreement, quarterly differences between the calculated optional reduction amounts and the repayment schedule amounts were rescheduled for payment beginning in the second quarter of 2017. Any such deferred repayments will remain subject to continued application of the quarterly ceiling in amounts due established by the calculated threshold limitation based on quarterly Vascepa net revenues. No additional interest expense or liability is incurred as a result of such deferred repayments. These estimates are reevaluated each reporting period by the Company and adjusted if necessary, prospectively.

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 difference between the two fair values of the debt was determined to be the fair value of the embedded derivative, and upon closing the Company recorded a derivative liability of \$14.6 million as a reduction to the note payable. 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 year ended December 31, 2017, as compared to a \$5.5 million gain on change in fair value of derivative liability during the year ended December 31, 2016.

As of December 31, 2017 and 2016, the carrying value of the royalty-bearing instrument, net of the unamortized debt discount and issuance costs, was \$92.4 million and \$93.6 million, respectively. During the year ended December 31, 2017, the Company recorded cash and non-cash interest expense of \$6.4 million and \$2.1 million, respectively, in connection with the royalty-bearing instrument. During the year ended December 31, 2016, the Company recorded \$6.7 million and \$2.1 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 2012, May 2014, and November 2015 Exchangeable Senior Notes

In 2012, 2014 and 2015, the Company and its subsidiaries entered into a series of transactions pertaining to exchangeable notes. As of December 31, 2017, all debt issued in these transactions was exchanged or redeemed such that none remained outstanding.

In January 2012, the Company, through its wholly-owned subsidiary Corsicanto DAC (in liquidation) (formerly Corsicanto Limited) (“Corsicanto”), issued \$150.0 million in principal amount of 3.5% exchangeable senior notes due 2032 (the “2012 Notes”), resulting in net proceeds of \$144.3 million. In May 2014, the Company entered into separate, privately negotiated exchange agreements with certain holders of the 2012 Notes pursuant to which Corsicanto exchanged \$118.7 million in aggregate principal amount of the existing 2012 Notes for \$118.7 million in aggregate principal amount of new 3.5% May 2014 exchangeable senior notes due 2032 (the “2014 Notes”), following which \$31.3 million in aggregate principal amount of the 2012 Notes remained outstanding with terms unchanged. In November 2015, the Company entered into a privately negotiated subscription agreement with one of its existing investors, pursuant to which the investor agreed to purchase approximately \$31.3 million in aggregate principal amount of new 3.5% November 2015 exchangeable senior notes due 2032 (the “2015 Notes”) for approximately \$27.5 million. Approximately \$15.9 million of such proceeds were used to finance the repayment of \$16.2 million in aggregate principal amount of the 2012 Notes, following which \$15.1 million in aggregate principal amount of the 2012 Notes remained outstanding with terms unchanged through December 31, 2016. The 2012 Notes, 2014 Notes, and 2015 Notes are referred to collectively as the “Notes.”

In August 2016, Corsicanto gave notice to the holders of the 2014 Notes and 2015 Notes that certain equity conditions contained within the notes had been satisfied and exercised its option to mandatorily exchange \$118.7 million of aggregate principal amount of 2014 Notes and \$31.3 million of aggregate principal amount of 2015 Notes for equity with settlement in September 2016, such that all of the outstanding 2014 Notes and 2015 Notes were retired at that time. Consistent with the terms of the 2014 Notes and 2015 Notes, the final as-adjusted exchange rate was 402.0746 ADSs per \$1,000 of principal amount, resulting in 47,739,925 ADSs and 12,571,263 ADSs being issued in exchange for the 2014 Notes and 2015 Notes, respectively. In total, the Company mandatorily exchanged \$150.0 million in aggregate principal amount (\$127.3 million in carrying value, net of unamortized debt discount and issuance costs) of outstanding 2014 Notes and 2015 Notes, resulting in the issuance of 60,311,188 ADSs and recognition of \$40.1 million in common stock and \$87.4 million in additional paid-in capital during the year ended December 31, 2016. Included within this \$87.4 million is \$0.8 million of accrued but unpaid interest as of the exchange date deemed satisfied and discharged in full upon delivery of the ADSs consistent with the terms of the notes and ASC 470-20, less \$0.7 million of transaction costs.

The terms of the 2012 Notes allowed for repurchase in cash by the Company at the option of the holders on each of January 19, 2017, January 19, 2022, and January 19, 2027, as well as redemption by the Company for cash of all or part of the 2012 Notes on or after January 19, 2017, both at a price equal to 100% of the principal amount of the 2012 Notes to be repurchased or redeemed, plus accrued and unpaid interest to, but excluding, the repurchase or redemption date. Consequently, in January 2017, holders of the 2012 Notes exercised their option to put approximately \$15.0 million in aggregate principal amount of 2012 Notes to the Company for cash and, in March 2017, the Company redeemed the entirety of the remaining \$0.1 million in aggregate principal amount of 2012 Notes, such that no 2012 Notes remained outstanding as of December 31, 2017.

The 2012 Notes were exchangeable under certain circumstances into cash, ADSs, or a combination of cash and ADSs, at the Company's election. At the time of issuance, the Company calculated the fair value of the liability component of the 2012 Notes to be \$126.2 million and the excess of the principal amount of the debt over the liability component of \$23.8 million was allocated to the conversion option, resulting in a discount on the debt and corresponding increase in equity as a result of the cash settlement feature. The Company also recorded a debt discount to reflect the value of the underwriter's discounts and offering costs. The debt discount from underwriter's discounts and offering costs was allocated to the equity and liability components of the 2012 Notes in proportion to the proceeds allocated to each component. The \$23.8 million equity component allocated to the conversion option was reduced by the portion of offering costs allocated to the equity component, \$10.1 million upon extinguishment of the 2012 Notes as part of the 2014 Notes exchange and \$1.3 million upon extinguishment of the 2012 Notes as part of the 2015 Notes issuance, such that \$11.5 million remained in equity as of both December 31, 2017 and 2016. The conversion option was not remeasured each reporting period as it continued to meet the criteria for equity classification, and will remain in equity hereafter as a result of the repayment in full of the related debt instrument during the first quarter of 2017.

The portion of the debt discount from underwriter's discounts and offering costs allocated to the liability component as well as the discount created from allocating proceeds to the conversion option were amortized as interest expense over the estimated life of the 2012 Notes of twenty-four months. Such discounts were fully amortized prior to 2016. The carrying value of the 2012 Notes was nil and \$15.1 million as of December 31, 2017 and 2016, respectively, included within current portion of exchangeable senior notes, net of discount, due to the holders' January 19, 2017 optional put date.

The 2014 Notes were recorded at fair value of \$90.8 million representing a \$27.9 million discount to par. In addition, the Company recognized a discount of \$2.5 million in underwriter's fees and offering costs. The 2015 Notes were recorded at fair value of \$27.5 million representing a \$3.8 million discount to par. In addition, the Company recognized a discount of \$0.1 million in offering costs. These discounts were amortized as interest expense over the expected terms of the 2014 Notes and 2015 Notes, which was expected to be through the first optional put date in January 2019 for each. The carrying value of the 2014 Notes and 2015 Notes was nil as of both December 31, 2017 and 2016.

The 2014 Notes and 2015 Notes contained a provision that if a fundamental change (as defined in the 2014 Notes and 2015 Notes) had occurred prior to the notes being exchanged, holders may have required the Company to repurchase all or part of their notes for cash at a fundamental change repurchase price equal to 100% of the aggregate principal amount of the 2014 Notes and 2015 Notes to be repurchased, plus accrued and unpaid interest to, but not including, the fundamental change repurchase date. The Company determined that these fundamental change redemption features represented embedded derivatives requiring bifurcation from the respective debt liabilities and allocated \$3.5 million of the \$90.8 million fair value of the 2014 Notes and \$0.5 million of the \$27.5 million fair value of the 2015 Notes to derivative liabilities. The fair value of these derivative liabilities was remeasured at each reporting period, with changes in fair value recognized in the statement of operations. During the year ended December 31, 2016, the Company recognized a \$2.1 million gain and a \$0.6 million gain on the change in fair value of the redemption features of the 2014 Notes and 2015 Notes, respectively.

The Notes had a stated interest rate of 3.5% per year, payable semiannually in arrears on January 15 and July 15 of each year. During the year ended December 31, 2017, the Company recognized cash interest expense of less than \$0.1 million related to the Notes. During the year ended December 31, 2016, the Company recognized aggregate interest expense of \$9.9 million related to the Notes, of which \$5.7 million represents non-cash interest and \$4.2 million represents contractual coupon interest. As of December 31, 2017 and December 31, 2016, the Company had total accrued interest on the Notes of nil and \$0.2 million, respectively, which is included in current portion of exchangeable senior notes, net of discount. The Company made the contractual interest payments due on the Notes during the year ended December 31, 2017 and 2016 of \$0.3 million and \$5.4 million, respectively.

#### January 2017 Exchangeable Senior Notes

On January 20, 2017, the Company and Corsicanto II DAC ("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 (the "2017 Notes") at an issue price of 100%. The net proceeds from the offering were \$28.8 million after deducting placement agent fees and offering expenses payable by the Company. The offering of the 2017 Notes closed on January 25, 2017.



Corsicanto II has no assets, operations, revenues or cash flows other than those related to the issuance, administration and repayment of the 2017 Notes.

The 2017 Notes were issued pursuant to an Indenture (the “Indenture”) entered into by the Company, Corsicanto II and Wilmington Trust, National Association, as trustee (the “Trustee”). The 2017 Notes are the senior unsecured obligations of Corsicanto II and are guaranteed by the Company. The 2017 Notes bear interest at a rate of 3.5% per annum from, and including, January 25, 2017, payable semi-annually in arrears on January 15 and July 15 of each year, beginning on July 15, 2017 and ending upon the 2017 Notes’ maturity date of January 15, 2047, unless earlier repurchased, redeemed or exchanged.

At any time after the issuance of the 2017 Notes and prior to the close of business on the second business day immediately preceding January 15, 2047, holders may exchange their 2017 Notes for ADSs at their option and at the exchange rate described below. If prior to January 19, 2021, a make-whole fundamental change (as defined in the Indenture) occurs and a holder elects to exchange its 2017 Notes in connection with such make-whole fundamental change, such holder may be entitled to an increase in the exchange rate as described in the Indenture.

The initial exchange rate is 257.2016 ADSs per \$1,000 principal amount of the 2017 Notes (equivalent to an initial exchange price of approximately \$3.89 per ADS (the “Exchange Price”)), subject to adjustment in certain circumstances. The initial exchange price for the 2017 Notes represents a premium of approximately 35% over the last reported sale price of \$2.88 per share of the Company’s ADSs on The NASDAQ Global Market on January 19, 2017. Upon exchange, the 2017 Notes are to be settled in ADSs. The exchange rate is subject to adjustment from time to time upon the occurrence of certain events, including, but not limited to, the payment of cash dividends. In the event of physical settlement, the 2017 Notes would be exchangeable into a total of 7,716,048 ADSs. Based on the closing price of the Company’s stock as of December 31, 2017, the value of the shares if converted on that date would exceed the principal value of the 2017 Notes by \$0.9 million.

Prior to January 19, 2021, Corsicanto II may not redeem the 2017 Notes at its option other than in connection with certain changes in the tax law of a relevant taxing jurisdiction that results in additional amounts (as defined in the Indenture) becoming due with respect to payments and/or deliveries on the 2017 Notes. On or after January 19, 2021, Corsicanto II may redeem for cash all or a portion of the 2017 Notes at a redemption price of 100% of the aggregate principal amount of the 2017 Notes to be redeemed, plus accrued and unpaid interest to, but not including, the redemption date. If a Fundamental Change (as defined in the Indenture) occurs, holders may require Corsicanto II to repurchase all or part of their 2017 Notes for cash at a Fundamental Change repurchase price equal to 100% of the aggregate principal amount of the 2017 Notes to be repurchased, plus accrued and unpaid interest to, but not including, the Fundamental Change repurchase date. In addition, holders of the 2017 Notes may require Corsicanto II to repurchase all or any portion of the 2017 Notes on January 19, 2022 for cash at a price equal to 100% of the aggregate principal amount of the 2017 Notes to be repurchased, plus accrued and unpaid interest to, but not including, the repurchase date.

Corsicanto II may elect at its option to cause all or any portion of the 2017 Notes to be mandatorily exchanged in whole or in part at any time prior to the close of business on the business day preceding January 15, 2047 if the Daily VWAP (as defined in the Indenture) equals or exceeds 130% of the Exchange Price then in effect (which quotient equals approximately \$5.05 on the date hereof) for at least 20 VWAP Trading Days (as defined in the Indenture) in any 30 consecutive VWAP Trading Day period. Corsicanto II may only exercise its optional exchange rights upon satisfaction of specified equity conditions, including that the ADSs issuable upon exchange of the 2017 Notes be eligible for resale without registration by non-affiliates and listed on The NASDAQ Global Market, its related exchanges or the New York Stock Exchange. If Corsicanto II elects to exercise its optional exchange rights on or prior to January 19, 2021, each holder whose 2017 Notes are exchanged may upon exchange receive a specified number of additional ADSs as set forth in the Indenture.

The Indenture contains customary terms and covenants and events of default. If an event of default (other than certain events of bankruptcy, insolvency or reorganization involving Corsicanto II) occurs and is continuing, the Trustee by notice to Corsicanto II, or the holders of at least 25% in principal amount of the outstanding 2017 Notes by notice to Corsicanto II and the Trustee, may declare 100% of the principal of and accrued and unpaid interest, if any, on all of the 2017 Notes to be due and payable. Upon such a declaration of acceleration, such principal and accrued and unpaid interest, if any, will be due and payable immediately. Upon the occurrence of certain events of bankruptcy, insolvency or reorganization involving Corsicanto II, 100% of the principal of and accrued and unpaid interest, if any, on all of the 2017 Notes will become due and payable automatically. Notwithstanding the foregoing, the Indenture will provide that, to the extent Corsicanto II elects and for up to 360 days, the sole remedy for an event of default relating to certain failures by Corsicanto II or the Company, as the case may be, to comply with certain reporting covenants in the Indenture consists exclusively of the right to receive additional interest on the 2017 Notes.

Corsicanto II agreed to use commercially reasonable efforts to procure the listing of the 2017 Notes on the Global Exchange Market operated under the supervision of the Irish Stock Exchange (or on another recognized stock exchange for the purposes of Section 64 of the Taxes Consolidation Act 1997 of Ireland and within the meaning of Section 1005 ITA 2007 of the United Kingdom) prior to July 15, 2017, which was the first interest payment date for the 2017 Notes.

The 2017 Notes were recorded at par of \$30.0 million. In addition, the Company recorded a discount of \$1.2 million in placement agent fees and offering expenses. Such costs are presented as a direct deduction from the debt liability on the consolidated balance

sheet. This discount is being amortized as interest expense over the estimated life of the 2017 Notes, through the first optional put date in January 2022. As of December 31, 2017, the carrying value of the 2017 Notes, net of unamortized discount, was \$29.0 million.

Because the conversion option in the 2017 Notes receives an exception from derivative accounting and only requires gross physical settlement in shares, the embedded option does not require separate accounting and is therefore accounted for as part of the debt host at amortized cost. In addition, the Company determined that the fundamental change redemption feature is clearly and closely related to the debt host in accordance with ASC 815-15 and therefore does not require bifurcation.

During the year ended December 31, 2017, the Company recognized interest expense of \$1.2 million related to the 2017 Notes, of which \$0.2 million represents non-cash interest and \$1.0 million represents contractual coupon interest. As of December 31, 2017, the Company had accrued interest of \$0.5 million related to the 2017 Notes, which is presented as current portion of exchangeable senior notes, net of discount, on the consolidated balance sheet. The Company made the contractual interest payment due on the 2017 Notes during the year ended December 31, 2017 of \$0.5 million.

## **(9) Commitments and Contingencies**

### Litigation

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. ("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.

The Company introduced to the market its 0.5-gram dose strength of Vascepa in October 2016. 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 abbreviated new drug application, or 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. 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 is seeking, 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. This new lawsuit against Teva has been consolidated with the pending lawsuits against Teva, West-Ward, and DRL referenced above based on the 1-gram dose strength of Vascepa, and all four lawsuits will proceed on the same schedule.

On April 26, 2016, the U.S. District Court for the District of New Jersey granted the Company's motion to dismiss the putative consolidated class action lawsuit captioned *In re Amarin Corporation plc, Securities Litigation*, No. 3:13-cv-06663 (D.N.J. Nov. 1, 2013). The class action was dismissed without prejudice with leave for plaintiffs to file an amended complaint. The lawsuit sought unspecified monetary damages and attorneys' fees and costs alleging that the Company and certain of its current and former officers and directors made misstatements and omissions regarding the FDA's willingness to approve Vascepa's ANCHOR indication and related contributing factors and the potential relevance of data from the ongoing REDUCE-IT trial to that potential approval. The April 2016 dismissal was the second motion to dismiss granted in favor of Amarin and related defendants in this litigation. The first motion to dismiss in this litigation was granted in June 2015 in response to the original complaint and related amendment. On May 26, 2016, plaintiffs appealed the most recent dismissal to the Third Circuit Court of Appeals. On May 23, 2017, the Third Circuit Court of Appeals affirmed the judgment of the U.S. District Court for the District of New Jersey that granted the Company's motion to dismiss the putative consolidated class action lawsuit (Case No. 16-2640). Plaintiffs sought a rehearing and *en banc* review of such affirmation, each of which were denied. The appeal period for this matter has expired. The Company considers this matter closed.

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.

### Leases

The Company leases office space under operating leases. Future minimum lease payments under these leases, net of sublease rental income, as of December 31, 2017 are as follows:

<i>In thousands</i> Year Ending December 31,	Operating Leases
2018	\$ 642
2019	156
2020-2022	—
Total	\$ 798

On September 30, 2011, the Company entered into an agreement for 320 square feet of office space at 2 Pembroke House, Upper Pembroke Street 28-32 in Dublin, Ireland. The office space was subsequently reduced to 270 square feet, effective November 1, 2013. The agreement began November 1, 2011 and terminates on October 31, 2018 and can be extended automatically for successive one-year periods. Monthly rent is approximately €2,900 (approximately \$3,500 at the time of filing). The agreement can be terminated by either party with three months prior written notice.

On July 1, 2011, the Company leased 9,747 square feet of office space in Bedminster, New Jersey. The lease, as amended, terminates on April 30, 2019, and may also be terminated with six months prior notice. On December 6, 2011 the Company leased an additional 2,142 square feet of space in the same location. On December 15, 2012 and May 8, 2013, the Company leased an additional 2,601 and 10,883 square feet of space, respectively, in the same location. In January 2014 and April 2014, the Company entered into separate transactions with the landlord of this property to vacate approximately 2,142 and 2,000 square feet of space in exchange for discounts on contractual future rent payments. In January 2015, the Company executed an agreement to sublease approximately 4,700 square feet of this property to a third party, effective April 1, 2015. This sublease agreement was terminated as of September 30, 2017. Additionally, in June 2015, the Company executed an agreement to sublease approximately 2,500 square feet of this property to a separate third party, effective June 16, 2015. On December 15, 2016, the Company leased an additional 732 square feet of space in the same location, effective January 1, 2017.

Total rent expense during the years ended 2017, 2016 and 2015 was approximately \$0.6 million, \$0.6 million, and \$0.8 million, respectively.

### 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, as detailed below.

The Company entered into its initial Vascepa API supply agreement with Nisshin Pharma, Inc (“Nisshin”) in 2010. In 2011, the Company entered into agreements with two additional suppliers, Chemport, Inc (“Chemport”) and BASF (formerly Equateq Limited), for the supply of API. In 2012, the Company agreed to terms with a fourth API supplier, a consortium of companies led by Slanmhor Pharmaceutical, Inc. (“Slanmhor”). The API supply agreement with BASF terminated in February 2014. In July 2014, the Company terminated the supply agreement with Slanmhor and subsequently, in June 2015, entered into a new supply agreement with Finorga SAS (“Novasep”). These agreements included 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 as described below.

Nisshin, Chemport and Novasep are currently the three manufacturers from which the Company purchases API. As of December 31, 2017, the Company has no royalty, milestone or minimum purchase commitments with Nisshin.

Chemport was approved by the FDA to manufacture API for commercial sale in April 2013 and the Company began purchasing commercial supply from Chemport in 2013. The agreement with Chemport contains a provision requiring the Company to pay Chemport in cash for any shortfall in the minimum purchase obligations. The Company began purchasing commercial supply from Novasep in 2015. API manufactured by Novasep was previously approved by the FDA in July 2014. The 2015 supply agreement with Novasep contains a provision requiring the Company to pay Novasep a cash remedy for any shortfall in the minimum purchase obligations.

Pursuant to the supply agreements, there is a total of \$40.1 million that is potentially payable over the term of such agreements based on minimum purchase obligations. The Company continues to meet its contractual purchase obligations.

Under the 2004 share repurchase agreement with Laxdale Limited (“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 \$10.1 million as of December 31, 2017). Also under the Laxdale agreement, upon receipt of a marketing approval in the United States or 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 \$6.7 million as of December 31, 2017) for each of the two potential market approvals (i.e., £10 million maximum, or approximately \$13.5 million as of December 31, 2017).

The Company has no provision for any of the obligations above since the amounts are either not probable or able to be estimated as of December 31, 2017.

## **(10) Equity**

### Preferred Stock

On March 5, 2015, the Company entered into a subscription agreement with four institutional investors (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 (“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 (“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 (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. During the year ended December 31, 2015, at the request of the holders, a portion of the Series A Preference Shares were consolidated and redesignated, resulting in the issuance of 6,283,333 ADSs such that a maximum of 32,818,464 ordinary shares remain issuable upon future consolidation and redesignation of the remaining Series A Preference Shares as of December 31, 2017, inclusive of the shares issued in July 2015 as discussed below, subject to certain adjustments for dilutive events.

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 (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 (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 (“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. (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 (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 may 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. At the time of the transaction, Dr. James Healy was a member of the Company’s Board and a managing general partner of Sofinnova Management VII, L.L.C., which is the general partner of Sofinnova. Dr. James Healy resigned as Director of the Company’s Board effective December 20, 2016.

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 (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.

#### Common Stock

In September 2016, the Company mandatorily exchanged \$118.7 million and \$31.3 million of aggregate principal amount of the 2014 Notes and 2015 Notes, respectively, resulting in the issuance of 47,739,925 ADSs and 12,571,263 ADSs, respectively, with each ADS representing one ordinary share of the Company (see Note 8—Debt).

In August 2016, the Company completed a public offering of 21,100,000 ADSs, with each ADS representing one ordinary share of the Company. Amarin also granted the underwriters a 30-day option to purchase an additional 3,165,000 ADSs at the same price, which was exercised in full. The underwriters purchased the ADSs from the Company at a price of \$2.679 per ADS after commission, resulting in net proceeds to the Company of approximately \$64.6 million, after deducting estimated offering expenses payable by the Company. Intended uses of the net proceeds from the offering were to advance its REDUCE-IT cardiovascular outcomes trial and for general corporate and working capital purposes.

#### Incentive Equity Awards

As of December 31, 2017, there were an aggregate of 24,108,455 stock options and 12,005,553 restricted stock units (“RSUs”) outstanding, representing approximately 7% and 4%, respectively, of outstanding shares (including common and preferred shares) on a fully diluted basis.

During the years ended December 31, 2017 and 2016, the Company issued 356,656 and 177,146 shares, respectively, as a result of the exercise of stock options, resulting in gross and net proceeds of \$0.6 million during the year ended December 31, 2017 and \$0.3 million during the year ended December 31, 2016.

On May 15, 2017, the Company granted a total of 91,504 RSUs and 131,575 stock options to members of the Company’s Board of Directors under the Amarin Corporation plc Stock Incentive Plan (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 15, 2017, the Company granted a total of 2,310,000 RSUs to employees under the 2011 Plan that vest over three years commencing after anticipated 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, 2017, the Company granted a total of 1,575,000 RSUs and 2,642,500 stock options to employees under the 2011 Plan. The RSUs vest annually over a three-year period and the stock options vest over a four-year period. The issuance of 989,000 of these RSUs was contingent upon shareholder approval to increase the aggregate number of shares authorized for issuance under the 2011 Plan, which was obtained at the Company’s Annual General Meeting of Shareholders held on May 15, 2017.

On July 11, 2016, the Company granted a total of 148,403 RSUs and 208,340 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, which is required to be made in shares.

On February 1, 2016, the Company granted a total of 1,607,500 RSUs and 2,442,000 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, 2017, the Company issued 494,885 common shares related to the vesting of these RSUs, of which 191,899 shares were retained as treasury shares as settlement of employee tax obligations.

See Note 12—Stock Incentive Plans and Stock Based Compensation for further information regarding the Company's incentive equity awards.

### Warrants

During the year ended December 31, 2015, the Company issued 1,844,585 shares upon the exercise of warrants, resulting in gross and net proceeds of \$2.8 million and \$2.7 million, respectively. There was no warrant activity during the years ended December 31, 2017 and 2016 and no warrants remained outstanding as of December 31, 2017 and 2016.

## **(11) 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 December 31, 2017 and \$1.5 million as of December 31, 2016.

The following is a reconciliation of the total amounts of unrecognized tax benefits for the years ended December 31, 2017, 2016 and 2015:

<i>In thousands</i>	<b>2017</b>	<b>2016</b>	<b>2015</b>
Beginning uncertain tax benefits	\$ 1,633	\$ 1,550	\$ 2,487
Prior year—increases	—	—	120
Prior year—decreases	(20)	—	(762)
Current year—increases	121	83	144
Current year—decreases for lapses in statutes of limitations	—	—	(439)
Ending uncertain tax benefits	<u>\$ 1,734</u>	<u>\$ 1,633</u>	<u>\$ 1,550</u>

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, 2017:

<b>Jurisdiction</b>	<b>Tax Years</b>
United States—Federal	2013-2017
United States—State	2012-2017
Ireland	2013-2017
United Kingdom	2016-2017

The Company does not expect any gross liabilities to expire in 2018 based on statutory lapses.

The components of loss from operations before taxes were as follows for the years ended December 31, 2017, 2016 and 2015:

<i>In thousands</i>	<b>2017</b>	<b>2016</b>	<b>2015</b>
United States	\$ (2,075)	\$ (8,115)	\$ (10,137)
Ireland and United Kingdom	(52,743)	(68,266)	(108,153)
	<u>\$ (54,818)</u>	<u>\$ (76,381)</u>	<u>\$ (118,290)</u>

The (provision for) benefit from income taxes shown in the accompanying consolidated statements of operations consists of the following for fiscal 2017, 2016 and 2015:

<i>In thousands</i>	2017	2016	2015
Current:			
United States—Federal	\$ 1,769	\$ 1,033	\$ 1,053
United States—State	196	138	113
Total current	<u>\$ 1,965</u>	<u>\$ 1,171</u>	<u>\$ 1,166</u>
Deferred:			
United States—Federal	5,760	(4,001)	(3,343)
United States—State	(487)	(334)	(605)
Ireland and United Kingdom	(16,306)	(143)	(9,023)
Change in valuation allowance	22,115	13,276	8,719
Total deferred	<u>\$ 11,082</u>	<u>\$ 8,798</u>	<u>\$ (4,252)</u>
Provision for (benefit from) income taxes	<u>\$ 13,047</u>	<u>\$ 9,969</u>	<u>\$ (3,086)</u>

The (provision for) benefit from income taxes differs from the amount computed by applying the statutory income tax rate to income before taxes due to the following for fiscal 2017, 2016 and 2015:

<i>In thousands</i>	2017	2016	2015
Benefits from taxes at statutory rate	\$ (13,698)	\$ (19,039)	\$ (29,572)
Rate differential	3,071	4,667	8,572
Change in valuation reserves	22,115	13,276	8,719
Derivative liabilities	—	(668)	187
Gain on extinguishment of debt	—	—	(328)
Nondeductible employee compensation	1,668	1,164	808
Stock option/RSU windfall	(1,182)	—	—
Research and development credits	(1,177)	(1,689)	(1,284)
Tax return to provision adjustments	5,788	4,524	2,248
U.S. rate change—tax reform	7,398	—	—
Cumulative translation adjustment	(12,554)	7,385	7,811
Permanent and other	1,635	(1,573)	(1,841)
Non-deductible interest expense	(17)	1,922	1,594
Provision for (benefit from) income taxes	<u>\$ 13,047</u>	<u>\$ 9,969</u>	<u>\$ (3,086)</u>

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, 2017, 2016, and 2015, 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 Tax Cuts and Jobs Act (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 is generally effective January 1, 2018, U.S. GAAP requires recognition of the tax effects of new legislation during the reporting period that includes the enactment date, which was December 22, 2017.

As a result of the financial reporting implications of the Act, the SEC provided guidance that allows 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, 2017, the Company has recorded a provisional amount 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. Given the complexity of the Act and anticipated guidance from the U.S. Treasury about implementing the Act, the Company's analysis and accounting for the tax effects of the Act is preliminary. The amounts are provisional estimates, as the Company has not fully completed its analysis of certain other aspects of the Act that could result in adjustments. Upon completion of



the analysis in 2018, these estimates may be adjusted through income tax expense in the consolidated statement of operations. The Company will disclose the impact to the provisional amounts in the reporting period in which the accounting period is completed, which will not exceed one year from the date of enactment. Any change is not expected to have an impact to the tax provision or consolidated financial statements.

The primary impact of the Act on the Company relates 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, 2017 and 2016 includes \$1.3 million of excess tax benefits and \$0.4 million of excess tax deficiencies, 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 outstanding as of December 31, 2015, 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, 2017 and 2016 is as follows:

<i>In thousands</i>	<b>December 31, 2017</b>	<b>December 31, 2016</b>
<b>Deferred tax assets:</b>		
Net operating losses	\$ 110,715	\$ 95,181
Stock-based compensation	12,446	16,894
Tax credits	6,378	6,893
Other reserves and accrued liabilities	3,587	3,193
Gross deferred tax assets	133,126	122,161
Less: valuation allowance	(131,389)	(109,274)
Total deferred tax assets	1,737	12,887
<b>Deferred tax liabilities:</b>		
Depreciation and amortization	(1,145)	(1,050)
Other liabilities	(592)	(755)
Total deferred tax liabilities	(1,737)	(1,805)
Net deferred tax assets	\$ —	\$ 11,082

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, UK, and Israeli net operating losses and the related U.S. deferred tax assets, consisting primarily of stock-based compensation and R&D tax credits, would not be realized in future periods and a full valuation allowance has been recorded as of the current period.

The following table reflects the activity in the valuation allowance for the years ended December 31, 2017 and 2016:

<i>In thousands</i>	2017	2016
Beginning valuation allowance	\$ 109,274	\$ 95,999
Increase as reflected in income tax expense	11,466	17,951
Cumulative translation adjustment	10,649	(4,676)
Ending valuation allowance	<u>\$ 131,389</u>	<u>\$ 109,274</u>

During 2017, 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 Irish, UK, and Israeli net operating loss carryforwards of \$710.4 million, which do not expire. The total net operating loss carryforwards increased by approximately \$109.2 million from the prior year primarily as a result of current year losses generated by the Company's Irish subsidiaries. In addition, the Company has U.S. Federal tax credit carryforwards of \$6.0 million and state tax credit carryforwards of \$1.9 million. These amounts exclude the impact of any unrecognized tax benefits and valuation allowances. These carryforwards, which will expire between 2024 and 2036, may be used to offset future taxable income.

As of December 31, 2017, earnings of \$8.0 million have been retained indefinitely for reinvestment by foreign subsidiary or there is an expectation that any reinvestment can be recovered tax-free without significant cost, and the entity expects to ultimately use that means of recovery for domestic subsidiary companies; therefore, no provision has been made for income taxes that would be payable upon the distribution of such earnings and it would not be practicable to determine the amount of the related unrecognized deferred income tax liability.

The Company's and its subsidiaries' income tax returns are periodically examined by various taxing authorities. The Company is currently under audit by the United States Internal Revenue Service (IRS) for the years 2013 to 2014. 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.

## **(12) 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 ("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 ("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, 2017:

<i>In thousands (except per share amounts and years)</i>	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding as of January 1, 2017	21,188	\$ 3.37		
Granted	3,827	3.09		
Forfeited	(219)	2.52		
Expired	(331)	10.17		
Exercised	(357)	1.79		
Outstanding as of December 31, 2017	24,108	3.26	6.8 years	\$ 34,659
Exercisable as of December 31, 2017	16,115	3.68	6.0 years	21,976
Vested and expected to vest as of December 31, 2017	23,709	\$ 3.27	6.7 years	\$ 34,025
Available for future grant as of December 31, 2017	16,994			

The weighted average grant date fair value of stock options granted during the years ended December 31, 2017, 2016 and 2015 was \$3.09, \$1.62, and \$2.16, respectively. The total grant date fair value of options vested during the years ended December 31, 2017, 2016 and 2015 was \$7.1 million, \$6.5 million, and \$9.1 million, respectively.

During the years ended December 31, 2017, 2016 and 2015, the Company received proceeds from the exercise of options of \$0.6 million, \$0.3 million, and \$31 thousand, respectively. The total intrinsic value of options exercised during the years ended December 31, 2017, 2016 and 2015 was \$0.5 million, \$0.2 million, and \$6 thousand, 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, 2017, there was \$12.7 million of unrecognized stock-based compensation expense related to unvested stock option share-based compensation arrangements granted under the Company's stock award plans. This expense is expected to be recognized over a weighted-average period of approximately 2.3 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 \$7.0 million, \$6.6 million and \$7.9 million for the years ended December 31, 2017, 2016 and 2015, respectively.

For 2017, 2016 and 2015, the Company used the following assumptions to estimate the fair value of share-based payment awards:

	2017	2016	2015
Risk-free interest rate	1.77% - 2.01%	1.07% - 1.70%	1.37% - 1.68%
Expected dividend yield	0.00%	0.00%	0.00%
Expected option life (years)	6.25	6.25	6.25
Expected volatility	73% - 82%	83% - 86%	86% - 97%

### 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, 2017 and 2016:

<i>In thousands (except per share amounts)</i>	Shares	Weighted Average Grant Date Fair Value
Outstanding as of January 1, 2016	10,887	\$ 2.12
Granted	1,756	1.47
Vested	(1,853)	1.62
Forfeited	(647)	1.74
Outstanding as of December 31, 2016	10,143	2.09
Granted	4,197	3.04
Vested	(2,179)	1.62
Forfeited	(155)	2.91
Outstanding as of December 31, 2017	12,006	\$ 2.50

The Company recorded compensation expense in relation to restricted stock units of \$7.0 million, \$7.0 million and \$6.0 million for the years ended December 31, 2017, 2016 and 2015 respectively.

The following table presents the stock-based compensation expense related to stock-based awards for the years ended December 31, 2017, 2016 and 2015:

<i>In thousands</i>	2017	2016	2015
Research and development	\$ 2,122	\$ 2,252	\$ 3,280
Selling, general and administrative	11,838	11,361	10,609
Stock-based compensation expense	\$ 13,960	\$ 13,613	\$ 13,889

### Employee Stock Purchase Plan

On March 13, 2017, the Board adopted, subject to shareholder approval, the Amarin Corporation plc 2017 Employee Stock Purchase Plan (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. The initial enrollment and offering periods commence in 2018, therefore, no compensation expense was recognized and no shares were purchased for the year ended December 31, 2017.

### **(13) 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 0.4 million and \$0.5 million of related compensation expense for the year ended December 31, 2017 and 2016 respectively. The Company did not make any contributions in 2015.

## (14) Related Party Transactions

### October 2009 Private Placement

Several of Amarin's former directors and funds connected with them purchased approximately 36.0 million of its ADSs (in the form of common stock) in the October 2009 private placement, including: (i) 17 million ADSs purchased by funds managed by Abingworth LLP, where Dr. Joseph Anderson, a former Director of Amarin, is a partner; (ii) 7 million ADSs purchased by Orbimed Advisors LLC, where Dr. Carl L. Gordon, a former Director of Amarin, is a General Partner; (iii) 7 million ADSs purchased by Sofinnova Venture Partners VII, L.P. (Sofinnova), where Dr. James I. Healy ("Dr. Healy"), a former Director of Amarin, is a Managing General Partner; and (iv) 5 million ADSs purchased by Fountain Healthcare Partners Fund 1, L.P. Fountain Healthcare Partners Ltd. is the sole General Partner of Fountain Healthcare Partners Fund 1, L.P. Dr. Manus Rogan is a Managing Partner of Fountain Healthcare Partners Ltd. and until December 2011 was a non-executive director of Amarin. In addition, for every ADS purchased, the investor received warrants to purchase 0.5 (one half) of an ADS. No warrants remained outstanding as of December 31, 2017 and 2016. Therefore, the fair value of the warrants held by the current and former directors of the Company and their related investment funds amounted to zero.

### March 2015 Private Placement

On March 30, 2015, in connection with the closing of the initial private placement described in Note 10—Equity, 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. The Company issued 38,867,180 restricted ADSs, each representing one Series A Preference Share, which may 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 shares are owned directly by Sofinnova. At the time of the transaction, Dr. Healy was a member of the Company's Board and a managing general partner of Sofinnova Management VII, L.L.C., which is the general partner of Sofinnova. Dr. Healy may have been deemed to have shared voting and dispositive power over the shares owned by Sofinnova, but disclaimed beneficial ownership over the shares owned by Sofinnova except to the extent of any pecuniary interest therein. Dr. Healy resigned as Director of the Company's Board effective December 20, 2016.

## (15) Quarterly Summarized Financial Information (Unaudited)

	Fiscal years ended December 31, 2017 and 2016							
	1st Quarter		2nd Quarter		3rd Quarter		4th Quarter	
	2017	2016	2017	2016	2017	2016	2017	2016
	(In thousands, except per share amounts)							
Total revenue, net	\$ 34,637	\$ 25,543	\$ 45,241	\$ 33,111	\$ 47,360	\$ 32,734	\$ 53,866	\$ 38,696
Net loss applicable to common shareholders	(20,941)	(29,771)	(13,634)	(13,354)	(10,825)	(15,772)	(22,465)	(27,453)
Loss per share:								
Basic	\$ (0.08)	\$ (0.16)	\$ (0.05)	\$ (0.07)	\$ (0.04)	\$ (0.08)	(0.08)	\$ (0.10)
Diluted	\$ (0.08)	\$ (0.16)	\$ (0.05)	\$ (0.07)	\$ (0.04)	\$ (0.08)	(0.08)	\$ (0.10)

## (16) Co-Promotion Agreement

On March 31, 2014, the Company entered into a Co-Promotion Agreement (the "Agreement") with Kowa Pharmaceuticals America, Inc. related to the commercialization of Vascepa<sup>®</sup> (icosapent ethyl) capsules in the United States. Under the terms of the Agreement, Amarin 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 initial term of the Agreement extends until the end of 2018. The Agreement was amended on July 25, 2017 to reflect evolving promotional needs, including refinement of target lists.

During the term, Kowa Pharmaceuticals America, Inc. and Amarin have agreed to use commercially reasonable efforts to promote, detail and optimize sales of Vascepa in the United States. The performance requirements include a negotiated minimum number of details to be delivered by each party in the first and second position, and the use of a negotiated number of minimum sales representatives from each party. Kowa Pharmaceuticals America, Inc. has agreed to bear the costs incurred for its sales force associated with the commercialization of Vascepa and to pay for certain incremental costs associated with the use of its sales force, such as sample costs and costs for promotional and marketing materials. Amarin will continue to recognize all revenue from sales of Vascepa and will use commercially reasonable efforts to maintain a minimum amount of inventory of Vascepa for use in the United States.

In exchange for Kowa Pharmaceuticals America, Inc.'s co-promotional services, Kowa Pharmaceuticals America, Inc. is entitled to a quarterly co-promotion fee based on aggregate Vascepa gross margin that varies during the term. The percentage of aggregate Vascepa gross margin earned by Kowa Pharmaceuticals America, Inc. was, as amended, approximately eighteen percent (18%) in 2017, partially offset by certain other refinements. During 2018, which is the last year of the Agreement, as amended, the Company anticipates incurring expense for both the annual co-promotion fee, which in 2018 will again be calculated as a percentage of Vascepa gross margin at a modestly higher rate than in 2017, plus accrual for co-promotion tail payments. Assuming Kowa Pharmaceuticals America, Inc. fulfills its obligations in accordance with the terms of the Agreement, as amended, after expiration of the Agreement, Kowa Pharmaceuticals America, Inc. is eligible to receive up to three years of co-promotion tail payments equal to declining percentages of the co-promotion fee amount earned in the final year of the Agreement with the sum of the three years of co-promotion tail payments totaling less than the co-promotion fee amount earned in the final year of the agreement.

As of both December 31, 2017 and 2016, the Company had a net payable of \$8.3 million and \$2.5 million, respectively, to Kowa Pharmaceuticals America, Inc. representing co-promotion fees payable to Kowa Pharmaceuticals America, Inc., net of reimbursable amounts incurred for samples and other marketing expenses.

## **(17) Development, Commercialization and Supply Agreements**

### **Eddingpharm (Asia) Macao Commercial Offshore Limited**

In February 2015, the Company entered into a Development, Commercialization and Supply Agreement (the "DCS Agreement") with Eddingpharm (Asia) Macao Commercial Offshore Limited ("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 ongoing REDUCE-IT clinical trials of Vascepa.

Under the DCS Agreement, Eddingpharm will be solely responsible for development and commercialization activities in the China Territory and associated expenses. The Company will provide development assistance and be responsible for supplying finished and later bulk drug product at defined prices under negotiated terms. The Company will retain all Vascepa manufacturing rights. Eddingpharm has agreed to certain restrictions regarding the commercialization of competitive products globally and the Company has 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 will be paid by Eddingpharm to the extent such costs are incurred in connection with the negotiated development plan or otherwise incurred by Eddingpharm. Eddingpharm will be 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, which it will recognize as revenue over the estimated period in which the Company is required to provide initial and on-going regulatory and development support and clinical supply for obtaining regulatory approvals in the China Territory and through the estimated period in which the Company is required to provide commercial supply, which is currently estimated to be a period of approximately 16 years. In March 2016, Eddingpharm submitted its clinical trial application ("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 which it will recognize as revenue over the estimated period in which the Company is required to provide on-going development support needed to support the successful approval for a new drug application, which is currently estimated to be a period of approximately four years. 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 \$1.0 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 recognizes contingent consideration from activities that is earned upon the achievement of a substantive milestone in the period in which the milestone is achieved.

#### Biologix FZCo

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

#### HLS Therapeutics, Inc.

In September 2017, the Company entered into an agreement with HLS Therapeutics Inc. (“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.

Upon closing of the agreement, the Company received one-half of a non-refundable \$5.0 million up-front payment, with the remaining half to be received upon the six-month anniversary of the closing. The up-front payment will be recognized as revenue over the estimated period in which the Company is required to provide initial and on-going regulatory support for obtaining regulatory approvals in Canada and through the estimated period in which the Company is required to provide commercial supply, which is currently estimated to be a period of approximately 12.5 years. In addition to the non-refundable, up-front payment, the Company is entitled to receive certain regulatory and sales-based milestone payments of up to an additional \$60.0 million, the timing and achievability of which cannot be determined at least until discussions with Canadian regulatory authorities have commenced, as well as tiered double-digit royalties on net sales of Vascepa in Canada.

#### Licensing and Deferred Revenues

Licensing and deferred revenues currently consist of revenue attributable to receipt of up-front, non-refundable payments and milestone payments as described above. Up-front and milestone payments under such agreements are typically recognized as licensing revenue over the estimated period in which the Company is required to provide regulatory and development support and clinical and commercial supply pursuant to the agreements. During the years ended December 31, 2017 and 2016, the Company recognized \$1.3 million and \$1.1 million of up-front and milestone payments as licensing revenue in connection with the Eddingpharm DCS Agreement, respectively, and recorded \$18.8 million and \$15.1 million as deferred revenue as of December 31, 2017 and 2016, respectively.

#### **(18) Subsequent Events**

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 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 \$65.0 million, after deducting estimated offering expenses payable by the Company. The Company has also granted the underwriters a 30-day option to purchase an additional 2,876,712 ADSs. The stated uses of proceeds in connection with this offering were as follows: to expand medical education and market awareness initiatives, including, in advance of REDUCE-IT results being known, pilot testing of new promotional initiatives for potential broader application following REDUCE-IT results, to increase its inventory balances for incremental inventory build prior to REDUCE-IT results and for general corporate and working capital purposes.

## AMARIN CORPORATION PLC

## 2017 EMPLOYEE STOCK PURCHASE PLAN

The purpose of the Amarin Corporation plc Employee Stock Purchase Plan (“the Plan”) is to provide eligible employees of each Designated Company (as defined in Section 11) of Amarin Corporation plc (the “Company”) with opportunities to purchase ordinary shares of £0.50 each (the “Ordinary Shares”) or American Depositary Shares, each representing one Ordinary Share, as the case may be (the “Shares”). An aggregate of 3,000,000 Shares have been approved and reserved for this purpose. The Plan is intended to constitute an “employee stock purchase plan” within the meaning of Section 423(b) of the Internal Revenue Code of 1986, as amended (the “Code”), and shall be interpreted in accordance with that intent.

1. **Administration.** The Plan will be administered by the person or persons (the “Administrator”) appointed by the Company’s Board of Directors (the “Board”) for such purpose. The Administrator has authority at any time to: (i) adopt, alter and repeal such rules, guidelines and practices for the administration of the Plan and for its own acts and proceedings as it shall deem advisable; (ii) interpret the terms and provisions of the Plan; (iii) make all determinations it deems advisable for the administration of the Plan; (iv) decide all disputes arising in connection with the Plan; and (v) otherwise supervise the administration of the Plan. All interpretations and decisions of the Administrator shall be binding on all persons, including the Company and the Participants. No member of the Board or individual exercising administrative authority with respect to the Plan shall be liable for any action or determination made in good faith with respect to the Plan or any option granted hereunder.

2. **Offerings.** The Company will make one or more offerings to eligible employees to purchase Shares under the Plan (“Offerings”). Unless otherwise determined by the Administrator, the initial Offering will begin on December 1, 2017 and will end on May 31, 2018 (the “Initial Offering”). Thereafter, unless otherwise determined by the Administrator, an Offering will begin on the first business day occurring on or after each June 1<sup>st</sup> and December 1<sup>st</sup> and will end on the last business day occurring on or before the following May 31<sup>st</sup> and November 30<sup>th</sup>, respectively. The Administrator may, in its discretion, designate a different period for any Offering, provided that no Offering shall exceed six months in duration or overlap any other Offering.

3. **Eligibility.** All individuals classified as employees on the payroll records of each Designated Company are eligible to participate in any one or more of the Offerings under the Plan, provided that as of the first day of the applicable Offering (the “Offering Date”) they are customarily employed by a Designated Company for more than 20 hours a week and have completed at least six months of employment. Notwithstanding any other provision herein, individuals who are not contemporaneously classified as employees of a Designated Company for purposes of the applicable Designated Company’s payroll system are not considered to be eligible employees of any Designated Company and shall not be eligible to participate in the Plan. In the event any such individuals are reclassified as employees of a Designated Company for any purpose, including, without limitation, common law or statutory employees, by any action of any third party, including, without limitation, any government agency, or as a result of any private lawsuit, action or administrative proceeding, such individuals shall, notwithstanding such reclassification, remain ineligible for participation. Notwithstanding the foregoing, the exclusive means for individuals who are not contemporaneously classified as employees of a Designated Company on the Designated Company’s payroll system to become eligible to participate in this Plan is through an amendment to this Plan, duly executed by the Company, which specifically renders such individuals eligible to participate herein.

4. **Participation.**

(a) An eligible employee who is not a Participant in any prior Offering may participate in an Offering by submitting an enrollment form to his or her appropriate payroll location at least 15 business days before the Offering Date (or by such other deadline as shall be established by the Administrator for the Offering).

(b) **Enrollment.** The enrollment form will (a) state a dollar amount or whole percentage to be deducted from an eligible employee’s Compensation (as defined in Section 11) per pay period, (b) authorize the purchase of Shares in each Offering in accordance with the terms of the Plan and (c) specify the exact name or names in which Shares purchased for such individual are to be issued pursuant to Section 10. An employee who does not enroll in accordance with these procedures will be deemed to have waived the right to participate. Unless a Participant files a new enrollment form or withdraws from the Plan, such Participant’s deductions and purchases will continue at the same amount or percentage of Compensation for future Offerings, provided he or she remains eligible.

(c) Notwithstanding the foregoing, participation in the Plan will neither be permitted nor be denied contrary to the requirements of the Code.

5. **Employee Contributions.** Each eligible employee may authorize payroll deductions at a minimum of one percent up to a maximum of 15 percent of such employee’s Compensation for each pay period. The Company will maintain book accounts showing the amount of payroll deductions made by each Participant for each Offering. No interest will accrue or be paid on payroll deductions.

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6. Deduction Changes. Except as may be determined by the Administrator in advance of an Offering, a Participant may not increase or decrease his or her payroll deduction during any Offering, but may increase or decrease his or her payroll deduction with respect to the next Offering (subject to the limitations of Section 5) by filing a new enrollment form at least 15 business days before the next Offering Date (or by such other deadline as shall be established by the Administrator for the Offering). The Administrator may, in advance of any Offering, establish rules permitting a Participant to increase, decrease or terminate his or her payroll deduction during an Offering.

7. Withdrawal. A Participant may withdraw from participation in the Plan by delivering a written notice of withdrawal to his or her appropriate payroll location. The Participant's withdrawal will be effective as of the next business day. Following a Participant's withdrawal, the Company will promptly refund such individual's entire account balance under the Plan to him or her (after payment for any Shares purchased before the effective date of withdrawal). Partial withdrawals are not permitted. Such an employee may not begin participation again during the remainder of the Offering, but may enroll in a subsequent Offering in accordance with Section 4.

8. Grant of Options. On each Offering Date, the Company will grant to each eligible employee who is then a Participant in the Plan an option ("Option") to purchase on the last day of such Offering (the "Exercise Date"), at the Option Price hereinafter provided for, the lowest of (a) a number of Shares determined by dividing such Participant's accumulated payroll deductions on such Exercise Date by the Option Price (as defined below), (b) a number of Shares determined by multiplying \$2,083 by the number of full months in such Offering and dividing the result by the Fair Market Value of the Shares on the Offering Date; or (c) such other lesser maximum number of Shares as shall have been established by the Administrator in advance of the Offering; provided, however, that such Option shall be subject to the limitations set forth below. Each Participant's Option shall be exercisable only to the extent of such Participant's accumulated payroll deductions on the Exercise Date. The purchase price for each Share purchased under each Option (the "Option Price") will be 85 percent of the Fair Market Value of the Shares on the Offering Date or the Exercise Date, whichever is less.

Notwithstanding the foregoing, no Participant may be granted an option hereunder if such Participant, immediately after the option was granted, would be treated as owning shares possessing five percent or more of the total combined voting power or value of all classes of shares of the Company or any Parent or Subsidiary (as defined in Section 11). For purposes of the preceding sentence, the attribution rules of Section 424(d) of the Code shall apply in determining the share ownership of a Participant, and all shares that the Participant has a contractual right to purchase shall be treated as shares owned by the Participant. In addition, no Participant may be granted an Option that permits his or her rights to purchase Shares under the Plan, and any other employee stock purchase plan of the Company and its Parents and Subsidiaries, to accrue at a rate that exceeds \$25,000 of the fair market value of such shares (determined on the option grant date or dates) for each calendar year in which the Option is outstanding at any time. The purpose of the limitation in the preceding sentence is to comply with Section 423(b)(8) of the Code and shall be applied taking Options into account in the order in which they were granted.

9. Exercise of Option and Purchase of Shares. Each employee who continues to be a Participant in the Plan on the Exercise Date shall be deemed to have exercised his or her Option on such date and shall acquire from the Company such number of whole Shares reserved for the purpose of the Plan as his or her accumulated payroll deductions on such date will purchase at the Option Price, subject to any other limitations contained in the Plan. Any amount remaining in a Participant's account at the end of an Offering solely by reason of the inability to purchase a fractional Share will be carried forward to the next Offering; any other balance remaining in a Participant's account at the end of an Offering will be refunded to the Participant promptly.

10. Issuance of Certificates. Certificates representing Shares purchased under the Plan may be issued only in the name of the employee, in the name of the employee and another person of legal age as joint tenants with rights of survivorship, or in the name of a broker authorized by the employee to be his, her or their, nominee for such purpose.

11. Definitions.

The term "Compensation" means the amount of base pay, prior to salary reduction pursuant to Sections 125, 132(f) or 401(k) of the Code, but excluding overtime, commissions, incentive or bonus awards, allowances and reimbursements for expenses such as relocation allowances or travel expenses, income or gains on the exercise of Company stock options, and similar items. The Administrator, in its discretion, may, on a uniform and nondiscriminatory basis, in advance of any Offering, establish a different definition of Compensation for that Offering and future Offerings.

The term "Designated Company" means the Company and/or any present or future Subsidiary (as defined below), in each case, that has been designated by the Board to participate in the Plan. The Board may so designate the Company and/or any Subsidiary, or revoke any such designation, at any time and from time to time, either before or after the Plan is approved by the shareholders. The current list of Designated Companies is attached hereto as Appendix A.

The term "Fair Market Value of the Shares" on any given date means the fair market value of the Shares determined in good faith by the Administrator; provided, however, that if the Shares admitted to quotation on the National Association of Securities

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Dealers Automated Quotation System (“NASDAQ”), the NASDAQ Stock Market or another national securities exchange, the determination shall be made by reference to the closing price on such date. If there is no closing price for such date, the determination shall be made by reference to the last date preceding such date for which there is a closing price.

The term “Parent” means a “parent corporation” with respect to the Company, as defined in Section 424(e) of the Code.

The term “Participant” means an individual who is eligible as determined in Section 3 and who has complied with the provisions of Section 4.

The term “Subsidiary” means a “subsidiary corporation” with respect to the Company, as defined in Section 424(f) of the Code.

12. Rights on Termination of Employment. If a Participant’s employment terminates for any reason before the Exercise Date for any Offering, no payroll deduction will be taken from any pay due and owing to the Participant and the balance in the Participant’s account will be paid to such Participant or, in the case of such Participant’s death, to his or her designated beneficiary as if such Participant had withdrawn from the Plan under Section 7. An employee will be deemed to have terminated employment, for this purpose, if the corporation that employs him or her, having been a Designated Company, ceases to be a Subsidiary, or if the employee is transferred to any corporation other than a Designated Company. An employee will not be deemed to have terminated employment for this purpose, if the employee is on an approved leave of absence for military service or sickness or for any other purpose approved by the Company, if the employee’s right to reemployment is guaranteed either by a statute or by contract or under the policy pursuant to which the leave of absence was granted or if the Administrator otherwise provides in writing.

13. Special Rules. Notwithstanding anything herein to the contrary, the Administrator may adopt special rules applicable to the employees of a particular Designated Company, whenever the Administrator determines that such rules are necessary or appropriate for the implementation of the Plan in a jurisdiction where such Designated Company has employees; provided that such rules are consistent with the requirements of Section 423(b) of the Code. Any special rules established pursuant to this Section 13 shall, to the extent possible, result in the employees subject to such rules having substantially the same rights as other Participants in the Plan.

14. Optionees Not Shareholders. Neither the granting of an Option to a Participant nor the deductions from his or her pay shall constitute such Participant a holder of the Shares covered by an Option under the Plan until such Shares have been purchased by and issued to him or her.

15. Rights Not Transferable. Rights under the Plan are not transferable by a Participant other than by will or the laws of descent and distribution, and are exercisable during the Participant’s lifetime only by the Participant.

16. Application of Funds. All funds received or held by the Company under the Plan may be combined with other corporate funds and may be used for any corporate purpose.

17. Adjustment in Case of Changes Affecting Shares. In the event of a subdivision of outstanding Shares, the payment of a dividend in Shares or any other change affecting the Shares, the number of Shares approved for the Plan and the Share limitation set forth in Section 8 shall be equitably or proportionately adjusted to give proper effect to such event.

18. Amendment of the Plan. The Board may at any time and from time to time amend the Plan in any respect, except that without the approval within 12 months of such Board action by the shareholders, no amendment shall be made increasing the number of Shares approved for the Plan or making any other change that would require shareholder approval in order for the Plan, as amended, to qualify as an “employee stock purchase plan” under Section 423(b) of the Code.

19. Insufficient Shares. If the total number of Shares that would otherwise be purchased on any Exercise Date plus the number of Shares purchased under previous Offerings under the Plan exceeds the maximum number of Shares issuable under the Plan, the Shares then available shall be apportioned among Participants in proportion to the amount of payroll deductions accumulated on behalf of each Participant that would otherwise be used to purchase Shares on such Exercise Date.

20. Termination of the Plan. The Plan may be terminated at any time by the Board. Upon termination of the Plan, all amounts in the accounts of Participants shall be promptly refunded.

21. Governmental Regulations. The Company’s obligation to sell and deliver Shares under the Plan is subject to obtaining all governmental approvals required in connection with the authorization, issuance, or sale of such Shares.

22. Governing Law. This Plan and all Options and actions taken thereunder shall be governed by, and construed in accordance with, the laws of the State of [New York], applied without regard to conflict of law principles.

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23. Issuance of Shares. Shares may be issued upon exercise of an Option from authorized but unissued Shares, from Shares held in the treasury of the Company, or from any other proper source.

24. Tax Withholding. Participation in the Plan is subject to any minimum required tax withholding on income of the Participant in connection with the Plan. Each Participant agrees, by entering the Plan, that the Company and its Subsidiaries shall have the right to deduct any such taxes from any payment of any kind otherwise due to the Participant, including Shares issuable under the Plan.

25. Notification Upon Sale of Shares. Each Participant agrees, by entering the Plan, to give the Company prompt notice of any disposition of Shares purchased under the Plan where such disposition occurs within two years after the date of grant of the Option pursuant to which such Shares were purchased or within one year after the date such Shares were purchased.

26. Effective Date and Approval of Shareholders. The Plan shall take effect on the later of the date it is adopted by the Board and the date it is approved by the holders of a majority of the votes cast at a meeting of shareholders at which a quorum is present.

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## APPENDIX A

### **Designated Companies**

Amarin Pharma, Inc.

December 20, 2017

BioPharma Secured Debt Fund II Holdings Cayman LP  
c/o Walkers Corporate Limited  
Cayman Corporate Centre  
27 Hospital Road, George Town  
Grand Cayman KY1-9008  
Cayman Islands  
Attention: Pedro Gonzalez de Cosio

Pharmakon Advisors LP  
110 East 59th Street, #3300  
New York, NY 10022  
Attn: Pedro Gonzalez de Cosio

This Consent and Waiver is delivered by Amarin Pharmaceuticals Ireland Limited and its permitted successors and assigns ("Amarin") and Amarin Corporation PLC and its permitted successors and assigns ("Amarin Parent" and, together with Amarin, the "Amarin Parties") pursuant to that certain Purchase and Sale Agreement (as amended, supplemented or modified from time to time, the "Purchase Agreement"), dated as of December 6, 2012, by and among Amarin, Amarin Parent and BioPharma Secured Debt Fund II Holdings Cayman LP and its permitted successors and assigns ("Purchaser"). Capitalized terms not otherwise defined in this Consent and Waiver shall have the meanings set forth in the Purchase Agreement.

**WITNESSETH:**

WHEREAS, Purchaser intends to sell, transfer, assign and convey to one or more of the unaffiliated third parties set forth on Schedule 1 hereto, which Purchaser may modify from time to time (the "Prospective Transferees"), all of Purchaser's right, title and interest in, to or under the Purchase Agreement, that certain Intellectual Property Charge Agreement dated as of December 19, 2012 between Amarin and Seller (the "Irish Intellectual Property Charge Agreement"), and that certain Patent Security Agreement dated as of December 19, 2012 between Amarin and Seller (the "U.S. Patent Security Agreement" and, together with the Irish Intellectual Property Charge Agreement, the "IP Charge Agreements", and, collectively with the Purchase Agreement, the "Amarin Agreements"). All of Purchaser's right, title and interest in, to or under each of the Amarin Agreements, together with all of its rights and obligations thereunder, is referred to herein as the "Purchased Assets";

WHEREAS, pursuant to Section 9.3 of the Purchase Agreement, Purchaser may not sell, assign, hypothecate or otherwise transfer the Purchase Agreement or any of its rights or obligations thereunder, in whole or in part, without the prior written consent of the Amarin Parties;

WHEREAS, pursuant to Section 21.2 of the Irish Intellectual Property Charge Agreement, Purchaser may not assign, transfer or otherwise dispose of all or any of its

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rights and/or obligations under the Irish Intellectual Property Charge Agreement or all or part of the security constituted thereby without the prior written consent of Amarin;

WHEREAS, pursuant to Section 9.7 of the Purchase Agreement, the Amarin Parties may waive in writing any term or condition of the Purchase Agreement;

WHEREAS, pursuant to Section 9.6 of the Purchase Agreement, any agreement, consent or approval required under the Purchase Agreement must be specific and in writing; and

WHEREAS, the Amarin Parties have requested that Purchaser consent to certain amendments to the Transaction Documents to facilitate inventory and receivables financings by the Amarin Parties as contemplated by Section 4.4(a) of and clause (k) of the definition of "Permitted Indebtedness" in the Purchase Agreement (such amendments, the "A/R Financing Amendments");

WHEREAS, Purchaser has agreed to the A/R Financing Amendments to the extent set forth in this Consent and Waiver and the Amarin Parties have agreed to waive the restrictions set forth in Section 9.3 of the Purchase Agreement and Section 21.2 of the Irish Intellectual Property Charge Agreement and any other provision of the Purchase Agreement and/or the Irish Intellectual Property Charge Agreement and any provision of the U.S. Patent Security Agreement that would otherwise prohibit, in whole or in part, the consummation by Purchaser of any sale, transfer, assignment and conveyance to one or more of the Prospective Transferees of the Purchased Assets (the "Transaction"), and, accordingly, to provide its consent to Purchaser in order to enable Purchaser to consummate the Transaction, subject to the terms and conditions of this Consent and Waiver.

NOW, THEREFORE, in consideration of the foregoing and other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, each of the Amarin Parties hereby agrees with and in favor of Purchaser as follows:

1. Effective as of the date hereof, the Purchase Agreement is amended as follows:
  - (a) The definition of Permitted Encumbrances is amended to delete the "and" after clause (h), replace the period at the end of clause (i) with "; and" and to include the following new clause (j):

“(j) Encumbrances on Permitted A/R Financing Collateral (as defined in Section 9.4(c)) securing obligations under a Permitted A/R Financing; provided, that to the extent such Encumbrances are on the Purchased Receivables (or any portion thereof), such Encumbrances, in each case, are subject to a subordination, intercreditor or other similar agreement that is in form and substance reasonably satisfactory to Purchaser and the lenders (or agent) providing such Permitted A/R Financing;
  - (b) Clause (k) of the definition of Permitted Indebtedness is replaced with the following new clause (k):

"Indebtedness incurred by any Amarin Party pursuant to a working capital facility or inventory and receivable financing; provided, that the Indebtedness outstanding thereunder shall not exceed at any time an amount equal to 80% of the sum of (A) the face amount of the accounts receivables of such Amarin Party plus (B) the greater of the cost and the value of inventory of such Amarin Party (such value to be reasonably determined in good faith by Chief Financial Officer, Treasurer or Controller of Seller or Parent, as applicable) (such working capital facility or inventory and receivable financing, a "Permitted A/R Financing"); provided, further, that any Encumbrance on the Purchased Receivables (or any portion thereof) securing such Indebtedness is a Permitted Encumbrance hereunder and is subject to a subordination, intercreditor or other similar agreement that is in form and substance reasonably satisfactory to Purchaser and the lenders (or agent) providing such Permitted A/R Financing;"

(c) The following provision is added as Section 9.4(c) of the Purchase Agreement:

In connection with any Permitted A/R Financing, to the extent requested by the lenders or any agent for the lenders (collectively, the "A/R Secured Parties") providing such financing, Purchaser and such lenders (or agent) shall enter into a subordination, intercreditor or other similar agreement to which such Permitted A/R Financing is subject (and any related documentation in respect of the Intellectual Property Charge Agreements solely if and to the extent necessary in light of the nature of the Permitted A/R Financing Collateral (as defined below)), in form and substance reasonably satisfactory to such lenders (or agent) and Purchaser, pursuant to which Purchaser shall subordinate any Encumbrances in favor of Purchaser on the Purchased Receivables and/or Permitted A/R Financing Collateral under the Transaction Documents to the Encumbrances in favor of the A/R Secured Parties under the Permitted A/R Financing solely on the Purchased Receivables and/or Permitted A/R Financing Collateral, with the effect that the Encumbrances on the Purchased Receivables and/or Permitted A/R Financing Collateral in favor of the A/R Secured Parties shall be superior in rank and order of priority and enforcement to any Encumbrances in favor of Purchaser on the Purchased Receivables and/or Permitted A/R Financing Collateral; provided, that, unless otherwise agreed by the A/R Secured Parties, such subordination, intercreditor or other similar agreement shall not require any cash or other Permitted A/R Financing Collateral specifically be set aside for the payment of the Purchased Receivables.

For purposes hereof, "Permitted A/R Financing Collateral" shall mean (i) any inventory (whether or not produced using Vascepa Product Rights) of Seller, (ii) any accounts receivables of Seller arising out of the sale of such inventory, (iii) any books and records of Seller in respect of the items described in clauses (i) and (ii) above, (iv) any Supporting Obligations (as defined in the UCC) in favor of Seller in

respect of the items described in clauses (i) and (ii) above and (v) the proceeds of the foregoing (including cash and cash equivalents arising from such accounts receivables and/or such inventory); it being understood and agreed, however, that "Permitted A/R Financing Collateral" shall exclude any other Additional Collateral (including any proceeds, royalties or other payments of any kind from any sale, license or other transfer of any Vascepa Product Rights).

- (d) The following provision is added as Section 4.15 of the Purchase Agreement:

**4.15 PERMITTED A/R FINANCING.**

**(a)** Seller shall comply in all material respects with its obligations under any Permitted A/R Financing and shall not take any action or forego any action that would reasonably be expected to constitute a material breach thereof. Promptly, and in any event within five (5) Business Days, after receipt of any (written or oral) notice from any A/R Secured Party of an alleged breach by Seller under any Permitted A/R Financing, Seller shall give notice thereof to the Purchaser, including delivering to the Purchaser a copy of any such written notice. The Seller shall use its commercially reasonable efforts to cure any breaches by it under any Permitted A/R Financing and shall give written notice to the Purchaser upon curing any such breach.

**(b)** If Seller fails, or expects to fail, to satisfy any of its material obligations under any Permitted A/R Financing, including any payment obligations owed to any A/R Secured Party, when such obligations are due, Seller shall immediately notify the Purchaser of the specifics regarding such failure or expected failure.

- (e) The definition of "U.S. Patent Security Agreement" is amended to add the following language after "attached hereto as **Exhibit C**": ", as amended, restated, supplemented or otherwise modified from time to time".

2. Effective as of the date hereof:

- (a) Each of the Amarin Parties hereby (i) consents to Purchaser's sale, transfer, assignment and conveyance to one or more of the Prospective Transferees of the Purchased Assets, and (ii) waives any prohibition set forth in Section 9.3 of the Purchase Agreement, Section 21.2 of the Irish Intellectual Property Charge Agreement, any other provision of the Purchase Agreement and/or the Irish Intellectual Property Charge Agreement and any provision of the U.S. Patent Security Agreement that would otherwise prohibit, in whole or in part, the consummation by Purchaser of the Transaction; provided that the Prospective Transferee(s) shall agree to be bound by the terms and conditions of the Purchase Agreement (as amended pursuant to Section 1 of this Consent and Waiver).
- (b) Furthermore, each of the Amarin Parties hereby: (i) consents to the disclosure to a Prospective Transferee of any Confidential Information furnished by or on behalf of either of the Amarin Parties to Purchaser or its Affiliates pursuant to any of the Amarin Agreements; provided that such



Prospective Transferee shall have entered into a confidentiality and non-disclosure agreement with the Amarin Parties in form and substance reasonably acceptable to the Amarin Parties (such non-disclosure agreement, a "NDA"); and (ii) waives any prohibition set forth in Section 5.1 and any other provision of the Purchase Agreement and in any provision of the IP Charge Agreements that would otherwise prohibit, in any respect, any such disclosure by Purchaser to any Prospective Transferee that has entered into a NDA.

- (c) Purchaser hereby agrees and confirms that any and all right, title and interest in, to or under the Collateral and/or the Additional Collateral that Purchaser has, has had or hereafter otherwise might have (including, for the avoidance of doubt, with respect to any and all payments or proceeds therefrom) (the "PSA Collateral") is included among the Purchased Assets; and
- (d) Purchaser hereby agrees to provide the Amarin Parties with written notice regarding the consummation of the Transaction (the "Consummation Notice"), which such notice will include the identity of the Prospective Transferee party to the Transaction (which, for the avoidance of doubt, will be CPPIB Credit Europe S.à r.l.), its notice details and the details of the account of such Prospective Transferee in which any and all payments from the Amarin Parties in respect of the Purchased Assets will be paid or remitted.

3. Effective upon, and subject in all events to, the consummation of the Transaction, each of the Amarin Parties hereby consents to and authorizes the Prospective Transferee(s) identified in the Consummation Notice and its designees to file (a) a UCC financing or amendment statement in the appropriate filing office and/or any other document required by such Prospective Transferee(s) in its reasonable determination (including with respect to the U.S. Patent Security Agreement), and (b) the particulars of the security interest in the CRO and/or any other document required by such Prospective Transferee(s) in its reasonable determination (including a filing in the Irish Patents Office, the European Trade Marks and Design Registration Office and the EPO in connection with the European Patents), in each case if and to the extent required to evidence, preserve, enforce, protect and perfect the validity and priority the security interests and other Encumbrances created by any of the Amarin Agreements in the Collateral and/or the Additional Collateral in favor of such Prospective Transferee(s). In addition, on or prior to the consummation of the Transaction, Amarin will execute and deliver to the Prospective Transferee referred to in Section 2(d), to be effective upon and subject to the consummation of the Transaction, (i) an acknowledgment to that certain Patent Security Assignment and Assumption Agreement, (ii) an amendment and restatement of the U.S. Patent Security Agreement, and (iii) the Intellectual Property Charge, in each case substantially in the form attached hereto as Exhibits A, B and C, respectively.

4. Effective upon, and subject in all events to, the consummation of the Transaction, each of the Amarin Parties hereby agrees that, upon receipt of the Consummation Notice, (a) the Amarin Parties will deliver any future payment under Section 2.1 and Article 8 of the Purchase Agreement and any other payments due and payable by the Amarin Parties under the Purchase Agreement to the Prospective Transferee(s) identified in the Consummation Notice in accordance with the account details set forth therein, and (b) the Amarin Parties (as applicable) will deliver any future

Quarterly Reports, Annual Reports, Unaudited Financial Statements, Resource Allocation Statements and any other reports or statements contemplated under Section 2.2 of the Purchase Agreement or otherwise by the Purchase Agreement, and any notices or other communications in connection with the Amarin Agreements, to such Prospective Transferee(s) in accordance with the notice details set forth in the Consummation Notice.

5. Each of the Amarin Parties hereby agrees and confirms that Purchaser shall be permitted to deliver a copy of this Consent and Waiver to the Prospective Transferees.

6. Except as expressly set forth herein, nothing contained in this Consent and Waiver shall be deemed or construed to amend, supplement or modify any of the Amarin Agreements or otherwise affect the rights and obligations of any party thereto, all of which remain in full force and effect in accordance with their terms. For the avoidance of doubt, the consents provided for in Sections 2, 3, 4 and 5 above shall apply solely to the Transaction and not to any subsequent sale, transfer, assignment and conveyance of the Purchased Assets.

7. This Consent and Waiver, and the effectiveness hereof, is expressly conditioned upon, and subject in all events to, this Consent and Waiver being duly executed and delivered by each of the Amarin Parties and Purchaser.

8. For the avoidance of doubt, the Amarin Parties and Purchaser hereby agree that this Consent and Waiver constitutes a Transaction Document for any and all purposes for which such term is used in the Purchase Agreement.

9. This Consent and Waiver will be governed by, and construed, interpreted and enforced in accordance with, the internal substantive laws of the State of New York, without regard to principles of conflicts of law.

10. This Consent and Waiver may be executed in any number of counterparts, all of which shall be deemed an original and constitute one and the same instrument, and each party hereto may execute this Consent and Waiver by signing and delivering one or more counterparts. Delivery of an executed counterpart of this Consent and Waiver electronically or by facsimile shall be effective as delivery of an original executed counterpart of this Consent and Waiver.

*[Signature Pages Follows]*

IN WITNESS WHEREOF, each of the undersigned has executed this Consent and Waiver as of the date first above written.

Very truly yours,

AMARIN PHARMACEUTICALS IRELAND LIMITED

By: /s/ Patrick J. O'Sullivan

Name: Patrick J. O'Sullivan

Title: Director

AMARIN CORPORATION PLC

By: /s/ Joseph T. Kennedy

Name: Joseph T. Kennedy

Title: Executive Vice President, General Counsel

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AGREED TO AND ACCEPTED:

BIOPHARMA SECURED INVESTMENTS II HOLDINGS CAYMAN LP

By: Pharmakon Advisors, LP,  
its Investment Manager

By: Pharmakon Management I, LLC,  
its General Partner

By: /s/ Pedro Gonzalez de Cosio  
Name: Pedro Gonzalez de Cosio  
Title: Managing Member

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## Schedule 1

### Prospective Transferees

CPPIB Credit Europe S.à r.l., a private limited liability company (société à responsabilité limitée) incorporated and organized under the Laws of the Grand Duchy of Luxembourg, having its registered office at 10-12 Boulevard Roosevelt, L-2450 Luxembourg, Grand Duchy of Luxembourg and registered with the Luxembourg Register of Commerce and Companies under number B 151 453

**DISTRIBUTION AGREEMENT**

DATED AS OF MARCH 8, 2016  
BY AND AMONG

BIOLOGIX FZCo

AND

AMARIN PHARMACEUTICALS IRELAND LIMITED AND

AMARIN PHARMA, INC.

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CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH “[\*\*\*]”. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT UNDER RULE 24b-2 OF THE SECURITIES EXCHANGE ACT OF 1934.

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## DISTRIBUTION AGREEMENT

This Distribution Agreement (this “Agreement”) is dated as of March 8, 2016 (the “Effective Date”) by and among Biologix FZCo, a company incorporated under the laws of United Arab Emirates (“UAE”), with the Head Office of Biologix at Dubai Airport Free Zone, Warehouse C17 PO Box 54405, Al Tawar Dubai, UAE, and its Affiliates (“Biologix”), on the one hand, and Amarin Pharmaceuticals Ireland Limited, a company incorporated under the laws of Ireland (registered number 408912), with offices at 2 Pembroke House Upper Pembroke Street 28-32, Dublin 2, Ireland (“Amarin Ireland”), and Amarin Pharma, Inc., a Delaware corporation, with offices at 1430 Route 206 North, Suite 101, Bedminster, NJ 07921 (“Amarin Pharma”, and collectively with Amarin Ireland, “Amarin”), on the other hand. Biologix and Amarin may be referred to herein as a “Party” or, collectively, as “Parties”.

### 1. Definitions

. Unless otherwise specifically provided herein, the following terms shall have the following meanings:

- 1.1 “Active Moiety” means the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds) or other non-covalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance.
  - 1.2 “Adverse Event” means any adverse event associated with the use of a drug product in humans, whether or not it is considered drug related, including the following: an adverse event occurring during the use of a drug product in professional practices, either by prescription or in an ongoing clinical study; an adverse event occurring via a drug overdose, whether accidental or intentional; an adverse event occurring from drug abuse; an adverse event occurring from drug withdrawal; any significant failure of expected pharmacological action (lack of efficacy).
  - 1.3 “Affiliate” means a Person that controls, is controlled by or is under common control with a Party, but only for so long as such control exists. For the purposes of this Section 1.3, the word “control” (including, with correlative meaning, the terms “controlled by” or “under the common control with”) means the actual power, either directly or indirectly through one or more intermediaries, to direct the management and policies of such Person or entity, whether by the ownership of more than fifty percent (50%) of the voting stock of such entity, or by contract or otherwise.
  - 1.4 “Applicable Incoterms” means the International Chamber of Commerce Incoterms (2010) [\*\*\*].
  - 1.5 “Applicable Law(s)” means any (a) applicable law, statute, rule, regulation, guideline, ordinance or other pronouncement of any Governmental Body having the effect of law or (b) guidance of any Governmental Body in the Territory.
-

- 1.6 “Applicable Service Fee Percentage” means the percentage set forth in Section 11.3.2, as same may be adjusted in accordance with Section 11.3.5.
- 1.7 “Business” means business resulting from the sale of Products to Customers by Biologix and delivered by Biologix to Customers and based on the local market needs of the Territory other than Tender Business.
- 1.8 “Certificate of Analysis” means a document identified as such and provided by Amarin to Biologix that sets forth the analytical test results against the specifications (in accordance with the Quality Agreement) for a specified lot of Product shipped to Biologix.
- 1.9 “Change of Control” means, with respect to Biologix: (a) a transaction or series of related transactions that results in the sale or other disposition of all or substantially all of Biologix’s assets; or (b) a merger or consolidation in which Biologix is not the surviving corporation or in which, if Biologix is the surviving corporation, the shareholders of Biologix immediately prior to the consummation of such merger or consolidation do not, immediately after consummation of such merger or consolidation, possess, directly or indirectly through one or more intermediaries, a majority of the voting power of all of the surviving entity’s outstanding stock and other securities and the power to elect a majority of the members of Biologix’s board of directors; or (c) a transaction or series of related transactions (which may include a tender offer for Biologix’s stock or the issuance, sale or exchange of stock of Biologix) if the shareholders of Biologix immediately prior to the initial such transaction do not, immediately after consummation of such transaction or any of such related transactions, own, directly or indirectly through one or more intermediaries, stock or other securities of the entity that possess a majority of the voting power of all of Biologix’s outstanding stock and other securities and the power to elect a majority of the members of Biologix’s board of directors. For the avoidance of doubt, the reorganization of a holding company owned by the shareholders of record of Biologix immediately prior to such reorganization shall not be considered as a Change of Control; provided, that immediately following such reorganization, Biologix is wholly-owned by such holding company and such shareholders possess at least a majority of the voting power of all of the outstanding stock and other securities of, and the power to elect a majority of the members of board of directors of, such holding company.
- 1.10 “Competing Product” means [\*\*\*].
- 1.11 “Confidential Information” of a Party, means information relating to the business, operations or products of a Party or any of its Affiliates, including any technical information, know-how, trade secrets, or inventions that such Party discloses to the other Party under this Agreement, or otherwise becomes known to the other Party by virtue of this Agreement.

- 1.12 “Customers” means any Person within the Territory who is solicited to place or who places an order for Products with Biologix, and to whom Products are delivered by Biologix.
- 1.13 “Dollars” and “\$” means United States dollars.
- 1.14 “Field” means the (a) treatment of (i) very high triglycerides (VHTG) (e.g., levels of at least 500mg/dL), (ii) high triglycerides (HTG) (e.g., levels of 200mg/dL to 499mg/dL) and (b) risk reduction of cardiovascular disease associated with elevated triglyceride levels (e.g., levels of at least 150 mg/dL) and (c) add on therapy or a combination to or with a statin or fenofibrate.
- 1.15 “First Commercial Sale” means the first sale for use or consumption of any Product in any Part of the Territory whether resulting from named patient sales or after Product Registration has been obtained for commercial sale of such Product in such Part of the Territory.
- 1.16 “Floor Price” means [\*\*\*].
- 1.17 “GMP” means all applicable standards relating to manufacturing practices for intermediates, active pharmaceutical ingredients or finished pharmaceutical products, including (a) the principles detailed in the U.S. Current Good Manufacturing Practices, 21 C.F.R. Parts 210 and 211, The Rules Governing Medicinal Products in the European Community, Volume IV Good Manufacturing Practice for Medicinal Products, and Q7 A Good Manufacturing Practice Guidance For Active Pharmaceutical Ingredients (ICH Q7 A), and (b) the principles promulgated by any applicable Governmental Body having jurisdiction over the manufacture of the API and drug product, in the form of laws, rules or regulations, in each case as in effect at the Effective Date and as amended, promulgated or accepted by any applicable Governmental Body from time to time during the Term.
- 1.18 “Governmental Body” means any: (a) nation, principality, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature; (b) federal, state, local, municipal, foreign or other government; (c) governmental or quasi-governmental authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, board, instrumentality, officer, official, representative, organization, unit, body or entity and any court or other tribunal); (d) multi-national or supranational organization or body; or (e) individual, entity, or body exercising, or entitled to exercise, any executive, legislative, judicial, administrative, regulatory, police, military or taxing authority or power of any nature.

- 1.19 “Marketing Authorization” means the approval from an applicable Governmental Body to commence marketing of the Product in the Field in the Territory or any Part of the Territory.
- 1.20 “Part of the Territory” means, individually, each country of the Territory.
- 1.21 “Person” means any natural person, corporation, firm, business trust, joint venture, association, organization, company, partnership or other business entity, or any Governmental Body or political subdivision thereof.
- 1.22 “Product(s)” means a pharmaceutical preparation in current (as of the Effective Date) capsule dosage form incorporating icosapent ethyl as an active ingredient to be administered to humans for therapeutic uses. For clarity, the Product is currently being commercialized by Amarin in the United States market under the trademark VASCEPA® (formerly known as AMR-101).
- 1.23 “Product Complaint” means any written, verbal or electronic expression of dissatisfaction regarding any Product sold by or on behalf of Biologix (or any of its Sub-Distributors) in the Territory, including reports of actual or suspected product tampering, contamination, mislabelling, misbranding or inclusion of improper ingredients.
- 1.24 “Product Registration(s)” means all authorizations, licences, consents and governmental approvals, including Marketing Authorizations, granted by Governmental Bodies in the Territory necessary to permit the importation, distribution, promotion, marketing and sale of Product in the Field in the Territory, and any price and reimbursement approvals (“P&R Approvals”) required for this purpose.
- 1.25 “Purchase Order” means a written formal purchase order sent by Biologix to Amarin, delivered to Amarin electronically or by other means, detailing the specific type and exact quantity of Product requested to be purchased, purchase price and the requested delivery date. All Purchase Orders must be delivered to Amarin at least [\*\*\*] in advance of the requested delivery date and conform to a previously issued Forecast.
- 1.26 “Quality Agreement” means that certain quality agreement, defining certain terms of quality control and quality assurance relating to Product supplied by Amarin to Biologix, for distribution and commercial sale in the Field in the Territory, during the Term, and negotiated and entered into by the Parties [\*\*\*] of the Effective Date; provided, that the Quality Agreement shall be consistent with the terms and conditions of this Agreement, and, in the event of conflict between the terms of this Agreement and the Quality Agreement, the terms of the Quality Agreement shall govern.
- 1.27 “Representatives” means, with respect to a given Party, its employees, consultants, contractors, advisors and agents.

- 1.28 “Sample” means a unit of prescription drug that is not intended to be sold and is intended to be distributed to a licensed practitioner to promote the sale of the Product in the Field in the Territory in accordance with this Agreement and all Applicable Laws.
- 1.29 “Sample Cost” means, [\*\*\*].
- 1.30 “Sample Pack” means a Sample bottle or package containing [\*\*\*] of Product.
- 1.31 “Selling Price” means the per capsule gross price for Product invoiced by Biologix to Sub-Distributors and Customers in any Part of the Territory; provided, that in no event shall the Selling Price be equal to or lower than the Floor Price, unless approved in advance in writing by Amarin.
- 1.32 “Service Fee” means an amount equal to the Applicable Service Fee Percentage of the Supply Price.
- 1.33 “Service Fee Payment” means an amount equal the Supply Price Payment times the Applicable Service Fee Percentage.
- 1.34 “Supply Price” means [\*\*\*].
- 1.35 “Supply Price Payment” means [\*\*\*].
- 1.36 “Tender Business” means business resulting from a Governmental Body requesting a quotation for Product from Biologix and, upon an award by such Governmental Body, such Product is sold to such Governmental Body by and with the assistance of Biologix.
- 1.37 “Territory” means Lebanon, Syria, Jordan, Saudi Arabia, Kuwait, Qatar, Bahrain, Oman, United Arab Emirates, Yemen, Iran, Iraq, Morocco, Algeria, Tunisia, Libya and Egypt.
- 1.38 “Third Party” means any Person other than Biologix, or Amarin or any of its Affiliates.
- 1.39 “Trademark(s)” means any word, name, symbol, color, shape, designation or any combination thereof, including any trademark, service mark, trade name, trade dress, brand name, sub-brand name, product configuration rights, design rights certification mark, collective mark, logo, tagline, slogan, design or business symbol, that functions as an identifier of source, quality, or, origin, whether or not registered, and all statutory and common law rights therein, and all registrations and applications therefor, together with all goodwill associated with, or symbolized by, any of the foregoing, including the marks on Exhibit A hereto.
- 1.40 “Unit” means [\*\*\*].

- 1.41 “United States” or “U.S.” means the United States of America and its territories and possessions, including the District of Columbia, the U.S. Virgin Islands and the Commonwealth of Puerto Rico.
- 1.42 “VAT” means a value added tax or similar payment.
- 1.43 Additional Definitions. The following terms have the meanings set forth in the corresponding Sections of this Agreement:

Term	Section/Article
“Agreement”	Preamble
“Amarin”	Preamble
“Amarin Competitor”	<a href="#">13.1</a>
“Amarin Ireland”	Preamble
“Amarin Pharma”	Preamble
“Amarin Promotional Materials”	<a href="#">2.1.6</a>
“Binding Forecast Period”	<a href="#">3.1.2</a>
“Biologix”	Preamble
“Biologix Promotional Materials”	<a href="#">2.1.6</a>
“Compliance Audit”	<a href="#">10.3</a>
“CTD”	<a href="#">6</a>
“Delivery Time”	<a href="#">4.1.1</a>
“Effective Date”	Preamble
“Estimated Service Fee Payment”	<a href="#">11.3.2</a>
“Estimated Supply Payment”	<a href="#">3.3.6</a>
“FCPA”	<a href="#">13.2.1</a>
“Forecast”	<a href="#">3.1.1</a>
“GAAP”	<a href="#">17.6</a>
“Indemnatee”	<a href="#">7.4.3</a>
“Intellectual Property”	<a href="#">12.2</a>
“Latent Defects”	<a href="#">4.2.3</a>
“LCIA Rules”	<a href="#">17.10</a>
“Losses”	<a href="#">7.4.1</a>
“Marketing and Promotion Services”	<a href="#">Exhibit B</a>
“Marketing Plan”	<a href="#">Exhibit B</a>
“Minimum Sales”	<a href="#">Exhibit B</a>
“OECD Convention”	<a href="#">13.2.1</a>
“OFAC”	<a href="#">13.4</a>
“Party” or “Parties”	Preamble
“P&R Approvals”	<a href="#">1.24</a>
“Prepaid Purchase Deposit”	<a href="#">11.2.1</a>
“Product Warranty”	<a href="#">7.2.3</a>

“Provisional Unit Supply Price”	<a href="#">3.3.5</a>
“Reconciliation Payment”	<a href="#">3.3.8</a>
“Redacted Agreement”	<a href="#">16.7</a>
“Regulatory Services”	<a href="#">6</a>
“Service Fee Reconciliation Payment”	<a href="#">11.3.3</a>
“Sub-Distributor”	<a href="#">2.2.2</a>
“Term”	<a href="#">14.1.1</a>
“Third Party Claim”	<a href="#">7.4.1</a>
“UAE”	Preamble
“UK Bribery Act”	<a href="#">13.2.1</a>
“Upfront Payment”	<a href="#">11.1.1</a>

## 2. Distribution

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### 2.1 Scope of Appointment for Distribution Services

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2.1.1 Amarin Ireland hereby appoints Biologix as its exclusive distributor for the distribution and sale of the Products in the Field in the Territory, subject to the terms and conditions set forth herein.

2.1.2 Biologix shall register, promote, market, distribute and sell the Products in the Field in the Territory as supplied by Amarin, under the packaging provided to Biologix by Amarin and under the Trademarks. Biologix shall not make any changes or alterations whatsoever to the Products or packaging, without the prior written consent of Amarin, except as otherwise mutually agreed to by the Parties.

2.1.3 Biologix shall at its own expense handle and carry out the following tasks related to the Products: (i) incoming inspection, (ii) storage, (iii) order processing, (iv) order picking, (v) shipment to Customers and (vi) debt collection and handling of returned Products. Biologix shall at all times act in accordance with Amarin’s instructions and perform activities under GMP, where required or applicable.

2.1.4 Subject to Section 7.1.11(ii), Biologix shall commence its promotion and sale of the Product in each Part of the Territory [\*\*\*] of receiving the Marketing Authorization for the Product in such country.

2.1.5 Unless otherwise provided for in this Agreement, all costs related to the marketing, Product Registration, distributing and sale of the Product shall be solely borne by Biologix. Amarin may, in its sole and absolute discretion, provide reasonable support to Biologix in furtherance thereof.

2.1.6 Biologix shall not start or perform, directly or indirectly, any clinical trials or any studies with respect to the Product. Biologix has no publication rights whatsoever related to the



Product. For clarity, with respect to the Product, Biologix shall not, and does not have any rights to, make any proposed academic, scientific or medical publications relating to any (i) clinical trials, clinical data or other studies or the results therefrom with respect to the Product, (ii) other data generated under this Agreement relating to the Product or (iii) Confidential Information of Amarin. Notwithstanding anything herein to the contrary, Amarin shall provide Biologix with copies of its publications and presentations related to the Product that it uses for promotional purposes (the “Amarin Promotional Materials”). Biologix is permitted to use the Amarin Promotional Materials as-is, without foreign (non-English) language translation. In the event that Biologix determines that it would be necessary or useful to translate or make modifications to the Amarin Promotional Materials for use in the Territory, Biologix may use such materials as the basis to prepare translated publications and new presentations of same for use in the Territory (the “Biologix Promotional Materials”); provided, that the Biologix Promotional Materials shall comply with all Applicable Laws and regulatory requirements in the Territory, and any language translation (from English) of the Biologix Promotional Materials shall be performed by certified medical translators to ensure the truth and accuracy of the facts and conclusions contained therein. During the Term, Biologix shall promptly provide Amarin with copies of all Biologix Promotional Materials and copies of same shall be included in each annual Marketing Plan. During the Term, Biologix undertakes to archive copies of all Biologix Promotional Materials which shall be subject to Amarin’s audit rights under Section 10.3.

## 2.2 Restrictive Covenants and Territory Exclusivity

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- 2.2.1 Biologix shall not subcontract any of its rights or obligations under this Agreement to any Person, without the prior written consent of Amarin. Biologix will notify Amarin which of the Biologix Affiliates is acting as a distributor in any Part of the Territory in the event that Biologix FZCo decides to subcontract all or a portion of its rights or obligations hereunder to an Affiliate, Biologix FZCo shall first notify Amarin in writing and provide the identity of such Affiliate, the purpose of such subcontract and any other information requested by Amarin in connection therewith. Notwithstanding anything herein to the contrary, Biologix FZCo shall (a) ensure that all such Affiliates shall be bound by and comply with all applicable terms and conditions of this Agreement, including Section 2.2 and (b) remain solely responsible and liable for the performance by any Affiliate of any of the obligations delegated to it by Biologix FZCo under to the terms of this Agreement.
- 2.2.2 Notwithstanding anything herein to the contrary, Biologix shall have the right to appoint, subject to the prior written consent of Amarin (not to be unreasonably withheld), [\*\*\*] sub-distributor for each Part of the Territory (“Sub-Distributor”); provided, that, Biologix shall (a) ensure that all such Sub-Distributors shall be bound by and comply with all applicable terms and conditions of this Agreement, including Sections 2.2, 7.1 and 10.3, and (b) remain solely responsible and liable for the performance by any such Sub-Distributor of any of the obligations delegated to it by Biologix under to the terms of

this Agreement. Notwithstanding anything herein to the contrary, Sub-Distributors shall only be permitted to distribute Product in the Territory and shall have no right to promote, market, or use Product in the Territory, including to any healthcare providers, pharmacies, physicians, physician's assistants, nurse practitioners or other medical professionals licensed to prescribe, administer, or dispense drugs, and for clarity shall not perform any Marketing and Promotion Services. For clarity, Amarin shall provide Biologix with reasonable advance written notice of a Compliance Audit of a Sub-Distributor and Biologix shall, and shall cause such Sub-Distributor to, cooperate with all reasonable requests of Amarin in connection therewith, in accordance with this Section 2.2.2 and Section 10.3.

2.2.3 Biologix shall not, directly or indirectly [\*\*\*].

2.2.4 [\*\*\*].

[\*\*\*].

2.2.5 Amarin may appoint any Affiliate to perform any of its obligations or exercise any of its rights under this Agreement.

### 3. Supply

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#### 3.1 Supply and Forecasts

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3.1.1 [\*\*\*], Biologix shall provide to Amarin a written rolling twelve (12) month forecast of Biologix's monthly requirements of Product (the "Forecast") which shall represent a good faith estimate of the expected monthly purchase quantities of Product with a breakdown by month and for each Part of the Territory for Business. Biologix shall provide to Amarin, [\*\*\*] an update of the Forecast. Notwithstanding the fact that there will be no Forecasting requirements for Tender Business, Biologix shall submit Purchase Orders in connection therewith.

3.1.2 The volumes of Product shown for the [\*\*\*] of each Forecast, unless otherwise agreed to in advance in writing by Amarin, shall constitute a binding purchase obligation for Biologix (the "Binding Forecast Period"). [\*\*\*].

3.1.3 Biologix shall order all quantities of Product sufficient to meet market and Customer demand in the Territory. Amarin shall use commercially reasonable efforts to supply Product to Biologix in sufficient quantities to meet the binding portion of the Forecast, as set forth in Section 3.1.2, for such Product and in accordance with the estimated requirements for such Product provided by Biologix in the Forecast, all subject to [\*\*\*].

- 3.1.4 All Product shall, at the time of delivery by Amarin to Biologix, have [\*\*\*]; provided, that the delivery date in the Purchase Order is consistent with the previously supplied Forecast.
- 3.1.5 In the event of Product in short supply, Amarin shall notify Biologix thereof. During any period of such shortage, Amarin shall allocate in a reasonable manner Product as is available to Amarin with the right to adjust accordingly the quantities to be delivered under any existing Purchase Orders.
- 3.1.6 Amarin shall notify Biologix if any Purchase Order submitted by Biologix cannot be fulfilled on or before the applicable Delivery Time.
- 3.1.7 Each Purchase Order issued by Biologix shall (i) identify the portion of such order which is related to Business, Tender Business, and Sample Packs (as applicable) and (ii) identify any penalties which could be imposed on Biologix as a result of a delay in the delivery of Product under such order.
- 3.1.8 Subject to Section 17.7, in no event shall Amarin be responsible for any loss of any kind sustained or incurred by Biologix by reason of any failure or delay in Amarin supplying Product to Biologix unless such Product was included in the Binding Forecast Period and a related Purchase Order was accepted by Amarin pursuant to Section 3.2. Amarin's obligations hereunder are dependent on Amarin's ability to obtain the necessary raw materials and other elements of supply.
- 3.2 Order Process. No Purchase Order for Products is binding on Amarin until it is acknowledged and accepted in writing by Amarin. [\*\*\*]. Each Purchase Order for Product shall be exclusively governed by this Agreement. None of the preprinted terms or conditions received from Biologix will amend or supplement this Agreement even if accepted by Amarin.
- 3.3 Prices for Sample Packs, Business and Tender Business
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- 3.3.1 Sample Packs shall be sold by Amarin to Biologix at the Sample Cost.
- 3.3.2 For Business, Products shall be sold by Amarin to Biologix at the Supply Price established in the applicable Part of the Territory, as may be modified during the Term.
- 3.3.3 [\*\*\*].
- 3.3.4 [\*\*\*].
- 3.3.5 [\*\*\*].
- 3.3.6 [\*\*\*].

3.3.7 [\*\*\*].

3.3.8 [\*\*\*].

3.3.9 [\*\*\*].

3.4 Payment Terms

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3.4.1 Payment by Biologix shall be by bank transfer to bank account details indicated in the invoice and due in accordance with the terms set forth in Section 3.3.

3.4.2 With respect to all monies whatsoever to be paid by one Party to the other Party pursuant to this Agreement which are not paid on the due date, such amounts shall carry interest from such due date until receipt of payment by the applicable Party of all such monies at the then prevailing LIBOR interest rate [\*\*\*].

3.4.3 To the extent possible and, in accordance with Section 11.2.1, the Parties will endeavor to off-set against one another all invoices sent from one Party to the other Party under this Agreement.

3.5 Invoicing; Collection of Invoices

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3.5.1 Biologix shall directly invoice the Sub-Distributors and Customers for Product at the Selling Price. Biologix shall at its risk and expense, collect all monies, taxes and charges due in connection with such sales. Biologix shall assume any and all bad debt expenses, taxes and charges related to such sales. The payment to Biologix by Sub-Distributors or Customers of invoices for Product in an amount below the Selling Price, whether due to standardized or government mandated pricing or otherwise, in any Part of the Territory, is at Biologix's risk and expense.

3.6 Amarin's Third Party Suppliers

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3.6.1 Biologix acknowledges that Amarin uses Third Party manufacturers for the supply of Product and that Amarin has supply agreements in place with such Third Parties. Amarin has certain obligations to such Third Party suppliers under such agreements and Biologix agrees, upon request by Amarin, to provide all information required under such agreements that is under Biologix's control and provide reasonable assistance to Amarin in otherwise complying with such obligations.

4. **Delivery, Inspection, Storage and Sale**

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4.1 Delivery of the Products

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- 4.1.1 Amarin shall dispatch Product for delivery in accordance with Applicable Incoterms [\*\*\*] from date of acceptance by Amarin of the applicable Purchase Order (the “Delivery Time”). Delivery of Product shall be in accordance with Applicable Incoterms.
- 4.1.2 Notwithstanding the foregoing, Biologix shall promptly take all necessary steps to unload Product (including maintenance and compliance with the proscribed temperature control requirements for such Product) at their arrival in the Territory, to clear all customs formalities and importation formalities and to transport the Product to its warehousing where such Product shall be stored. In addition, Biologix shall pay all customs duties or other taxes which are payable with respect to the importation and resale of the Product in the Territory. For clarity, during the Term, Biologix shall be the importer of record for Product in the Territory.
- 4.1.3 Risk of loss in the Product will pass to Biologix in accordance with Applicable Incoterms. After such delivery, Biologix shall be responsible for the Product and all related costs, including loading the Product, insurance of the Product, all customs and excise duties or fees, all transport from Amarin’s facility and from all ports, storage of the Product and delivery of the Product to Customers. Title to the Product shall transfer to Biologix in accordance with Applicable Incoterms. For the avoidance of doubt, Biologix will not have the right of return of any Product unless Biologix timely complies with the provisions of Section 4.2.
- 4.1.4 This Agreement and all shipments made hereunder shall at all times be subject to the approval by Amarin of Biologix’s financial condition. If the financial condition of Biologix at any time results in its inability to pay its debts when due, or if Biologix fails to make any payment when due, or if Biologix is the affected Party under Section 14.2.2, in addition to any other rights Amarin may have, including under Section 14.2, Amarin may defer or decline to make any shipment or shipments hereunder or may condition any such shipment upon receipt of satisfactory security or cash payments in advance.
- 4.2 Quality Controls; Receipt of Product
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- 4.2.1 Prior to each shipment of Product, Amarin shall provide Biologix with a Certificate of Analysis acceptable to and approved by Amarin, and, at Biologix’s reasonable request, Amarin shall provide Biologix with reasonable access to any applicable supporting data all in accordance with the Quality Agreement. If any quality control of the Product is required by Applicable Laws or Amarin in the Territory upon importation of the Product (including maintenance and compliance with the proscribed temperature control requirements for such Product as set forth in Section 4.1.2), Biologix shall perform or cause to be performed such quality controls, and Amarin shall provide all reasonably requested units of samples for such controls on a free of charge basis. In furtherance of the foregoing, if United States release testing methods need to be transferred to any applicable regulatory body in the Territory, then Biologix shall be solely responsible for the costs thereof; provided, that Amarin shall use commercially reasonable efforts to

cause its vendors to effect such transfer to Biologix and Biologix shall be solely responsible for the costs thereof. All Product shall be transported and stored by Biologix in accordance with the Quality Agreement and any specifications provided in writing to Biologix by Amarin, from time to time, during the Term.

- 4.2.2 Biologix shall provide Amarin with a written acknowledgment of receipt within [\*\*\*] of its receipt of Product at Biologix's warehouses. This written acknowledgment shall confirm the quantity of Product delivered, the delivery date and, if applicable, the quantity of Product with any apparent defects. In the event Biologix fails to provide such written acknowledgement within aforesaid deadline, such Product shall be deemed to have been received in accordance with this Agreement, in particular in terms of delivery date, quantity and quality of Product. Any claim regarding quantity of Products, delivery date and apparent defects received after such deadline shall be time barred and Biologix shall be deemed to have waived its rights.
- 4.2.3 In the event of any defects not discoverable upon inspection ("Latent Defects"), Biologix shall have an obligation to notify Amarin [\*\*\*] upon discovery thereof, the failure of which shall result in such claim being time barred. Any claim for Latent Defects shall become time barred [\*\*\*] after discovery of the Latent defect.
- 4.2.4 When submitting a claim for defective Products, Biologix shall automatically, immediately and at its expense provide supporting documentation to substantiate such claim, including photographs, Third Party reports and any other evidence that may be requested by Amarin. In the event that Amarin has delivered a defective Product for which Biologix has timely notified Amarin and which Biologix has returned promptly to Amarin, Amarin shall, at Biologix's option, replace the returned Product or refund the Supply Price paid for such Product. This replacement or refund shall be Biologix's sole remedy to the exclusion of any other. Any defective Product shall be forthwith returned to Amarin at Amarin's cost or destroyed according to Amarin's instructions. Warranty claims shall not justify any delay in other payments due by Biologix to Amarin under this Agreement.
- 4.3 Storage and Minimum Inventory Levels
- .
- 4.3.1 Biologix shall maintain in the Territory adequate storage facilities (capable of maintaining and complying with the proscribed temperature control requirements for Product as set forth in Section 4.1.2), including competent personnel, to properly store and handle the Product and to perform its other obligations under this Agreement.
- 4.3.2 Biologix undertakes to properly store the Products in accordance with (a) the requirements on their packaging, (b) any storage conditions set forth in the Quality Agreement and (c) any specifications provided in writing to Biologix by Amarin, from time to time, during the Term. Biologix shall maintain adequate written procedures for warehouse, transport and storage control.

4.3.3 [\*\*\*]. Biologix shall direct to Amarin requests for shipments of Product sufficiently in advance for Biologix to meet such level of inventory. Such level of inventory may however be adjusted from time to time during the Term by Amarin in consultation with Biologix. Biologix shall ensure that all of its Sub-Distributors comply with the terms of this Section 4.3.

4.3.4 Biologix shall observe the correct rotation of the inventory according to the accounting principle FEFO (First Expired First Out). Biologix shall bear the financial risk of stock (expired Product) as Amarin shall not provide “free of charge” replacement of expired Products.

## 5. **Marketing and Promotion**

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### 5.1 Marketing and Promotion Services

. Biologix shall perform Marketing and Promotion Services relating to the Product in the Territory as set forth in [Exhibit B](#) hereto.

### 5.2 Marketing and Sales Efforts

. Biologix shall establish and maintain an appropriate sales force and marketing and medical staff in accordance with the agreed upon annual Marketing Plan as set forth in [Exhibit B](#) hereto.

### 5.3 Developments in the Territory

. Biologix shall use reasonable efforts to keep Amarin fully and promptly informed of conditions and developments in the market in the Territory regarding the Product (whether advantageous or disadvantageous thereto), Competing Products and the activities of competitors in the Territory on the basis of publicly available information or information legitimately gathered by its own sales force or other staff.

## 6. **Registration**

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A condition precedent to this Agreement and its validity is that Biologix warrants that it shall obtain and shall maintain any and all Product Registrations required to give full effect to the terms of this Agreement. Biologix shall procure that applications for all Marketing Authorizations and all required consents shall be made on behalf of, and once granted, held in the name of Amarin or its designee in each Part of the Territory, unless Applicable Law requires any such Marketing Authorizations or required consents to be maintained in the name of Biologix or its Sub-Distributors. In the event that Applicable Law requires any such Marketing Authorizations or required consents to be maintained in the name of Biologix or its Sub-Distributors, Biologix acknowledges and agrees that it shall apply for, maintain and/or hold all such Marketing Authorizations and required consents on behalf of and for the benefit of Amarin and all rights, title and ownership of same shall and does remain the property of Amarin and shall at all times be subject to Section [15.1](#). Upon written request from Amarin, Biologix shall provide Amarin or its Affiliates with certified copies of all Product Registrations and required consents, and notarized or certified translation of same. Amarin or its Affiliates may use such

documents in order to fulfil their responsibilities in the context of export and requirements under Applicable Law. All costs related to, but not limited to, obtaining, maintaining, registration, audit, transfer, handover, assignment (at the end of the Term or otherwise, each as applicable) or any Product Registration or required consents shall be borne by Biologix. Amarin shall provide Biologix with the regulatory dossier (in Common Technical Document (“CTD”) or electronic CTD format, as required by Applicable Law) and reasonable advice, assistance and documentation (legalized as necessary) in connection with obtaining or maintaining the Marketing Authorizations and required consents in accordance with the terms of this Agreement. Without prejudice to this Section [6](#) or any other provision of this Agreement, Biologix: (i) undertakes to perform the regulatory services for the registration and maintenance of the Product Registrations in the Territory (“Regulatory Services”) in accordance with the detailed terms and conditions of the Regulatory Services exhibit attached as [Exhibit C](#) to this Agreement and (ii) shall at all times act in a way as to ensure that Amarin is able to comply with its obligations under the Marketing Authorizations and Applicable Law. In the event of conflict between the terms of [Exhibit C](#) and the rest of this Agreement, the terms of the rest of this Agreement shall govern.

## 7. **Representations, Warranties, Covenants, Limitations of Liability and Indemnification**

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### 7.1 Representations, Warranties and Additional Covenants of Biologix

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7.1.1 Biologix represents and warrants that: (i) all services delivered to Amarin under this Agreement shall be performed in a timely and compliant manner in accordance with all terms and conditions set forth in this Agreement and Applicable Law and to the highest professional standards and (ii) it has the corporate power and authority to execute and deliver this Agreement and to perform its obligations hereunder, and the execution, delivery and performance of this Agreement has been duly and validly authorized and approved by proper corporate action.

7.1.2 Biologix represents, warrants and covenants that it shall act in compliance with Applicable Laws effective in the Territory concerning Product and deliver Product as supplied by Amarin only to those Customers who are authorized to purchase such Product under Applicable Laws. Biologix further represents, warrants and covenants that it shall deliver the Product in accordance with the requirements under Applicable Law.

7.1.3 Biologix represents, warrants and covenants that: (i) assuming due authorization, execution and delivery by Amarin, the execution, delivery and performance of this Agreement and the transactions contemplated hereby are legal and valid obligations binding on Biologix and enforceable against Biologix in accordance with its terms, (ii) this Agreement does not contravene or constitute a violation of (a) any Applicable Law in the Territory or of any Governmental Body and, to its knowledge, Biologix is in compliance in all material respects with all material Applicable Laws applicable to the



subject matter of this Agreement, or (b) any judgment, contract or other agreement to which Biologix is or will be a party or by which Biologix may be bound, (iii) Biologix shall comply with all Applicable Laws related to import and export control and (iv) the Product will not be resold, directly or indirectly, to prohibited countries under Applicable Law.

- 7.1.4 Biologix represents and warrants that, as of the Effective Date, all information provided to Amarin during the due diligence process, including Biologix's responses to Amarin's requests for information in connection therewith, is true and accurate in all material respects.
- 7.1.5 Biologix represents, warrants and covenants that, as of the Effective Date it has, and throughout the Term (at the time of execution or thereafter), it shall immediately notify Amarin in writing of the existence and content of any mandatory provision of Applicable Law in the Territory, or any other Applicable Laws, that conflict with any provision of this Agreement or which may negatively affect Amarin's rights under this Agreement.
- 7.1.6 Biologix represents, warrants and covenants that it shall not make any false or misleading representation to a Third Party with respect to Amarin or the Product and it will not make any representations, warranties or guarantees with respect to specifications, features or capabilities of the Product that are not consistent with the product specifications listed in the Marketing Authorization. Biologix shall not make any promises, representations or warranties with reference to the Product except as expressly made in Amarin Promotional Materials or otherwise authorized in writing by Amarin (in each case, to the extent compliant with Applicable Law).
- 7.1.7 Biologix represents, warrants and covenants that it shall not: (i) promote the Product for any unapproved-label indications, within the limits of its registration or Applicable Law, or beyond the approved patient population in the Field in the Territory, (ii) disparage, defame, discredit, or negatively comment to third parties in any way about or concerning the Product or Amarin (including Amarin's activities, operations or other products); provided, that Biologix shall promptly notify Amarin upon it becoming aware of any instance of same by a Third Party, (iii) utilize deceptive, misleading or unethical business practices or (iv) take any action or inaction that would reasonably be likely to prejudice the value of Product.
- 7.1.8 Biologix represents and warrants that, except with respect to Product Registrations, (i) all necessary consents, approvals and authorizations of, and (ii) all notices to, and filings by Biologix with, all Governmental Bodies required to be obtained or provided by Biologix as of the Effective Date in connection with the execution, delivery and performance of this Agreement have been obtained and provided, except for those approvals, if any, not required at the Effective Date. In connection therewith, Biologix represents that it and its Sub-Distributors are duly registered as pharmaceutical products distributors in each of their respective Parts of the Territory.

- 7.1.9 Biologix represents, warrants and covenants that it has not used, prior to the Effective Date, and shall not use, during the Term, in any capacity associated with or related to this Agreement, the services of any Persons who have been, or are in the process of being, (i) debarred under 21 U.S.C. § 335(a) or (b) or any comparable Applicable Law in the Territory, or (ii) excluded from participation in the Medicare program, any state Medicaid program or any other health care program. Furthermore, neither Biologix nor any of its officers, employees, Sub-Distributors or consultants have been convicted of an offense under either (x) a federal or state law that is cited in 21 U.S.C. § 335(a) as a ground for debarment, denial of approval or suspension, or (y) any other comparable Applicable Law as a ground for debarment, denial of approval or suspension. Biologix shall notify Amarin immediately upon learning of any circumstance that would cause this certification under this Section 7.1.9 to become false or inaccurate.
- 7.1.10 Biologix represents and warrants that, as of the Effective Date, neither Biologix, nor, to the knowledge of Biologix, its Sub-Distributors, have received written notice of any proceedings pending before or threatened by any Governmental Body with respect to any facility where the Product will be warehoused or stored.
- 7.1.11 Biologix represents, warrants and covenants that, during the Term, it (i) shall use commercially reasonable efforts to procure and maintain valid Product Registrations for the Product in the Territory, (ii) shall not market, promote, sell or distribute Product in the Territory until it has obtained valid Product Registrations required therefor unless local regulations allow for such supply and (iii) shall comply with the terms of usage for the Amarin Promotional Materials and Biologix Promotional Materials under Section 2.1.6.
- 7.1.12 Biologix represents, warrants and covenants that, during the Term, it shall comply with the terms and conditions of the Quality Agreement and the written pharmacovigilance agreement referenced in Section 8.1.
- 7.1.13 Biologix represents, warrants and covenants that: (i) as of the Effective Date, Biologix is solvent and has the ability to pay and perform all of its obligations as and when such obligations become due, including payment obligations and other obligations under this Agreement, (ii) as of the Effective Date, Biologix's compensation programs for its sales Representatives do not, and during the Term will not with respect to the Product, provide financial incentives for the promotion, sales, and marketing in violation of any Applicable Laws or any professional requirements, (iii) as of the Effective Date, no claim or demand of any Governmental Body has been asserted to Biologix arising out of Biologix's regulatory or distribution activities with respect to any other products that could reasonably be expected to impact Biologix's ability to perform any of its obligations under this Agreement, and no investigations are pending or, to the knowledge of Biologix, threatened relating to such activities and (iv) during the Term, Biologix's medical, regulatory or legal teams will review all training materials and programs prior to use by Biologix to ensure that such training materials and programs are in accordance

with the Marketing Plan and the Product Registrations and in compliance with Applicable Laws.

- 7.1.14 Biologix represents, warrants and covenants that, during the Term, all Product used by, or under authority of, Biologix shall be handled, stored and distributed by Biologix, in accordance with, and shall conform to, Applicable Law and the terms of this Agreement.
- 7.1.15 Failure to comply with any provision of this Section 7.1 shall constitute a material breach of this Agreement for which Amarin may terminate this Agreement effective immediately upon notice to Biologix pursuant to Section 14.2.1.

## 7.2 Representations and Warranties of Amarin

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- 7.2.1 Amarin represents and warrants that, it has the corporate power and authority to execute and deliver this Agreement and to perform its obligations hereunder, and the execution, delivery and performance of this Agreement has been duly and validly authorized and approved by proper corporate action.
- 7.2.2 Amarin represents, warrants and covenants that: (i) assuming due authorization, execution and delivery by Biologix, the execution, delivery and performance of this Agreement and the transactions contemplated hereby are legal and valid obligations binding on Amarin and enforceable against Amarin in accordance with its terms and (ii) this Agreement does not contravene or constitute a violation of (a) any Applicable Law in the Territory or of any Governmental Body and, to its knowledge, Amarin is in compliance in all material respects with all material Applicable Laws applicable to the subject matter of this Agreement, or (b) any judgment, contract or other agreement to which Amarin is or will be a party or by which Amarin may be bound.
- 7.2.3 Amarin hereby represents and warrants that Product when delivered to Biologix will comply with the product specifications listed in the Marketing Authorization (the "Product Warranty"). Amarin makes no other warranty, express or implied, in relation to the Product.

## 7.3 Limitation of Liability

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- 7.3.1 In no event shall a Party, its Affiliates or Representatives be liable, whether under contract, tort, indemnity or otherwise, for any indirect, incidental, special, consequential, exemplary, special, reliance or punitive damages, including: (i) loss of profits, income, revenue or anticipated savings, contracts or business relationships, (ii) loss of goodwill or (iii) loss of capital, regardless of whether it was advised or notified of such damages in advance..

- 7.3.2 The foregoing limitation shall apply to the fullest extent permitted by Applicable Laws in the applicable jurisdiction. In the event the foregoing limitation of liability shall be, for any reason, held unenforceable or inapplicable in any jurisdiction, [\*\*\*].
- 7.3.3 Such limitation in this Section 7.3 shall not apply to damages arising under this Agreement from indemnification obligations or breach by either Party of their confidentiality obligations or damages caused by gross negligence or willful misconduct. Further, such limitation in this Section 7.3 shall not apply for breach of material contractual obligations or product liability.
- 7.4 Indemnification and Insurance
- .
- 7.4.1 Amarin hereby agrees to save, indemnify, defend and hold Biologix and its respective directors, officers, agents and employees harmless from and against any and all losses, damages, liabilities, costs and expenses (including reasonable attorneys' fees and expenses) (collectively, "Losses") arising in connection with any and all charges, complaints, actions, suits, proceedings, hearings, investigations, claims, demands, judgments, orders, decrees, stipulations or injunctions by a Third Party (each a "Third Party Claim") to the extent resulting or otherwise arising from (i) any breach by Amarin or its Affiliates, sublicensees or subcontractors of any of Amarin's representations, warranties, covenants or obligations pursuant to this Agreement, (ii) the negligence or willful misconduct by Amarin or its Affiliates, sublicensees or subcontractors or their respective officers, directors, employees, agents or consultants in performing any obligations under this Agreement or (iii) any matter related to the manufacturing of the Product (including, for clarity, product liability Losses resulting therefrom) by Amarin or its Affiliates, sublicensees or subcontractors or their respective officers, directors, employees, agents or consultants.
- 7.4.2 Biologix hereby agrees to save, indemnify, defend and hold Amarin, its Affiliates, and their respective directors, agents and employees harmless from and against any and all Losses arising in connection with any and all Third Party Claims resulting or otherwise to the extent arising from (i) any breach by Biologix (or by any of its subcontractors, wholesalers or Sub-Distributors) of any of Biologix's representations, warranties, covenants or obligations pursuant to this Agreement, (ii) the negligence or willful misconduct by Biologix (or by any of its subcontractors, wholesalers or Sub-Distributors) or their respective officers, directors, employees, agents or consultants in performing any obligations under this Agreement, (iii) any matter related to the Territory specific packaging and labelling of Product, or the importation, exportation, distribution, promotion, marketing and sale of Product in the Field in the Territory (including, for clarity, any product liability Losses resulting therefrom) by Biologix (or by any of its subcontractors, wholesalers or Sub-Distributors) or their respective officers, directors, employees, agents or consultants, (iv) the failure by Biologix to initiate a Product recall, withdrawal or market notification that is proposed by Amarin under Article 9 or (v) any

claim with respect to a Latent Defect not timely notified by Biologix in accordance with Section 4.2.3.

7.4.3 The obligations to indemnify and defend set forth in Section 7.4.1 and 7.4.2 shall be contingent upon the Party seeking indemnification (the “Indemnatee”): (a) notifying the indemnifying Party of a claim, demand or suit [\*\*\*] (provided, however, that Indemnatee’s failure or delay in providing such notice shall not relieve the indemnifying Party of its indemnification obligation except to the extent the indemnifying Party is prejudiced thereby), (b) allowing the indemnifying Party and/or its insurers the right to assume direction and control of the defense of any such Third Party Claim, (c) using its commercially reasonable efforts to cooperate with the indemnifying Party and/or its insurers in the defense of such Third Party Claim at the indemnifying Party’s expense, and (d) agreeing not to settle or compromise any Third Party Claim without prior written authorization of the indemnifying Party. Indemnatee shall have the right to participate in the defense of any such Third Party Claim referred to in this Section 7.4.3 utilizing attorneys of its choice, at its own expense; provided, however, that the indemnifying Party shall have full authority and control to handle any such Third Party Claim. The indemnifying Party shall have the right to settle or compromise any action or otherwise seek to terminate any pending or threatened action for which indemnity may be sought hereunder (whether or not any indemnified Party is a party thereto) as long as such settlement, compromise or termination includes an unconditional release of, and does not include an admission of liability by, each indemnified Party from all liability in respect of such Third Party Claim.

7.4.4 Each Party shall procure and maintain insurance that is available on commercially reasonable terms, including general liability, clinical trial insurance (as applicable), product liability insurance and other insurance as necessary, adequate to cover its obligations hereunder and which is consistent with normal business practices of prudent companies similarly situated at all times during which Product is being commercially distributed or sold by a Party pursuant to this Agreement, and such insurance coverage shall be, in no event less than, in amounts per loss occurrence and in the aggregate as are customary in the industry in the Territory. It is understood that such insurance shall not be construed to create a limit of either Party’s liability with respect to its indemnification obligations under Section 7.4 or 17.1. Each Party shall provide the other Party with written evidence of such insurance upon request of the other Party and upon expiration of any one coverage. Each Party shall provide the other Party with written notice at least thirty (30) days prior to the cancellation, nonrenewal or material change in such insurance which materially adversely affects the rights of the other Party hereunder.

## 8. **Pharmacovigilance**

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### 8.1 Pharmacovigilance Generally

- . Subject to the terms of this Section 8.1, each Party shall be responsible for its respective pharmacovigilance obligations under Applicable Laws. To the extent permitted under Applicable Laws, Biologix shall be responsible for the

collection, review, assessment, tracking and filing of information related to Adverse Events and Product Complaints associated with the Product in the Territory (whether or not Marketing Authorization has been obtained), in each case in accordance with Applicable Laws, this Agreement and the pharmacovigilance agreement (and Biologix shall ensure that, in the performance of its obligations and services under this Agreement, it will record, investigate, summarize, notify, report and review all Adverse Events and Product Complaints in accordance with Applicable Laws, including, for clarity, laws relating to Adverse Event and Product Complaint reporting in both the United States and the Territory). Amarin (or its designee) shall be responsible for the collection, review, assessment, tracking and filing of information related to Adverse Events and Product Complaints associated with the Product in the countries outside the Territory. The safety units from each of the Parties shall meet and agree upon a written pharmacovigilance agreement for exchanging Adverse Event, Product Complaint and other safety information relating to the Product within [\*\*\*] of the Effective Date; such agreement shall specify, among other things, detailed processes (including timing of notice delivery) for how Adverse Events and Product Complaints will be coordinated between the Parties, including the periodic reporting requirements in connection therewith and other standard terms and conditions customary in the pharmaceutical industry for agreements of this nature and companies engaged in comparable activities. Such written pharmacovigilance agreement shall be reviewed annually by the Parties and updated to comply with changes in Applicable Law (including laws of the United States) and shall ensure that Adverse Events and Product Complaints associated with the Product and other safety information is exchanged according to a schedule that will permit each Party (and its designees or Sub-Distributors, as applicable) to comply with Applicable Laws and regulatory requirements in their respective markets. Biologix shall not make any safety or performance claims related to the Product which have not been made in Amarin Promotional Materials or otherwise previously approved in writing by Amarin (in each case, to the extent compliant with Applicable Law). For the avoidance of doubt, with respect to the each Party's pharmacovigilance obligations, in the event of any conflict between the terms of this Agreement and the terms of the written pharmacovigilance agreement, the written pharmacovigilance agreement shall control.

## 8.2 Global Safety Database

- . Amarin shall be responsible for maintaining the global safety database for Product. The written pharmacovigilance agreement prescribed by Section [8.1](#) shall ensure that Adverse Event and other safety information is exchanged according to a schedule that will permit Amarin (and each of its designees) to comply with Applicable Laws and regulatory requirements in their respective markets. Amarin shall provide Biologix with reasonable access to such global safety database without any compensation to Amarin.

## 8.3 Medical Inquiries

- . Following the Effective Date, to the extent permitted by Applicable Laws, Biologix shall be responsible for handling all medical questions or inquiries in the Territory, including all Product Complaints, with regard to any Product sold by or on

behalf of Biologix (or any of its Affiliates or Sub-Distributors), in each case in accordance with Applicable Laws, the Product Registrations and this Agreement. Amarin shall provide a copy of any standardized responses to medical inquiries to Biologix for Biologix's use with respect to the Product in the Field in the Territory; provided, that Biologix shall provide Amarin with a copy of any medical questions or inquiries which fall outside of the scope of the standardized responses provided to Biologix hereunder. Amarin shall immediately forward any and all medical questions or inquiries which it receives with respect to any Product sold by or on behalf of Biologix (or any of its Affiliates or Sub-Distributors) in the Territory to Biologix in accordance with all Applicable Laws and Biologix shall immediately forward to Amarin any and all medical questions or inquiries that it receives with respect to Product not sold by or on behalf of Biologix (or any of its Affiliates or Sub-Distributors) outside the Territory, in accordance with all Applicable Laws. Notwithstanding the foregoing, Amarin shall be responsible for handling all Product Complaints other than those related to the importation, distribution, storage, promotion, marketing and sale of the Product in the Field in the Territory, and Biologix shall refer all such Product Complaints to Amarin within two (2) business days following receipt of such Product Complaint. Biologix shall be responsible for handling all Product Complaints related to the importation, distribution, storage, promotion, marketing and sale of the Product in the Field in the Territory, and Amarin shall refer all such Product Complaints to Biologix. The Parties shall specify in the Quality Agreement and/or written pharmacovigilance agreement detailed processes (including timing) for the periodic reconciliation of Product Complaints between the Parties.

#### 8.4 Communications from Governmental Bodies

- . Each Party shall promptly inform the other Party in writing of notification of any action by, or notification or other information which it receives (directly or indirectly) from, any Governmental Body whether inside the Territory or outside the Territory which (i) is non-routine or significant, (ii) raises any material concerns regarding the safety or efficacy of the Product, (iii) indicates or suggests a potential material liability of either Party to third parties in connection with the Product, (iv) is reasonably likely to lead to a recall, withdrawal, market notification or other Governmental Body action (affecting the sale or movement of Product) with respect to the Product whether inside the Territory or outside the Territory or (v) relates to expedited and periodic reports of Adverse Events with respect to the Product whether inside the Territory or outside the Territory, or Product Complaints, and which may have an adverse impact on Product Registration or the continued distribution, promotion, marketing and sale of the Product whether inside the Territory or outside the Territory. Biologix shall be solely responsible for responding to any such communications relating to the Product in the Field in the Territory and the Parties shall reasonably cooperate with and assist each other in complying with regulatory obligations, including by Amarin providing to Biologix such information and documentation which is in Amarin's possession as may be necessary for Biologix to prepare a response to an inquiry from a Governmental Body in the Territory with respect to the Product in the Field. Each Party

shall also promptly provide the other Party with a copy of all correspondence received from a Governmental Body whether inside the Territory or outside the Territory specifically regarding the matters referred to above. Amarin (or its designee) shall be solely responsible for any communications relating to the Product outside the Territory or outside the Field. Without limiting the generality of the foregoing, nothing herein shall relieve Biologix from its notification and reporting obligations under Section 13.7.

## **9. Recall, Withdrawal and Market Notification of Product**

### **9.1 Notification**

- . In the event either Party has reason to believe that one or more lots of Products should be recalled or withdrawn from distribution (or market notification issued), such Party shall immediately inform the other in writing.

### **9.2 Decisions**

- . To the extent permitted by circumstances, the Parties will confer before initiating any recall, withdrawal or issuing an advisory letter (or market notification) regarding reliability of or defects in a Product, but the decision whether to initiate a recall, withdrawal or an advisory letter (or market notification) shall be at Amarin's sole decision as the holder or beneficiary of the Marketing Authorization, and, if so decided, such recall, withdrawal or advisory letter (or market notification) shall be conducted by Amarin, with Biologix providing such local assistance as is requested by Amarin.

### **9.3 Assistance from Biologix**

- . Biologix shall comply with recommendations by Amarin and assist in recall, withdrawal or market notification campaigns (whether voluntary or requested) that Amarin decides to conduct. Biologix shall at all times utilize a batch tracing system which will enable the Parties to identify, on a prompt basis, Customers within the Territory who have been supplied with Product of any particular batch, and to recall or withdraw such Product from (or issue a market notification to) such Customers as set forth in Article [9](#).

### **9.4 [\*\*\*].**

## **10. Records, Stock Statements and Audits**

### **10.1 Records**

- . Biologix shall at all times maintain complete, detailed and accurate inventory, accounting, shipment and other records as may be required to document its performance and compliance under this Agreement for at least [\*\*\*] after the expiration or termination of this Agreement. In particular, Biologix shall maintain adequate written procedures and records regarding the distribution and shipment of the Product in such a form as to enable Amarin to trace immediately the location of all Product at any time.

### **10.2 Stock Statements. Biologix shall provide Amarin with a monthly stock statement containing the following information, per individual Product: (i) total amount held in stock on first day of month with expiration dates, (ii) total amount held in stock on last day of month with expiration dates, (iii) total amount of deliveries received in the month**



and (iv) total amount distributed and invoiced by Biologix during the month detailed per named Customer. This report shall be provided to Amarin on the first working day of each month during the Term (as applicable, taking into account the First Commercial Sale and Marketing Authorization dates and when Biologix receives its first shipment of Product from Amarin).

### 10.3 Audits

- . Amarin shall have the right to conduct at least one (1) Compliance Audit prior to the first shipment of Product to Biologix, the results of which (including any remediation necessary to address any deviations or observations from such audit) shall be reasonably acceptable to Amarin prior to such shipment. During the Term, for the purpose of auditing and monitoring the performance of Biologix's compliance with this Agreement, Amarin shall have the right to inspect or have inspected by an independent auditor or other Representative and have access to, [\*\*\*] (or more frequently upon a showing of good reason), upon reasonable notice, all premises and records of Biologix that are relevant to the subject matter of this Agreement ("Compliance Audit"). Amarin shall have the right to make copies or extracts from the records of Biologix. In particular, Biologix shall allow authorized Representatives of Amarin access to Biologix's warehouse where the Products are stored (including, where its commercial documents are stored relating to: (a) Product Registrations, (b) compliance with this Agreement and marketing, sales and other registration requirements in the Territory and (c) all other relevant documents (including, training records) relating to general compliance with Applicable Law and this Agreement) and to inspect all stock and inventory of Products. Amarin shall provide a report detailing the results of any Compliance Audit to Biologix within [\*\*\*] receipt thereof, and Biologix shall respond to each audit observation detailed in such report within [\*\*\*] after receipt thereof, in reasonable detail and in form and substance reasonably acceptable to Amarin. Such rights of access, audit, inspection and making of copies for any year shall terminate [\*\*\*] after the close of each fiscal year in respect of deliveries made or amounts paid or payable for such year. To the extent that any Compliance Audit by or on behalf of Amarin requires access and review of any commercially or strategically sensitive information of Biologix or its Affiliates relating to the business of Biologix or its Affiliates, such activity shall be carried out by a Third Party professional advisor appointed by Amarin and such professional advisor shall only report back to Amarin such information as is directly relevant to informing Amarin on Biologix's compliance with the particular provisions of this Agreement being Compliance Audited (and shall enter into a commercially reasonable confidentiality agreement consistent with the foregoing). The costs and fees of any such Compliance Audit [\*\*\*]. The audit rights described in this Section 10.3 are without limitation of other audit rights described elsewhere in this Agreement.

## 11. **Payments**

### 11.1 Upfront Payment

11.1.1 In consideration of being appointed the exclusive distributor of the Product in the Field in the Territory, and in recognition of the historic product development costs incurred by Amarin, on the Effective Date, Biologix shall pay to Amarin a one-time upfront amount equal to [\*\*\*] (the “Upfront Payment”) by wire transfer of immediately available funds into an account designated in writing by Amarin. The Upfront Payment shall be non-refundable and non-creditable against any other payments due hereunder.

11.2 Deposit for Prepaid Purchases

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11.2.1 Biologix shall also make a one-time non-refundable deposit of [\*\*\*] (the “Prepaid Purchase Deposit”) by wire transfer of immediately available funds into an account designated in writing by Amarin to be allocated to future purchases of Product inventory from Amarin. The Prepaid Purchase Deposit shall be paid in two (2) equal instalments of [\*\*\*], to be paid on the six (6) and twelve (12) month anniversary dates of the Effective Date. Future invoices for (i) Product generated by Amarin pursuant to a corresponding Purchase Order and (ii) the Service Fee generated by Biologix, shall be credited against the Prepaid Purchase Deposit until the amount of such deposit is fully exhausted.

11.3 Service Fee

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11.3.1 During the Term, from the Effective Date through the [\*\*\*] following the first commercial launch of the Product in the Territory, Amarin shall pay Biologix a Service Fee in consideration of the services provided by Biologix under this Agreement; provided, that no Service Fee shall be payable on Sample Packs sold by Amarin to Biologix.

11.3.2 For all amounts of Product purchased by Biologix during any year of the Term, Biologix shall invoice Amarin, in the month of shipment [\*\*\*] (“Estimated Service Fee Payment”), and Amarin shall pay (subject to Section 11.2.1) such invoiced amount [\*\*\*] after receipt of the invoice. Where possible the Estimated Service Fee Payment will be set-off against payment of other invoices by Biologix.

11.3.3 [\*\*\*], Biologix shall prepare and send to Amarin a report stating, on a Part of the Territory-by-Part of the Territory basis: (A) [\*\*\*].

11.3.4 [\*\*\*].

11.3.5 [\*\*\*].

12. **Trademarks and Intellectual Property**

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12.1 Trademark License

. Amarin grants to Biologix a non-exclusive license to use the Trademarks in connection with importation, distribution, promotion, marketing and sale of Product in the Field in the Territory. Biologix agrees to use its best efforts to promote,

market and actively sell the Product in the Territory only under the respective Trademarks authorized by Amarin. Biologix's right to sublicense the license granted hereunder shall be governed by Section 2.2.1 and 2.2.2.

## 12.2 Intellectual Property

- . Other than the license set forth in Section [2.1](#), Biologix shall have no rights under this Agreement in the Trademarks, trade names, distinctive packaging, designs, copyrights, patents, or other intellectual property rights (the "Intellectual Property") of Amarin or any Affiliates of Amarin. Biologix agrees to use the Intellectual Property only as may be approved by Amarin. Biologix undertakes, upon termination or expiration of this Agreement, to discontinue all use of the Intellectual Property of Amarin. Any Intellectual Property conceived, discovered, invented, developed, created, made or reduced to practice by Biologix related to Product shall be the sole and exclusive property of Amarin.

## 12.3 Ownership and Registration of Local Marks

- . Biologix acknowledges the exclusive right, title and interest of Amarin or any Affiliates of Amarin in and to the Trademarks and will not do or cause to be done any act or thing contesting or, in any way, impairing or tending to impair any part of said right, title or interest, either during the Term of this Agreement or at any time after expiration or termination of this Agreement. In the event that the Parties determine that registration of a Trademark in the local language in the Territory is necessary or useful for the sale and distribution of the Product in the Territory, Amarin shall be responsible for the filing and cost of such registration and Amarin shall own and hold such Trademark in its name. Upon written request of Amarin, Biologix shall assist in the processing, filing and registration of such Trademark in the Territory.

## 12.4 Use Restrictions

- . In particular, Biologix shall not file, register or use any trademark, trade name or symbol that is identical with or similar to the Trademarks in respect of identical or similar goods or services or otherwise associate the Product with a trademark other than the Trademarks set forth on [Exhibit A](#) without the prior written consent of Amarin. Furthermore, Biologix shall use the Trademarks with the symbols <sup>TM</sup> or ® as appropriate.

## 12.5 No Warranty

- . Biologix acknowledges that Amarin does not give any warranty, either express or implied, as to the issuance and validity of the Trademarks.

## 12.6 Goodwill

- . Any goodwill arising from the use of the Trademarks by Biologix shall inure to the benefit of Amarin and its Affiliates, as appropriate. To this effect, Biologix shall use a license notice in conjunction with the Trademarks on the goods, their packaging or any advertising material such as "[Trademark] is a registered trademark of [Proprietor Name]" or in some other form as Amarin or its Affiliates may reasonably require from time to time.

## 12.7 Review of Materials

- . Biologix shall, not less than [\*\*\*] or upon request of Amarin or one of its Affiliates, submit to the requesting party prior to the printing or dissemination of any materials not provided by Amarin or one of its Affiliates, such as brochures, advertisements and the like using the Trademarks, to allow Amarin or its Affiliate to review and approve the manner in which the Trademarks are used. If Amarin does not respond to Biologix with comments or disapproval within [\*\*\*], such materials shall be deemed approved.

## 12.8 Notification of Infringement

- . Biologix shall promptly report to Amarin particulars of any use by any other party of a trademark, trade name or mode of advertising which comes to Biologix's attention and which might qualify as an infringement of the Trademarks or as unfair competition or in breach of any other Applicable Laws.

## 12.9 Notification of Challenge

- . In the event that it comes to the attention of Biologix that any party alleges that the Trademarks are invalid or that they infringe any rights of such party or that the Trademarks are open to any other form of attack, Biologix shall promptly report the matter to Amarin in writing.

## 12.10 Notification by Amarin

- . In the event that it comes to the attention of Amarin that any party alleges that the Trademarks are invalid or that they infringe any rights of such party or that the Trademarks are open to any other form of attack, Amarin shall promptly report the matter to Biologix in writing.

## 12.11 Cooperation of Biologix

- . In an event of any of the foregoing situations, Biologix shall not take any action, either amicably or legal, and shall let Amarin or one of its Affiliates or a nominee or designee of Amarin or such Affiliate take any action suitable in its judgment; provided, however, that Biologix, at Amarin's request, shall cooperate and assist in any action so taken. If Amarin chooses not to take action and Biologix believes action is in the Parties' best interest, the Parties agree to confer in good faith and determine whether and under what conditions Biologix may take action on Amarin's behalf.

## 13. **Compliance, Audit and Certification**

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### 13.1 Change of Control

- . Biologix shall inform Amarin in writing of any Change of Control of Biologix by a Third Party that, directly or indirectly, markets, promotes, sells or distributes a Competing Product (an "Amarin Competitor"), at least [\*\*\*] before such change is to become effective.

### 13.2 Compliance with Laws

- . Biologix acknowledges that it is aware of and will fully comply with the following:

#### 13.2.1 OECD Convention on combating bribery of foreign public officials in international business transactions (the "OECD Convention"), the Foreign Corrupt Practices Act of

1977 of the United States of America (“FCPA”) and the UK Bribery Act 2010 (the “UK Bribery Act”) and the Applicable Laws in the Territory. Biologix warrants that it will take no action in violation of the OECD Convention, the FCPA or the UK Bribery Act, and (without prejudice to the generality of the foregoing) will make no payment nor transfer anything of value, directly or indirectly, to any official of the Territory, political candidate of the Territory, political party of the Territory or official thereof, to influence any decision to obtain or retain business or gain an advantage in the conduct of business. Biologix further warrants that it will not promise or give a financial or other advantage, directly or indirectly, to induce a Person to perform a function improperly in violation of the FCPA or the UK Bribery Act’s prohibition against commercial bribery;

13.2.2 U.S. export laws and regulations, U.S. sanction laws and regulations (including OFAC’s general licenses for medicines to be exported to Iran and Syria), U.S. anti-corruption laws and regulations and U.S. anti-boycott laws and regulations as applicable to exports to a country in the Territory;

13.2.3 U.S. re-export laws and regulations and U.S. sanction laws and regulations (including OFAC’s general licenses for medicines for exports to Iran and Syria) as applicable to exports to a country in the Territory;

13.2.4 Third country export and sanction laws and regulations as applicable to exports to a country in the Territory; and

13.2.5 U.S. anti-corruption laws and regulations and U.S. anti-boycott laws and regulations as may be applicable to subsidiary companies that are owned and/or controlled by Amarin Pharma.

### 13.3 Government Officials

- . Biologix warrants that no governmental official of the Territory has any direct or indirect interest in its company and that none of its directors or officers are governmental officials of the Territory or related to governmental officials of the Territory.

### 13.4 Economic Sanctions

- . Biologix represents, warrants, covenants and agrees that (i) it is not, and will not, in connection with the marketing, promotion, export and sale of Product, do business with or sell directly or indirectly to any Persons (a) considered by the United States Office of Foreign Asset Control (“OFAC”) to be “Blocked Persons” or “Specifically Designated Nationals” as included in <http://sdnsearch.ofac.treas.gov/>) or (b) that are the subject of European Union or United Nations economic sanctions from time to time; (ii) it is not, and will not, (a) in connection with the re-export of the Product from a third country, do business with or sell directly or indirectly to any Persons considered by OFAC or by such third country to be “Blocked Persons” or “Specifically Designated Nationals” or (b) be owned or controlled, directly or indirectly by any Person that is the subject of U.S., European Union or United Nations economic sanctions from time to time and (iii) it is aware of and, hereby confirms its compliance with, all

applicable economic sanctions programs, including, any applicable economic sanctions imposed by the U.S., European Union, United Nations and/or any relevant third country.

### 13.5 Export Controls

- . Biologix shall comply with all applicable export and re-export controls imposed by the United States government, European Union and the government of any third country from which any of the Product is manufactured or which would by their terms be applicable to the export, re-export and import of Product hereunder, to the extent such restrictions relate to the export, or re-export, of Product or the transfer of any technical data of Amarin or any of its Affiliates. Biologix shall not, without the prior specific or general written license approval of the United States Department of Commerce, OFAC or any other applicable third country's governmental agency, sell, export or re-export any Product to any Customer that Biologix knows, or has reason to know, will use, directly or indirectly, such Product in any chemical or biological warfare application or any other end use that is prohibited or otherwise restricted by the U.S. government or by the government of any third country from which the Products are exported or re-exported. Biologix shall cooperate with Amarin, and shall submit all documentation requested by Amarin, to obtain the appropriate licenses prior to the export or re-export of the Product or the transfer of any such technical data. If required by Amarin, Biologix shall also obtain an end-use statement from the end-user of the Product. Biologix further agrees that it shall comply with all import and export restrictions of any country in which Biologix is doing business, including verification by Biologix that no end-user of the Product or recipient of technical data has been listed on any country's "denied parties" list. In the event that Biologix breaches any provision set forth in this Section [13.5](#), Amarin shall have no further obligation to supply Biologix with Product under this Agreement, until such breach is remedied, as determined by Amarin, in its sole and absolute discretion.

### 13.6 Compliance of Representatives

- . Biologix warrants and covenants that, it shall remain solely responsible and liable for the performance by its Representatives of any of the obligations delegated to them by Biologix hereunder and it shall ensure that such Representatives shall be bound by and comply with all applicable terms and conditions of this Agreement, including this Article [13](#). Biologix shall, without limitation: (i) exercise due diligence in selecting any Representatives, (ii) provide or ensure they have received appropriate training, including training with respect to Adverse Event and Product Complaint reporting, to ensure their compliance with this Agreement, (iii) monitor and audit their activities at reasonable intervals to ensure compliance with this Agreement and (iv) document and make available upon request of Amarin, all records and other documentation, correspondence or information available pertaining to measures adopted by Biologix to meet its obligations under this Agreement.

### 13.7 Compliance Program

- . Biologix shall maintain an effective comprehensive corporate compliance program that is compliant with Applicable Laws. Such compliance program will require Biologix to investigate any such report of wrongdoing and take appropriate

action reasonably calculated to avoid future violations. Biologix shall promptly provide to Amarin written copies in English of any reports of any investigations initiated by Governmental Bodies in the Territory (including immediate written notification of any such investigation and any final reports issued in connection therewith) and cooperate with Amarin to enable it to meet its compliance program obligations and its obligations to Governmental Bodies.

13.8 Certification of Compliance

- . Within [\*\*\*] of each anniversary of the Effective Date (i.e., once per calendar year on the anniversary of the Effective Date), Biologix shall submit to Amarin a written certification by an appropriate corporate officer of Biologix, in a form acceptable to Amarin, regarding Biologix's (and its Representatives, as applicable) compliance with the terms of this Article [13](#).

14. **Term and Termination**

14.1 Term

- 14.1.1 This Agreement shall become effective on the Effective Date and, unless earlier terminated pursuant to this Article 14, shall remain in effect until (10) years after the first commercial launch of Product in the Territory (the "Term").
- 14.1.2 The acceptance of one or more Purchase Orders by Amarin after the Term of this Agreement shall not constitute a renewal of this Agreement, but instead, distinct individual one-time Purchase Orders.

14.2 Termination

- 14.2.1 This Agreement may be terminated (in whole or in part) by either Party immediately upon written notice if the other Party fails to perform any of its duties or responsibilities or breaches any of its material obligations hereunder (including as set forth in Section 7.1.15), and such failure has not been remedied by such Party in breach within sixty (60) days from receipt of written notice of such breach. For the avoidance of doubt, if either Party is entitled to terminate this Agreement in accordance with the foregoing, such Party shall have the right not to terminate this Agreement (and, in the case of Amarin, it shall have the right to make this Agreement non-exclusive as to Biologix); provided, however, that, in such event, such Party may exercise its available rights and remedies in accordance with Section 17.10; provided, further, that each Party shall remain subject to its payment obligations accrued under this Agreement prior to the effective date of termination.
- 14.2.2 In the event that either Party files a petition of bankruptcy, enters into insolvency or liquidation proceedings either voluntarily or involuntarily, or if a receiver is appointed with respect to the assets of such Party, or any similar action is filed by or against such Party under bankruptcy or insolvency laws, or such Party executes a bill of sale, deed of

trust of assignment for the benefit of creditors and such measure is not dismissed within thirty (30) days, then the Party not so affected shall have the right to terminate this Agreement; provided, that, if the affected Party provides evidence reasonably satisfactory to the non-affected Party that any such action under this Section 14.2.2 is without merit, then the non-affected Party shall not have the right to terminate this Agreement.

14.2.3 Amarin may terminate this Agreement by written notice with immediate effect:

- (i) in the event Biologix breaches any of the restrictive covenants under Section 2.2.3 or fails to meet its minimum sales targets [\*\*\*] pursuant to Section 3.3 of Exhibit B;
- (ii) in the event Biologix undergoes a Change of Control by an Amarin Competitor; or
- (iii) in the event Biologix's conduct is deemed prejudicial to the interests of Amarin. Biologix acknowledges that any OECD Convention, FCPA, UK Bribery Act or other legislation violation, or refusal to subject itself to a Compliance Audit shall be considered highly prejudicial to the interests of Amarin.

14.2.4 Amarin may terminate this Agreement (on a Part of the Territory-by-Part of the Territory basis) by written notice to Biologix with immediate effect in accordance with Section 2.2.4 and 3.3.3.

14.2.5 Termination pursuant to this Section 14.2 shall be in addition to, and not in place of, Amarin's other rights and causes of action.

14.3 Survival

- . Termination of this Agreement shall not relieve either Party of any obligation or liability accrued prior to the termination date. The obligations of the Parties under Articles [3](#), [5](#), [6](#), [7](#), [9](#), [10](#), [11](#), [12](#), [13](#), [15](#), [16](#) and [17](#) shall survive termination of this Agreement.

15. **Rights after Termination and Expiration**

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15.1 Transfer of Marketing Authorization

- . [\*\*\*], Biologix shall immediately transfer, without compensation, to Amarin or Amarin's designees any Marketing Authorization documentation, licenses, permits and any other official approvals required for the importation, sale and distribution of Product in the Field in the Territory, including, the original documents relating thereto to ensure such transfer is effective on such expiration or termination date (or where such transfer is not Applicable Law, surrender the same and use its best efforts to ensure that Amarin obtains or Amarin's designee obtains equivalent Product Registrations), if not already in Amarin's name. Biologix shall promptly execute all documents reasonably required by Amarin in connection with such transfer or surrender and comply with Amarin's instructions.



15.2      Actions on Termination or Expiration

. On termination or expiration of this Agreement for any reason whatsoever:

- 15.2.1      Biologix shall immediately cease to sell, distribute, market and promote the Product in the Field in the Territory;
- 15.2.2      Biologix shall immediately cease to describe itself as a distributor of the Product in the Field in the Territory and cause to be de-registered with any Governmental Body their status as a licensed distributor in the Territory on a Part of the Territory-by-Part of the Territory basis;
- 15.2.3      Biologix shall immediately return to Amarin, destroy or caused to be destroyed, as requested by Amarin, all at Biologix's own cost, any and all documents (including, sales materials) and information which have been supplied by Amarin or been produced by or on behalf of Biologix hereunder and are in the possession of Biologix;
- 15.2.4      Biologix shall immediately cease to use any material, any stationery or any other document bearing a Trademark, trade name or symbols of Amarin or of its Affiliates;
- 15.2.5      Any amounts which Amarin is entitled to hereunder shall become immediately payable by Biologix;
- 15.2.6      Biologix shall not be entitled to exercise any rights granted by Amarin in this Agreement, except for the rights which, according to the provisions of this Agreement, shall survive termination or expiration thereof;
- 15.2.7      All unshipped orders of Biologix, even though previously accepted by Amarin shall automatically become null and void without any liability of either Party; provided, that (i) subject to Biologix's payment in advance to Amarin, Amarin shall ship valid and binding Purchase Orders (subject to Section 3.3.4) accepted and acknowledged in writing prior to notification of termination of this Agreement or its expiration and (ii) with respect to any unused portion of the Prepaid Purchase Deposit, Amarin shall decide, in its sole discretion, (a) whether to ship valid and binding Purchase Orders accepted and acknowledged in writing prior to notification of termination of this Agreement or its expiration and/or (b) to return any unused portion of such Prepaid Purchase Deposit to Biologix; and
- 15.2.8      Biologix shall provide all necessary assistance, at its own expense, to ensure a smooth transition to Amarin or any Person designated by Amarin of the activities contemplated by this Section 15.2; including, entering into good faith discussions with Amarin to assess the implications of any termination or expiration of this Agreement and assist with the development of an action plan to facilitate such transition to a Third Party and, in this case, Biologix shall take no steps to jeopardize or harm the prospects of Amarin in either

establishing its direct sales and marketing presence, or new relationship with a Third Party in the Territory.

15.3 Inventory of Products

.

15.3.1 [\*\*\*] from the date of termination or expiration of this Agreement, Biologix shall submit to Amarin a complete list of Product in stock and shall upon request grant Amarin's Representatives access to all such Product. [\*\*\*] from receipt of such list and the granting of such access, Amarin shall have the right to repurchase all or part of such Product then owned by Biologix, [\*\*\*].

15.3.2 If, in the reasonable opinion of Amarin, any of the Product owned by Biologix has become unfit for sale, such Product shall be disposed of by Biologix at its expense in accordance with instructions given by Amarin and there shall be no refund due to Biologix from Amarin in connection therewith.

15.3.3 Biologix shall promptly pack and ship to such destination as Amarin may direct the Product that Amarin has chosen to repurchase. [\*\*\*], Amarin shall repay to Biologix the Supply Price of such Product plus reasonable freight and insurance charges and applicable duties actually paid by Biologix. The Parties will cooperate in providing such assistance as either Party may require in order to obtain drawbacks or refunds or reductions of duties or taxes levied on the Product repurchased. In the event Amarin does not repurchase any inventory or purchases only part thereof, [\*\*\*]

15.4 No Liability

. Amarin shall not be liable to Biologix for any damages, indemnity or compensation whatsoever for reasons of termination, non-renewal or expiration of this Agreement, as provided herein, whether such damages, indemnity or compensation might be claimed for frustrated business expectations, anticipated sales, loss of investment, loss of present or prospective profits, loss of goodwill, indemnity for customers or business expenditures, or any other reason claimed to be caused from the termination or expiration of this Agreement. As a condition precedent of Amarin entering into this Agreement, Biologix expressly waives any rights it may have, however they may arise, to claim such damages, indemnity or compensation from Amarin upon the termination or expiration of this Agreement.

15.5 Existing Payment Obligations

. All indebtedness of each respective Party to the other shall become immediately due and payable without further notice or demand, which is hereby expressly waived.

16. **Confidentiality**

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16.1 Confidentiality Obligations

. Biologix agrees that, for the Term of this Agreement plus five (5) years thereafter, Biologix shall, and shall ensure that its Representatives and Sub-Distributors, hold in confidence all Confidential Information, unless such information:

- 16.1.1 is or becomes generally available to the public other than as a result of disclosure by Biologix;
- 16.1.2 is already known by or in the possession of Biologix at the time of disclosure by Amarin;
- 16.1.3 is independently developed by Biologix without use of or reference to the Amarin's Confidential Information; or
- 16.1.4 is obtained by Biologix from a Third Party that has not breached any obligations of confidentiality.

16.2 Non-Disclosure

- . Biologix shall not disclose any of the Confidential Information, except to its Representatives and Sub-Distributors who need to know the Confidential Information for the purpose of performing Biologix's obligations, or exercising its rights, under this Agreement and who are bound by obligations of non-use and non-disclosure substantially similar to those set forth herein. Biologix shall be responsible for any disclosure or use of the Confidential Information by its Representatives and Sub-Distributors. Biologix shall protect Confidential Information using not less than the same care with which it treats its own Confidential Information, but at all times shall use at least reasonable care. Biologix shall: (a) implement and maintain appropriate security measures to prevent unauthorized access to, or disclosure of, Amarin's Confidential Information, (b) promptly notify Amarin of any unauthorized access or disclosure of Amarin's Confidential Information and (c) cooperate with Amarin in the investigation and remediation of any such unauthorized access or disclosure.

16.3 Use

- . Notwithstanding Section [16.1](#), Biologix may use the Confidential Information of Amarin for the purpose of performing its obligations, or exercising its rights, under this Agreement.

16.4 Required Disclosure

- . Biologix may disclose the Confidential Information of Amarin to the extent required by Applicable Law or court order; provided, however, that Biologix promptly provides to Amarin prior written notice of such disclosure and provides reasonable assistance in obtaining an order or other remedy protecting such Confidential Information from public disclosure.

16.5 Publications

- . Biologix shall not make any announcement of the existence or subject matter of this Agreement or use the name, Trademarks or logos of Amarin or its Affiliates without Amarin's prior written consent.

16.6 Publicity

- . If, at any time during the Term, Amarin (in its sole discretion) desires to issue a press release in connection with this Agreement, it shall notify Biologix in writing and provide Biologix with a written copy thereof for its reasonable review and comment. Amarin shall consider in good faith all reasonable comments received from Biologix with respect to such press release; provided, that Amarin shall have the right in its sole

discretion to determine the contents of and make any such press release. Subject to the foregoing sentence, neither Party nor its respective Affiliates shall (without the prior written consent of the other Party, not be unreasonably withheld) make any press release or other public announcement of or otherwise disclose the provisions of this Agreement to any Third Party, except for: (i) disclosure to those of its directors, officers, employees, accountants, attorneys, underwriters, lenders and other financing sources, potential strategic partners, advisors, agents and Sub-Distributors, whose duties reasonably require them to have access to this Agreement; provided, that such directors, officers, employees, accountants, attorneys, underwriters, lenders and other financing sources, advisors, agents or Sub-Distributors, are required to maintain the confidentiality of this Agreement; (ii) disclosures which on the advice of the disclosing Party's counsel, are required by the rules and regulations of The NASDAQ Stock Market or any securities exchanges, in which case the disclosing Party shall provide the non-disclosing Party with at least sixty (60) hours' notice, but in any event no later than the time the disclosure required by such NASDAQ Stock Market or any securities exchange is made; (iii) disclosures as may be required by Applicable Laws, in which case the disclosing Party shall provide the non-disclosing Party with prompt advance notice of such disclosure and cooperate with the non-disclosing Party to seek a protective order or other appropriate remedy, including a request for confidential treatment in the case of a filing with the United States Securities and Exchange Commission; (iv) the report on Form 8-K, which may be filed by Amarin or an Affiliate of Amarin setting forth the press release referred to in the first sentence above, and/or this Agreement in redacted form (i.e., Redacted Agreement) as provided in Section 16.7 and/or a summary thereof; (v) disclosures that are consistent with or complementary to those described in clause (iv) but which do not contain any Confidential Information of the other Party; and (vi) other disclosures for which consent has previously been given. A Party may publicly disclose without regard to the preceding requirements of this Section 16.6 any information that was previously publicly disclosed pursuant to this Section 16.6, so long as the context of such disclosure is substantially similar to the context in which the initial disclosure was made.

#### 16.7 Required Filings

- . Notwithstanding Section 16.6, Amarin may publicly disclose, without violation of this Agreement, such terms of this Agreement as are, on the advice of Amarin's counsel, required by the rules and regulations of the United States Securities and Exchange Commission or The NASDAQ Stock Market, Inc. ("Redacted Agreement"); provided, that Amarin shall advise Biologix of such intended disclosures and provide Biologix with reasonable opportunity to request that Amarin seek confidential treatment of such disclosures to be filed with the United States Securities and Exchange Commission. Subject to the immediately preceding sentence, Amarin shall consult with Biologix, and Biologix shall have the right to review and comment with respect to the Redacted Agreement or Biologix's Confidential Information as part of the confidential treatment request to the United States Securities and Exchange Commission. Excluding any public disclosures of the terms of this Agreement that are authorized by the preceding sentences or Section 16.6, if Amarin desires to make a public

announcement concerning the material terms of this Agreement, or Biologix's Confidential Information, then Amarin shall give reasonable prior advance notice of the proposed text of such announcement to Biologix for its prior review and approval (except as otherwise provided herein), such approval not to be unreasonably withheld, conditioned or delayed; provided, that Biologix shall provide its comments, if any, within [\*\*\*] in the event Amarin is required to make such disclosure pursuant to Applicable Laws or stock exchange rules) after receiving the public announcement for review (and failure for Biologix to provide comments within such time period shall be deemed to constitute Biologix's consent to such public announcement). In relation to Biologix's review of such an announcement, Biologix may make specific, reasonable comments on such proposed public disclosure within the prescribed time for commentary. Amarin shall not be required to seek the permission of Biologix to disclose any information already disclosed or otherwise in the public domain, provided such information remains accurate.

## 17. **General Provisions**

### 17.1 Taxes

- . Biologix shall, with respect to any Applicable Laws in effect on the date of this Agreement be solely responsible for, shall bear and shall pay any and all government taxes and other charges imposed upon, arising out of or related to Biologix property, operations, sales or performance under this Agreement, which are levied and assessed by any Governmental Body. Such taxes and other charges shall include, by way of illustration and not limitation, income taxes, gross receipt taxes, social security taxes, social insurance charges, value added taxes, property taxes, excise taxes and stamp duties. Biologix shall also be solely responsible for, shall bear and shall pay any and all taxes and other charges of any Governmental Body assessed against or with respect to Biologix's Representatives or other agents by reason of wages, salaries or benefits earned and paid by said personnel or Biologix's or their benefits, or by reason of their presence or the performance of services within the Territory. Without limitation to its indemnification obligations under Sections [7.3](#) and [7.4](#), Biologix shall indemnify and save Amarin and its Affiliates harmless from and against the results of Biologix's failure to pay or withhold any such taxes and charges set forth in this Section [17.1](#).

### 17.2 Relationship of the Parties

- . Nothing in this Agreement is intended or shall be deemed, for financial, tax, legal or other purposes, to constitute a partnership, agency, joint venture or employer-employee relationship between the Parties.

### 17.3 Assignment

- 17.3.1 Except as expressly provided herein, neither this Agreement nor any interest hereunder shall be assignable, nor any other obligation delegable, by Biologix without the prior written consent of Amarin.

- 17.3.2     Amarin may assign this Agreement, in whole or in part, without the consent of Biologix to (i) any Affiliate or (ii) any Third Party to whom Amarin sells all or substantially all of the assets related to this Agreement; provided, that, as a condition to such assignment, the acquirer of such assets shall agree to be bound by the terms and conditions of this Agreement. Amarin shall give written notice to Biologix promptly following any such assignment; and provide Biologix with any necessary documents as required by the Governmental Bodies so as to maintain the Marketing Authorizations (and where applicable other Product Registrations) in the Territory.
- 17.3.3     No assignment under this Section 17.3 shall relieve the assigning Party of any of its responsibilities or obligations hereunder and, as a condition of such assignment, the assignee shall agree in writing to be bound by all obligations of the assigning Party hereunder. This Agreement shall be binding upon the successors and permitted assigns of the Parties.
- 17.3.4     Any assignment not in accordance with this Section 17.3 shall be void.
- 17.4       Performance and Exercise by Affiliates
- . Amarin shall have the right to have any of its obligations hereunder performed, or its rights hereunder exercised, by, any of its Affiliates and the performance of such obligations by any such Affiliate shall be deemed to be performance by Amarin; provided, however, that Amarin shall be responsible for ensuring the performance of its obligations under this Agreement and that any failure of any Affiliate performing obligations of Amarin hereunder shall be deemed to be a failure by Amarin to perform such obligations. For clarity, the foregoing means that Amarin may designate an Affiliate to perform its obligations hereunder or to be the recipient of Biologix's performance obligations hereunder.
- 17.5       Further Actions
- . Each Party agrees to execute, acknowledge and deliver such further instruments and to do all such other acts as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.
- 17.6       Accounting Procedures
- . Each Party shall calculate all amounts, and perform other accounting procedures required, under this Agreement and applicable to it in accordance with United States generally accepted accounting principles ("GAAP").
- 17.7       Force Majeure
- . Neither Party shall be liable to the other Party or be deemed to have breached or defaulted under this Agreement for failure or delay in the performance of any of its obligations under this Agreement for the time and to the extent such failure or delay is caused by or results from acts of God, earthquake, riot, civil commotion, terrorism, war, strikes or other labor disputes, fire, flood, failure or delay of transportation, omissions or delays in acting by a Governmental Body, acts of a Governmental Body or judicial orders or decrees or restrictions or any other reason which is beyond the control of the respective Party. The Party affected by force majeure shall provide the other Party with full particulars thereof as soon as it becomes aware of the same (including its best

estimate of the likely extent and duration of the interference with its activities), and will use commercially reasonable efforts to overcome the difficulties created thereby and to resume performance of its obligations hereunder as soon as practicable.

17.8 Entire Agreement of the Parties; Amendments

- . This Agreement and the Exhibits hereto constitute and contain the entire understanding and agreement of the Parties respecting the subject matter hereof and cancel and supersede any and all prior negotiations, correspondence, understandings and agreements between the Parties, whether oral or written, regarding such subject matter. No waiver, modification or amendment of any provision of this Agreement shall be valid or effective unless made in a writing referencing this Agreement and signed by a duly authorized officer of each Party.

17.9 Captions

- . The captions to this Agreement are for convenience only, and are to be of no force or effect in construing or interpreting any of the provisions of this Agreement.

17.10 Governing Law and Disputes

- . This Agreement and any non-contractual obligations arising out of or in connection with it are governed by English law. The United Nations Convention of Contracts for the International Sales of Goods shall not apply to this Agreement. In the event of any dispute arising out of or in connection with this Agreement or regarding its validity, the dispute shall be escalated to the most senior management level (CEO or managing director) of each Party. If the dispute has not been settled on the most senior management level within fifteen (15) days following the escalation by one Party or within such other period as the Parties may agree in writing, the dispute shall be referred to final and binding arbitration in London, England, pursuant to the Arbitration Rules of the London Court of International Arbitration (LCIA) (the "LCIA Rules"). The language of the arbitration proceedings shall be English. Such arbitration shall be conducted by an arbitrator appointed in accordance with LCIA Rules. Any provision of the LCIA Rules relating to the nationality of an arbitrator shall to that extent not apply. The seat or legal place of arbitration shall be deemed to be England, and accordingly the substantive laws of England shall be applicable for purposes of the arbitration. The procedural law for any reference to arbitration shall be English law. Any right of appeal or reference on points of law to the courts is hereby waived, to the extent that such waiver can be validly made. The arbitral tribunal shall have the power to order on a provisional basis any relief which it would have power to grant in a final award.

17.11 Notices and Deliveries

- . Any notice, request, approval or consent required or permitted to be given under this Agreement shall be in writing and shall be deemed to have been sufficiently given if delivered in person, transmitted by facsimile (receipt verified) or by express courier service (signature required) to the Party to which it is directed at its address or facsimile number shown below or such other address or facsimile number as such Party shall have last given by notice to the other Party.

<b>If to Amarin Pharma:</b> Name: Amarin Pharma, Inc. Street: 1430 Route 206, Suite 101 City/State: Bedminster, NJ 07921 Country: U.S.A. Attn: Chief Executive Officer Facsimile: 1-908-719-3012	<b>With a copy to:</b> Name: Amarin Pharma, Inc. Street: 1430 Route 206, Suite 101 City/State: Bedminster, NJ 07921 Country: U.S.A. Attn: General Counsel Facsimile: 1-908-719-3012
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<b>If to Amarin Ireland:</b> Name: Amarin Pharmaceuticals Ireland Limited Street: 88 Harcourt Street, Dublin 2, Co City/State: Dublin Country: Ireland Attn: Chief Executive Officer Facsimile: Not valid notice	<b>With a copy to:</b> Name: Amarin Pharma, Inc. Street: 1430 Route 206, Suite 101 City/State: Bedminster, NJ 07921 Country: U.S.A. Attn: Chief Executive Officer and General Counsel, respectively Facsimile: 1-908-719-3012
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<b>If to Biologix:</b> Name: Nabil KHoury Street: Road WB 21, Warehouse C17 PO Box 54405, Al Tawar Dubai City: Dubai Airport Free Zone Area Country: United Arab Emirates Attn: Nabil KHoury Facsimile: +971 4 2997172	<b>With a copy to:</b> Name: Nicole Bardawil Street: Sea Road - Algorithm Bldg. City: Zouk Country: Lebanon Attn: Selim Ghorayeb Facsimile: +961 9 222141
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17.12 Language

- . The official language of this Agreement and between the Parties for all correspondence shall be the English language

17.13 Waiver

- . A waiver by either Party of any of the terms and conditions of this Agreement in any instance shall not be deemed or construed to be a waiver of such term or condition for the future, or of any other term or condition hereof. All rights, remedies, undertakings, obligations and agreements contained in this Agreement shall be cumulative and none of them shall be in limitation of any other remedy, right, undertaking, obligation or agreement of either Party.

17.14 Severability

- . When possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under Applicable Laws, but if any provision of this Agreement is held to be prohibited by or invalid under Applicable Laws, such provision will be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this Agreement. The Parties shall make a good faith effort to replace the invalid or unenforceable provision with a valid one which in its economic effect is most consistent with the invalid or unenforceable provision.



17.15 No Implied License

- . No right or license is granted to Biologix hereunder by implication, estoppel, or otherwise to any know-how, patent or other intellectual property right owned or controlled by Amarin or its Affiliates.

17.16 Interpretation

- . The words “include,” “includes” and “including” shall be deemed to be followed by the phrase “without limitation.” All references herein to Sections, Articles and Exhibits shall be deemed references to Sections of, Articles of, and Exhibits to, this Agreement unless the context shall otherwise require.

17.17 Counterparts

- . This Agreement may be executed in counterparts, each of which will be deemed an original, and all of which together will be deemed to be one and the same instrument. A facsimile or a portable document format (PDF) copy of this Agreement, including the signature pages, will be deemed an original.

**[SIGNATURE PAGE FOLLOWS]**

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH “[\*\*\*]”. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT UNDER RULE 24b-2 OF THE SECURITIES EXCHANGE ACT OF 1934.

IN WITNESS WHEREOF, duly authorized representatives of the panics have executed this Agreement as of the Effective Date.

**BIOLOGIX FZCo**

**AMARIN PHARMACEUTICALS IRELAND LIMITED**

By: By: /s/ Patrick O’Sullivan

[\*\*\*] Name: Patrick O’Sullivan

Title: Director

**AMARIN PHARMA, INC.**

By: /s/ John F. Thero

Name: John F. Thero

Title: President & CEO

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[\*\*\*]

A-1

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**MARKETING AND PROMOTION SERVICES**

Biologix undertakes to perform the following marketing and promotion services for the import, [\*\*\*]

B-1

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**REGULATORY SERVICES**

Biologix, undertakes to perform the following Regulatory Services for the Products in the Field in the [\*\*\*]

C-1

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\*\*\*

D-1

**DEVELOPMENT, COMMERCIALIZATION AND SUPPLY AGREEMENT**

**DATED AS OF SEPTEMBER 25, 2017**

**BY AND AMONG**

**AMARIN PHARMACEUTICALS IRELAND LIMITED AND**

**AMARIN PHARMA, INC.**

**AND**

**HLS THERAPEUTICS INC.**

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# DEVELOPMENT, COMMERCIALIZATION AND SUPPLY AGREEMENT

This Development, Commercialization and Supply Agreement (this “**Agreement**”) is entered into as of the 25<sup>th</sup> day of September, 2017 (the “**Effective Date**”) by and among Amarin Pharmaceuticals Ireland Limited, a company incorporated under the laws of Ireland (registered number 408912) with offices at 2 Pembroke House Upper Pembroke Street 28-32, Dublin 2, Ireland (“**Amarin Ireland**”), and Amarin Pharma, Inc., a Delaware corporation with offices at 1430 Route 206 North, Suite 200, Bedminster, NJ 07921 (“**Amarin Pharma**”, and collectively with Amarin Ireland, “**Amarin**”), on the one hand, and HLS Therapeutics Inc., located at 10 Carlson Court, Suite 410, Etobicoke, Ontario Canada M9W 6L2 (“**Licensee**”), on the other hand. Amarin and Licensee are sometimes referred to herein individually as a “**Party**” and collectively as the “**Parties**.”

## RECITALS

**WHEREAS**, Amarin Ireland owns certain intellectual property and regulatory rights relating to a drug known as Vascepa® (icosapent ethyl) capsules (the “**Product**” as defined in more detail below);

**WHEREAS**, Amarin Ireland has granted to Amarin Pharma certain rights related the Product;

**WHEREAS**, Licensee has experience in the development and commercialization of pharmaceutical products in the Territory; and

**WHEREAS**, Licensee and Amarin desire to establish a collaboration for the development and commercialization of the Product in the Territory for the Field.

**NOW THEREFORE**, in consideration of the foregoing premises and the mutual promises, covenants and conditions contained in this Agreement, the Parties agree as follows:

## ARTICLE 1 DEFINITIONS

As used in this Agreement, the following initially capitalized terms shall have the meanings set forth in this Article 1 or as otherwise defined elsewhere in this Agreement:

**1.1** “**Accounting Standards**” means generally accepted accounting principles in the United States (GAAP) or the International Financial Reporting Standards (IFRS) as applicable, in each case as consistently applied.

**1.2** “**Active Moiety**” means the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds) or other non-covalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance.

**1.3** “**Affiliate**” means, as of the Effective Date or during the Term, as applicable, in relation to a Party, any person, corporation, firm or partnership or other entity, whether *de jure* or *de facto*, that directly or indirectly through one or more intermediaries controls, is controlled by or is under common control with such Party. An entity shall be deemed to control another entity if it: (a) owns, directly or indirectly, more than fifty percent (50%) of the outstanding voting securities or capital stock of such other entity, or has other comparable ownership interest with respect to any entity other than a corporation, or (b) has the power, whether pursuant to contract, ownership of securities or otherwise, to direct the management and policies of the entity. For the avoidance of doubt, neither of the Parties, or any of their respective Affiliates, shall be deemed to be an “Affiliate” of the other Party.

**1.4** “**Amarin In-License**” means any agreement under which Amarin licenses and/or sublicenses rights that are necessary or reasonably useful for the Development or Commercialization of the Product in the Territory for the Field.

**1.5** “**Amarin Invention**” means an Invention that is created or conceived during the Term by an employee of Amarin or its Affiliates or a Person under an obligation of assignment to Amarin or its Affiliates (solely or jointly with a Third Party) which is necessary or reasonably useful for the Development, Manufacturing or Commercialization of the Product in the Territory for the Field. For clarity, “Amarin Invention” shall not include the Amarin Patents, Amarin Manufacturing Patents or Amarin Manufacturing Know-How.

**1.6** “**Amarin Know-How**” means all Know-How that is (a) Controlled by Amarin (or its Affiliates) as of the Effective Date or at any time during the Term or (b) an Amarin Invention or Amarin’s interest in a Joint Invention, in each case of (a) or (b) which is necessary or reasonably useful for the Development or Commercialization of the Product in the Territory for the Field; provided, however that “Amarin Know-How” shall not include any Amarin Manufacturing Know-How. For clarity, “Amarin Know-How” shall not include the Amarin Patents, Amarin Manufacturing Patents or Amarin Manufacturing Know-How.

**1.7** “**Amarin Manufacturing Know-How**” means all Know-How that is (a) Controlled by Amarin (or its Affiliates) as of the Effective Date or at any time during the Term or (b) an Amarin Invention or a Joint Invention, in each case of (a) or (b) which is necessary or reasonably useful for the Manufacture of the Product, including any CMC information.

**1.8** “**Amarin Manufacturing Patent**” means any Patent that is (a) Controlled by Amarin (or its Affiliates) as of the Effective Date or at any time during the Term or (b) an Amarin Invention or a Joint Invention, in each case of (a) or (b), which is necessary or reasonably useful for the Manufacture of the Product; provided, however, that an “Amarin Manufacturing Patent” shall not include any Amarin Patent.

**1.9** “**Amarin Patent**” means any Patent in the Territory that is (a) Controlled by Amarin (or its Affiliates) as of the Effective Date, including the Patents listed in Schedule 1.9, or

(b) that comes under the Control of Amarin (or its Affiliates) during the Term (including Amarin's interest in a Joint Patent), in each case of (a) or (b) which is necessary or reasonably useful for the Development or Commercialization of the Product in the Territory for the Field; provided, however that "Amarin Patent" shall not include any Amarin Manufacturing Patents.

**1.10** "Amarin Technology" means the Amarin Patents and Amarin Know-How.

**1.11** "Anti-Corruption Laws" means the U.S. Foreign Corrupt Practices Act, as amended, the UK Bribery Act 2010, as amended, the Corruption of Foreign Public Officials Act (Canada), and all other Applicable Laws relating to anti-corruption or anti-bribery laws affecting companies doing business in the Territory, as well as Applicable Laws related to the prevention of fraud, racketeering, money laundering or terrorism.

**1.12** "Applicable Laws" means, with respect to any Person, property, transaction, activities, or other matters contemplated under this Agreement, any and all statutes, ordinances, regulations, rules, or guidance of any kind whatsoever and any and all requirements under permits, orders, decrees, judgments or directives and requirements of applicable Governmental Authorities, in each case pertaining to such Person, property, transaction, activities or other matters, including any regulations and guidelines promulgated by any Regulatory Authority in the Territory, all as amended from time to time.

**1.13** "Business Day" means a day other than a Saturday, Sunday, or a day on which banking institutions in New York, New York or Toronto, Ontario are closed.

**1.14** "Calendar Quarter" means each successive period of three (3) calendar months commencing on January 1, April 1, July 1 and October 1; provided, that (a) the first Calendar Quarter hereunder shall be deemed to commence upon the Effective Date and end at the start of the immediately following Calendar Quarter, and (b) the final Calendar Quarter hereunder shall be deemed to expire upon the effective date of expiration or termination of this Agreement.

**1.15** "Calendar Year" means (a) for the first calendar year, the period commencing on the Effective Date and ending on December 31, 2017, (b) for each successive period, beginning on January 1 and ending twelve (12) consecutive calendar months later on December 31, and (c) for the calendar year in which this Agreement is terminated, the period beginning on January 1 of such calendar year and ending on the effective date of the termination of this Agreement.

**1.16** "Cardiovascular Risk Reduction" means the reduction of the risk of adverse cardiovascular events in adult patients with at least MHTG, specifically the elements of the efficacy endpoints set forth in the clinical study being conducted by Amarin and referred to as the "REDUCE-IT" study.

**1.17** "Change of Control" means (a) a transaction or series of related transactions that results in the sale or other disposition of all or substantially all of Amarin's assets, or (b) a merger or consolidation in which Amarin is not the surviving corporation or in which, if Amarin

is the surviving corporation, the shareholders of Amarin immediately prior to the consummation of such merger or consolidation do not, immediately after consummation of such merger or consolidation, possess a majority of the voting power of all of Amarin's outstanding stock and other securities and the power to elect a majority of the members of Amarin's board of directors, or (c) a transaction or series of related transactions (which may include without limitation a tender offer for Amarin's stock or the issuance, sale or exchange of Amarin's stock) if the shareholders of Amarin immediately prior to the initialization of such transaction do not, immediately after consummation of such transaction or any of such related transactions, own stock or other securities of the entity that possess a majority of the voting power of Amarin's outstanding stock and other securities and the power to elect a majority of the members of Amarin's board of directors.

**1.18** "Commercialize", "Commercializing" or "Commercialization" means all activities directed to the marketing, promotion, selling or offering for sale of a Product for an indication, including planning, market research, Pre-Marketing, advertising, educating, marketing, promoting, distributing and post-marketing safety surveillance and reporting. For clarity, "Commercialization" shall not include any activities related to clinical research, Manufacturing or Development of the Product.

**1.19** "Commercially Reasonable Efforts" means, with respect to a Party's obligation to perform or achieve a specified obligation for the Product or generally under this Agreement, the efforts, expertise, degree of skill, and resources that are comparable in quality and scope to those efforts, expertise, degree of skill and resources that are generally used by such Party to perform or achieve a comparable obligation for a pharmaceutical product Controlled by such Party, which has the same regulatory requirements or status (for example, requires a prescription or is available over-the-counter), is at a comparable stage of development or product life as the Product, and that has similar market potential as the Product, taking into account relative safety and efficacy, product profile, the competitiveness of the marketplace, relevant regulatory circumstances, the extent of market exclusivity, and other relevant factors then prevailing, including technical, legal, payer environment, scientific and/or medical factors, but in any event, a Party's effort shall be no less than the effort that a comparable pharmaceutical company would expend with respect to a comparable pharmaceutical product Controlled by such company taking into consideration the factors outlined above. Without limiting the foregoing, Commercially Reasonable Efforts requires, with respect to such obligations, that the Party: (i) promptly assign responsibility for such obligation to specific employee(s) who are held accountable for progress and monitor such progress on an on-going basis, (ii) set objectives for carrying out such obligations, and (iii) allocate resources designed to advance progress with respect to such objectives.

**1.20** "Competing Product" means [\*\*\*]

**1.21** "Control" means, with respect to any Know-How, physical material, Patents, or other intellectual property right, possession by a Party or its Affiliates (whether by ownership, license grant or other means) of the legal right to grant the right to access or use, or to grant a

license or a sublicense to, such Know-How, physical material, Patent, or other intellectual property right as provided for herein without violating the proprietary rights of any Third Party or any terms of any agreement or other arrangement between such Party (or any of its Affiliates) and any Third Party. Notwithstanding the foregoing, for the purpose of defining whether any Know-How, physical material, Patent, or other intellectual property right is Controlled by a Party or its Affiliates, if such Know-How, physical material, Patent, or other intellectual property right is first acquired, licensed or otherwise made available to such Party after the Effective Date, and if the use, practice or exploitation thereof by or on behalf of the other Party, its Affiliates or sublicensees would require the first Party to pay any amounts to the Third Party from which the first Party acquired, licensed or otherwise obtained such Know-How, physical material, Patent, or other intellectual property right (“Additional Amounts”), such Know-How, physical material, Patent, or other intellectual property right shall be deemed to be Controlled by the first Party only if the other Party agrees to pay (if necessary) and does in fact pay all Additional Amounts with respect to such other Party’s use of or license to such Know-How, physical material, Patent, or other intellectual property right to the extent specified in Section 2.3.2. Further, notwithstanding anything in this Agreement to the contrary, a Party will be deemed not to Control any Know-How, physical material, Patent, or other intellectual property right that is owned or controlled by a Third Party described in the definition of “Change of Control” or such Third Party’s Affiliates prior to the closing of such Change of Control, except to the extent that such Know-How, physical material, Patent, or other intellectual property right was Controlled by such Party or any of its Affiliates prior to such Change of Control.

**1.22** “**Cost of Goods**” means, for Drug Product or placebo, as applicable, manufactured by Amarin or a Third Party, Amarin’s actual costs of manufacturing, packaging, and testing such Product or placebo and amounts paid to a Third Party, calculated in accordance with the Accounting Standards, including: [\*\*\*]

**1.23** “**Cover(ed)**” means, with respect to any Patent and the subject matter at issue, that, but for a license granted under a Valid Claim of such Patent, the manufacture, use, sale, offer for sale or importation of the subject matter at issue would infringe such Valid Claim, or in the case of a Patent that is a patent application, would infringe a Valid Claim in such patent application if it were to issue as a patent.

**1.24** “**Clinical Trial Application**” or “**CTA**” means an application to the applicable Regulatory Authority, such as a clinical trial application or a clinical trial exemption, the filing of which is necessary to commence or conduct clinical testing of a pharmaceutical product in humans in such jurisdiction.

**1.25** “**Develop**”, “**Developing**” or “**Development**” means all activities relating to research, non-clinical, preclinical and clinical trials, toxicology testing, statistical analysis and reporting, necessary or reasonably useful or otherwise requested or required by a Regulatory Authority as a condition or in support of obtaining or maintaining all Regulatory Approvals, including Phase IV Clinical Trials and other post-Regulatory Approval studies that are required to obtain or maintain Regulatory Approval or are otherwise conducted. For clarity,

“Development” shall exclude any activities related to Commercialization or Manufacturing or to the preparation of the filing for Regulatory Approvals in the Territory.

**1.26** “**Development Activities**” means those Development activities undertaken by or on behalf of a Party or its Affiliates with respect to the Product for the Field.

**1.27** “**Development Costs**” means the direct costs and expenses incurred by a Party or its Affiliates attributable to, or reasonably allocable to, the Development of the Product for the Field, including costs of conducting clinical trials and Phase IV Clinical Trials (as well as other post-Regulatory Approval studies (including physician-initiated studies)). “Development Costs” shall include (a) Out-of-Pocket Costs and (b) internal costs (e.g., staff or administrative) that are attributable to, or reasonably allocable to, the Development of the Product for the Field. For clarity, Development Costs shall exclude Regulatory Costs.

**1.28** “**Distributor**” means a Third Party bona fide wholesaler or distributor engaged by Licensee only to market, distribute and/or sell the Product in the Territory for the Field (but, for clarity, not to Develop or Manufacture the Product in any way).

**1.29** “**Drug Product**” means the finished Product in final presentation form ready for release to end-users which meets regulatory specifications.

**1.30** “**Drug Substance**” means icosapent ethyl.

**1.31** “**Drug Substance Specifications**” means those Manufacturing, performance and quality-control specifications for the Drug Substance in the Territory, which initially shall be set forth in a schedule to the Quality Agreement, as such specifications may be amended from time to time pursuant to the terms of this Agreement and the Quality Agreement.

**1.32** “**EPA**” means eicosapentaenoic acid in any chemical form (e.g., ethyl ester, triglyceride, free fatty acid, re-esterified, etc.) or stemming from any API manufacturing source or process.

**1.33** “**Facility**” means, as applicable, a Party’s Manufacturing facility and such other facilities used by such Party (or those of its Affiliates or Third Party contractors) in the Manufacture of (a) Drug Substance, (b) Drug Product or (c) materials utilized in the Manufacture or packaging and labeling of Drug Substance or Drug Product, including raw materials, auxiliary materials, intermediates, containers and packing materials, in each case with respect to the Product for Development or Commercialization in the Territory for the Field hereunder.

**1.34** “**FDA**” means the U.S. Food and Drug Administration or its successor.

**1.35** “**FD&C Act**” means the United States Federal Food, Drug and Cosmetic Act, 21 U.S.C. 301 et seq., as it may be amended from time to time, and relevant regulations and guidelines promulgated thereunder.

**1.37** “**First Commercial Sale**” means, with respect to a Product, the first sale of such Product in the Territory by or on behalf of Licensee or its Affiliates to a Third Party (including Distributors), after receipt of Regulatory Approval for such Product in the Territory.

**1.38** “**Food and Drugs Act**” means the Food and Drugs Act (Canada), as it may be amended from time to time, and relevant regulations and guidelines promulgated thereunder.

**1.39** “**Force Majeure**” means, in respect of a Party, circumstances beyond the reasonable control of such Party, including acts of God, fires, explosions, earthquakes, floods, droughts, riots, acts of terrorism, wars, civil disturbances, sabotage, cyber attacks, accidents, strikes or other labor disputes, unforeseen material shortages of raw materials or supplier failures, compliance with any binding action or decision of a government or any international body (such as an embargo, prohibition or similar limitation) or any other event or circumstance of the like of different character to the foregoing beyond the reasonable control and without the fault or negligence of a Party.

**1.40** “**General Development Activities**” means all Development Activities other than Territory Development Activities.

**1.41** “**Generic Product**” means any pharmaceutical product that has received Regulatory Approval or is marketed in the Territory as a generic version of the Product.

**1.42** “**Good Clinical Practices**” or “**GCP**” means all applicable Good Clinical Practice standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials, including, as applicable, (a) those standards required by Health Canada, (b) as set forth in the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (“ICH”) Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) and any other guidelines for good clinical practice for trials on medicinal products in the Territory, (c) the Declaration of Helsinki (2004) as last amended at the 52nd World Medical Association in October 2000 and any further amendments or clarifications thereto, (d) U.S. Code of Federal Regulations Title 21, Parts 50 (Protection of Human Subjects), 56 (Institutional Review Boards) and 312 (Investigational New Drug Application), as may be amended from time to time, and (e) the equivalent Applicable Laws in any relevant country, each as may be amended and applicable from time to time and in each case, that provide for, among other things, assurance that the clinical data and reported results are credible and accurate and protect the rights, integrity, and confidentiality of trial subjects.

**1.43** “**Good Laboratory Practices**” or “**GLP**” means all applicable Good Laboratory Practice standards, including, as applicable, (a) those standards required by Health Canada, (b) as set forth in the then-current good laboratory practice standards promulgated or endorsed by the

FDA as defined in 21 C.F.R. Part 58, and (c) the equivalent Applicable Laws in any relevant country, each as may be amended and applicable from time to time.

**1.44** “**Good Manufacturing Practices**” or “**GMP**” means all applicable Good Manufacturing Practices including, as applicable, (a) those standards required by Health Canada, (b) the principles detailed in the U.S. Current Good Manufacturing Practices, 21 C.F.R. Sections 210, 211, 601 and 610, (c) the principles detailed in the ICH Q7 guidelines, and (d) the equivalent Applicable Laws in any relevant country, each as may be amended and applicable from time to time.

**1.45** “**Government Official**” means (a) any elected or appointed government official (e.g., a member of a ministry of health), (b) any employee or person acting for or on behalf of a government official, agency, or enterprise controlled by government and performing a governmental function, (c) any political party, candidate for public office, officer, employee, or person acting for or on behalf of a political party or candidate for public office, and (d) any employee or person acting for or on behalf of a public international organization (e.g., the United Nations). For clarity, healthcare providers employed by government-owned hospitals shall be considered Government Officials.

**1.46** “**Governmental Authority**” means any multinational, federal, state, provincial, local, municipal or other governmental authority of any nature (including any governmental division, prefecture, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal), in each case, having jurisdiction over the applicable subject matter.

**1.47** “**Health Canada**” means the Canadian Federal Department known as Health Canada, or any successor agency thereto, and its divisions, including the Therapeutic Products Directorate and the Health Products and Food Branch Inspectorate.

**1.48** “**High Triglyceride**” or “**HTG**” means the treatment of adult patients with high triglycerides (TG  $\geq 200$  but  $< 500$  mg/dL) whether or not with mixed dyslipidemia and whether or not as an adjunct to diet or statin therapy.

**1.49** “**Housemark**” means the name and logo of Licensee or Amarin or any presentation of the Product label in French, as the case may be, or any of its respective Affiliates, as identified by one Party to the other from time to time.

**1.50** “**Indirect Taxes**” means VAT, sales taxes, consumption taxes and other similar taxes required by law to be disclosed on the invoice.

**1.51** “**Invention**” means any invention, discovery, improvement, modification, enhancement or creation, whether or not patentable, and any Patents, Know-How or other intellectual property rights arising from any of the foregoing.



**1.52** “**Joint Development Committee**” or “**JDC**” means the joint steering committee formed by the Parties as described in Section 3.1.

**1.53** “**Joint Invention**” means an Invention that is created or conceived during the Term jointly by or on behalf of each of Amarin and Licensee or any of their respective Affiliates which is necessary or reasonably useful for the Development, Manufacturing or Commercialization of the Product in the Territory for the Field.

**1.54** “**Know-How**” means all present and future information, whether or not in written form, whether or not in the public domain and shall include biological, chemical, pharmacological, toxicological, medical or clinical, analytical, quality, manufacturing, research, or sales and marketing information, including processes, methods, procedures, techniques, strategies, plans, programs and data.

**1.55** “**Licensed Trademarks**” means the VASCEPA® trademark and all other trademarks relating to the Product in the Territory listed in Schedule 1.55.

**1.56** “**Licensee Invention**” means an Invention that is created or conceived during the Term by or on behalf of Licensee or any of its Affiliates (solely or jointly with a Third Party) which is necessary or reasonably useful for the Development or Commercialization of the Product in the Territory for the Field. For clarity, Licensee Inventions exclude Joint Inventions.

**1.57** “**Licensee Know-How**” means all Know-How that is (a) Controlled by Licensee (or its Affiliates) as of the Effective Date or comes under the Control of Licensee (or its Affiliates) during the Term (other than to the extent such Control results from the licenses granted by Amarin to Licensee under this Agreement) that is necessary or reasonably useful for the Development or Commercialization of the Product or (b) a Licensee Invention. For clarity, Licensee Know-How excludes Joint Inventions.

**1.58** “**Licensee Patent**” means any Patent that (a) is Controlled by Licensee (or its Affiliates) as of the Effective Date or comes under the Control of Licensee (or its Affiliates) during the Term (other than as a result of the licenses granted by Amarin to Licensee under this Agreement) and (b) claims any Licensee Know-How. For clarity, Licensee Patent excludes Joint Patents.

**1.59** “**Licensee Technology**” means the Licensee Know-How and the Licensee Patents.

**1.60** “**Manufacture**” or “**Manufacturing**” means all activities related to the manufacturing of the Drug Product, Drug Substance, or any ingredient thereof, including production, manufacture, process of formulating, processing, purifying, filling, finishing, packaging, labeling, quality assurance and quality control activities, testing and release, shipping, preservation, shelf-life and storage of Products, all as conducted in accordance with GMP.

- 1.61** “**Medical Science Liaison**” means an individual who is employed by or on behalf of Licensee or its Affiliates and who provides educational services and other educational efforts directed towards the medical and/or scientific community.
- 1.62** “**Minimum Order Quantity**” means [\*\*\*]
- 1.63** “**Moderately High Triglyceride**” or “**MHTG**” means the treatment of adult patients with moderately high triglycerides (TG  $\geq$ 150 but <200 mg/dL) whether or not with mixed dyslipidemia and whether or not as an adjunct to diet or statin therapy.
- 1.64** “**Net Sales**” means [\*\*\*]
- 1.65** “**NDS**” means a New Drug Submission that is submitted to Health Canada to apply for Regulatory Approval to market the Product in the Territory in compliance with the requirements of Division 8 of Part C of the Food and Drug Regulations.
- 1.66** “**Out-of-Pocket Costs**” means costs and expenses paid to Third Parties (or payable to Third Parties and accrued in accordance with the Accounting Standards), other than Affiliates or employees, by either Party.
- 1.67** “**Patents**” means patents and patent applications and all substitutions, divisions, continuations, continuations-in-part, any patent issued with respect to any such patent applications, any reissue, reexamination, utility models or designs, renewal or extension (including any supplementary protection certificate) of any such patent, and any confirmation patent or registration patent or patent of addition based on any such patent, and all counterparts thereof in any country.
- 1.68** “**Patent Term Extension**” means any term extensions, supplementary protection certificates and equivalents thereof offering Patent protection beyond the initial term with respect to any issued Patents.
- 1.69** “**Person**” means any corporation, limited or general partnership, limited liability company, joint venture, trust, unincorporated association, governmental body, authority, bureau or agency, any other entity or body, or an individual.
- 1.70** “**Phase IV Clinical Trials**” means certain post-marketing studies to delineate additional information about a pharmaceutical product’s risks, benefits, and optimal use, commenced after receipt of regulatory approval for a product in the indication for which such trial is being conducted.
- 1.71** “**Pre-Marketing**” means marketing activities undertaken prior to and in preparation for the launch of the Product in the Territory. Pre-Marketing shall include market research, key opinion leader development, advisory boards, medical education, disease-related

public relations, health care economic studies, sales force training and other pre-launch activities prior to the First Commercial Sale of the Product in the Territory.

**1.72 “Product”** means a prescription product containing at least 96% pure icosapent ethyl as the only active pharmaceutical ingredient and only Active Moiety, sold under the Vascepa® trademark in the U.S., and improvements thereto for the Field. For clarity, [\*\*\*]

**1.73 “Product Approval”** means the approval of a Regulatory Authority necessary for the marketing and sale of the Product in a given country or regulatory jurisdiction, but which shall exclude any pricing or reimbursement approvals.

**1.74 “Product Complaint”** means any written, verbal or electronic expression of dissatisfaction regarding the Product sold by or on behalf of Licensee (or any of its Affiliates, Sublicensees or Distributors) in the Territory, including reports of actual or suspected product tampering, contamination, mislabeling or inclusion of improper ingredients.

**1.75 “Product Specifications”** means those Manufacturing, performance, quality-control, and packaging and labeling specifications for the Drug Product or Drug Substance, as applicable, in the Territory set forth in a schedule to the Quality Agreement, as such specifications may be amended from time to time pursuant to the terms of this Agreement and the Quality Agreement.

**1.76 “Promotional Materials”** means all written, printed, video or graphic advertising, promotional, educational and communication materials (other than the Product labels and package inserts) for marketing, advertising and promoting of the Product in the Territory for the Field, for use (a) by a Sales Representative, Medical Science Liaison, or other authorized employee or agent of Licensee, (b) by a Distributor, or (c) in advertisements, web sites or direct mail pieces.

**1.77 “Quality Agreement”** means each of the quality agreements between Licensee and Amarin relating to the Product for clinical and commercial uses.

**1.78 “REDUCE-IT Trial Primary Endpoint”** means the primary endpoint of the REDUCE-IT trial as defined within the protocol agreed to by the FDA under a Special Protocol Assessment agreement.

**1.79 “Regulatory Approvals”** means all approvals or licenses necessary for the Manufacture, Commercialization, importation and storage of the Product or a product for one or more indications in a country or regulatory jurisdiction, which may include satisfaction of all applicable regulatory and notification requirements, but which shall exclude any pricing or reimbursement approvals.

**1.80 “Regulatory Authority”** means, in a particular country or regulatory jurisdiction, any applicable Governmental Authority involved in granting Regulatory Approval and/or, to the

extent required in such country or regulatory jurisdiction, governmental pricing or reimbursement approval of a Product in such country or regulatory jurisdiction, including, in the Territory, Health Canada.

**1.81** “**Regulatory Costs**” means the costs and expenses incurred by Licensee or its Affiliates attributable to, or reasonably allocable to, the preparation, obtaining or maintaining of Regulatory Materials and Regulatory Approvals (including Product Approvals) for the Product (other than Manufacturing-related Regulatory Approvals), including any filing fees and such reasonable costs and expenses incurred by Amarin or its Affiliates to the extent requested by Licensee or required by this Agreement. “Regulatory Costs” shall include (a) Out-of-Pocket Costs and (b) internal costs (*e.g.*, staff or administrative) that are specifically and reasonably attributable to the preparation of Regulatory Materials, and obtaining or maintenance of Regulatory Approvals, for the Product in the Territory for the Field.

**1.82** “**Regulatory Data**” means any and all research data, pharmacology data, chemistry, manufacturing and control data, preclinical data, clinical data and all other documentation submitted, or required to be submitted, to Regulatory Authorities in association with regulatory filings for the Product (including any applicable Drug Master Files (“DMFs”), Chemistry, Manufacturing and Control (“CMC”) data, or similar documentation).

**1.83** “**Regulatory Exclusivity**” means any exclusive marketing rights or data exclusivity rights conferred by any applicable Regulatory Authority with respect to a Product, other than Patents, including regulatory data protection exclusivity under Part C, Section C.08.004.1 of the Food and Drug Regulations, or any other exclusivity or rights similar thereto..

**1.84** “**Regulatory Materials**” means regulatory applications, submissions, notifications, communications, correspondence, registrations, Regulatory Approvals and/or other filings made to, received from or otherwise conducted with a Regulatory Authority that are necessary in order to Develop, Manufacture, obtain marketing authorization, obtain Regulatory Exclusivity, market, sell or otherwise Commercialize the Product in a particular country or regulatory jurisdiction. Regulatory Materials include CTAs, New Drug Submissions, presentations, responses, and applications (including New Drug Applications submitted to Health Canada) for other Product Approvals.

**1.85** “**Royalty Term**” means, on a Product-by-Product basis in the Territory, the period of time beginning on the First Commercial Sale of such Product [\*\*\*]

**1.86** “**Safety Data**” means any and all scientific, technical, test, marketing or sales data pertaining to the Product that is generated by or on behalf of a Party or its Affiliates or Sublicensees that is related specifically to any adverse drug experiences and serious adverse drug experience as such information is reportable to Regulatory Authorities in or outside the Territory. Safety Data also includes “adverse events”, “adverse drug reactions” and “unexpected adverse

drug reactions” as defined in the ICH Harmonised Tripartite Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting.

**1.87** “**Sales Representative**” means an individual employed by Licensee who (a) engages in detailing and other activities as a commercial pharmaceutical sales representative that are in compliance with Applicable Laws, and who is trained with respect to the Product, including the Product labeling and the legal use of such labeling, to engage in such activities with respect to the Product in the Territory for the Field, and (b) has not been threatened with or excluded or debarred by any Regulatory Authority.

**1.88** “**Serious Adverse Event**” means an adverse drug experience or circumstance that results in any of the following outcomes: (a) death, (b) life-threatening condition, (c) inpatient hospitalization or a significant prolongation of existing hospitalization, (d) persistent or significant disability or incapacity or substantial disruption of the ability to conduct normal life functions, (e) or a congenital anomaly/birth defect or (f) significant intervention required to prevent permanent impairment or damage.

**1.89** “**Sublicense Revenue**” means any and all non-royalty cash and non-cash consideration received from a Sublicensee in connection with the grant of a sublicense under the Amarin Technology and/or Licensed Trademarks, [\*\*\*]

**1.90** “**Territory**” means Canada.

**1.91** “**Territory Development Activities**” means those Development Activities (other than Development Activities that have already been or are being conducted by Amarin as of the Effective Date) that are (a) necessary solely for obtaining or maintaining Regulatory Approval for the Product in the Territory for the Field and (b) post-Regulatory Approval-filing date Development Activities for the Product in the Territory for the Field. Such activities shall include, without limitation, designing, managing and conducting registration stability studies for the Product in the Territory for the Field, amending the shelf-life specifications to be in compliance with local Applicable Laws in the Territory, and assigning shelf-life/expiry dating of the Product. [\*\*\*]

**1.92** “**Territory-Specific Analytical Release Testing**” means all activities associated with carrying out the analytical testing, release and confirmatory testing of the Product which is necessary for delivery of the Product for Development or sale in the Territory for the Field, but which is not necessary for delivery of the Product for Development or sale in the U.S. for the Field. Such activities shall include: transferring test methods, developing and validating new analytical tests required in the Territory, amending the release specifications to be in compliance with local Applicable Laws in the Territory, conducting the release testing of the Product, final release of the Product (including raw materials, intermediates, drug substance, and drug product) and confirmatory testing of the Product. For clarity, preparation of reference standards to be used for Territory-Specific Analytical Release Testing includes analytical tests other than release

testing (e.g., mass spectrophotometry, isoelectrofocusing, etc.), which activities shall also be deemed Territory-Specific Analytical Release Testing hereunder.

**1.93** “**Third Party**” means any Person other than Amarin or Licensee or their respective Affiliates.

**1.94** “**United States of America**” or “**U.S.**” means the United States of America and its possessions and territories.

**1.95** “**Valid Claim**” means a claim of an Amarin Patent, a Licensee Patent or a Joint Patent that (i) has not been rejected, revoked or held to be invalid or unenforceable by a court or other authority of competent jurisdiction, from which decision no appeal can be further taken or (ii) has not been finally abandoned, disclaimed or admitted to be invalid or unenforceable through reissue or disclaimer.

**1.96** “**Very High Triglyceride**” or “**VHTG**” means the treatment of adult patients with very high triglycerides (TG ≥500 mg/dL) whether or not with mixed dyslipidemia and whether or not as an adjunct to diet or statin therapy.

**1.97 Interpretation**

. Except where expressly stated otherwise in this Agreement, the following rules of interpretation apply to this Agreement: (a) “include”, “includes” and “including” are not limiting; (b) “hereof”, “hereto”, “herein” and “hereunder” and words of similar import when used in this Agreement refer to this Agreement as a whole and not to any particular provision of this Agreement; (c) “knowledge” of a Party means the actual knowledge of any officer or senior management of such Party involved in the negotiation or review of this Agreement, without the obligation to perform due inquiry; (d) words of one gender include the other gender; (e) words using the singular or plural number also include the plural or singular number, respectively; (f) references to a contract or other agreement mean such contract or other agreement as from time to time amended, modified or supplemented; (g) references to a Person are also to its permitted successors and assigns; (h) references to an “Article”, “Section”, “Exhibit” or “Schedule” refer to an Article or Section of, or an Exhibit or Schedule to, this Agreement, unless expressly stated otherwise; and (i) references to a law include any amendment or modification to such law and any rules and regulations issued thereunder, whether such amendment or modification is made, or issuance of such rules and regulations occurs, before or after the Effective Date.

**1.98 Additional Definitions**

. The following terms have the meanings set forth in the corresponding Sections of this Agreement:

Term	Section
[***] “ <b>Additional Amounts</b> ”	[***] 1.21
[***] “ <b>Agreement</b> ”	[***] Preamble

Term	Section
“Amarin”	Preamble
“Amarin Ireland”	Preamble
“Amarin Pharma”	Preamble
“Annual Net Sales Threshold”	8.2.2
[***]	[***]
[***]	[***]
“CMC”	1.82
“Commercialization Budget”	6.2.3(e)
“Commercialization Data”	6.13.1
“Commercialization Plan”	6.2.1
“Committee”	3.3
“Compliance Audit”	6.8
“Confidential Information”	12.1
“Confidentiality Agreement”	12.1
“Controlling Party”	9.4.1(a)
“Defect” or “Defective”	7.6.2(a)
[***]	[***]
[***]	[***]
“Development Plan”	4.3.1
“Disbanding Notice”	3.5
“Disclosing Party”	12.1
“DMFs”	1.82
“Effective Date”	Preamble
[***]	[***]
“Executive Officer”	15.2
“Financial Audit”	8.10
[***]	[***]
“Forecast”	7.3.1
“Forecast Date”	7.3.1
“Global Branding Strategy”	6.12
“ICH”	1.42
“Indemnatee”	11.3
“Infringement Claim”	9.4.1
“Initial Commercialization Plan”	6.2.1
“Initial Forecast Date”	7.3.1
“Joint Patents”	9.1.1
[***]	[***]
“Latent Defects”	7.6.2(b)
“Licensee”	Preamble
“Long Range Forecast”	7.3.2
“Losses”	11.1

Term	Section
“Manufacturing Certificate of Analysis and Compliance”	7.6.2(a)
“Milestone Notification Notice”	8.2
***	***
“NOA”	9.4.2(a)
“Notice of Non-Conformance”	7.6.2(a)
“OOS”	7.6.3
“Party” or “Parties”	Preamble
***	***
“PM NOC”	9.4.2 (a)
“Price”	7.4.1
“Product”	Recitals
“Purchase Order”	7.3.3
“Purchase Order Acceptance Date”	7.3.4
“Receiving Party”	12.1
“Recovery”	9.4.2(c)(iv)
“Redacted Agreement”	12.5.2
“Representatives”	6.7.3
“Royalty Payments”	8.3.1
“Royalty Rates”	8.3.1
“Rules”	15.3
“Sublicense Revenue Payment”	8.3.3
“Sublicensee”	2.1.3
“Term”	13.1
“Third Party Claim”	11.1
***	***
“Upfront Payment”	8.1
“VAT”	8.5.2

## ARTICLE 2 LICENSES

### 2.1 Grant to Licensee

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#### 2.1.1

**General Grant to Licensee.** Subject to the terms and conditions of this Agreement, Amarin hereby grants to Licensee during the Term an exclusive (even as to Amarin and its Affiliates), royalty-bearing license with the right to sublicense solely in accordance with Section 2.1.3, to, under and with respect to the Amarin Technology, solely to Commercialize the Product in the Territory for the Field.



**2.1.2 Additional Grant to Licensee.** Subject to the terms and conditions of this Agreement, including in particular Section 6.11, Amarin hereby grants to Licensee during the Term an exclusive (even as to Amarin and its Affiliates), royalty-free license with the right to sublicense solely in accordance Section 2.1.3, to the Licensed Trademarks solely to Commercialize the Product in the Territory for the Field.

**2.1.3 Licensee's Right to Sublicense.** Licensee shall have the right to sublicense those rights granted to it under Sections 2.1.1 and 2.1.2 to (a) Affiliates, subject to Licensee's prior written notice to Amarin of the identity of such Affiliate and the purpose of such sublicense, and (b) Third Parties, subject to first obtaining Amarin's prior written consent (such consent not to be unreasonably withheld, conditioned or delayed) (each of (a) and (b), a **"Sublicensee"**); [\*\*\*]

**2.1.4 Performance by Affiliates and Subcontractors.** Licensee shall have the right to perform some or all of its obligations under this Agreement through Affiliates and/or Third Party subcontractors in the Territory; provided, however, that Licensee shall cause its Affiliates and subcontractors to comply with the terms and conditions of this Agreement in connection with such performance. For the avoidance of doubt, it shall not be deemed to be a sublicense for which consent is required to authorize a Distributor to whom Licensee or its Affiliates sells Product solely to resell such Product to the next level of the trade.

## **2.2 Grant to Amarin**

### **2.2.1 General Grants to Amarin.**

(a) Subject to the terms and conditions of this Agreement, Licensee hereby grants to Amarin during the Term a non-exclusive, royalty-free license or sublicense, as applicable, with the right to sublicense, under and with respect to the Licensee Technology, to Develop, Manufacture and Commercialize the Product either (i) outside the Territory, or (ii) subject to Section 2.4, in the Territory in connection with a New Indication for which Amarin is permitted to Develop and Commercialize the Product.

(b) Subject to the terms and conditions of this Agreement, Licensee hereby grants to Amarin during the Term an exclusive, paid-up, irrevocable, perpetual, worldwide license or sublicense, as applicable, with the right to sublicense, under and with respect to Licensee's interest in all Joint Inventions and Joint Patents, to Develop, Manufacture and Commercialize the Product either (i) outside the Territory, or (ii) subject to Section 2.4, in the Territory in connection with a New Indication for which Amarin is permitted to Develop and Commercialize the Product.

**2.2.2 Additional Grants to Amarin.** Subject to the terms and conditions of this Agreement, Licensee hereby grants to Amarin a non-exclusive, paid-up, irrevocable, perpetual, worldwide license or sublicense, as applicable, with the right to sublicense, under and with respect to the Licensee Technology, to Develop (including obtaining and maintaining

regulatory approval), make, have made, use, import, export, offer for sale and sell pharmaceutical products containing Drug Substance (other than the Product in the Field (or in respect of any New Indication for which Licensee is a current licensee to Develop or Commercialize the Product in accordance with Section 2.4) in the Territory) for sale anywhere in the world.

### **2.2.3 Grants after Expiration or Termination.**

(a) Subject to the terms and conditions of this Agreement, Licensee hereby grants to Amarin from and after the expiration or termination of this Agreement (on a Product-by-Product basis) by Amarin pursuant to Section 13.2, 13.3 or 13.4, a non-exclusive, paid-up, irrevocable, perpetual, license or sublicense, as applicable, with the right to sublicense, under and with respect to the Licensee Technology, to Develop, Manufacture and Commercialize such Product outside the Field (whether inside or outside the Territory) or for the Field (whether inside or outside the Territory) and to Develop (including obtaining and maintaining regulatory approval), make, have made, use, import, export, offer for sale and sell pharmaceutical products containing the Drug Substance for sale anywhere in the world.

(b) Subject to the terms and conditions of this Agreement, Licensee hereby grants to Amarin from and after the expiration or termination of this Agreement (on a Product-by-Product basis) an exclusive, paid-up, irrevocable, perpetual, worldwide license or sublicense, as applicable, with the right to sublicense, under and with respect to Licensee's interest in all Joint Inventions and Joint Patents, to Develop, Manufacture and Commercialize such Product outside the Field (whether inside or outside the Territory) or for the Field (whether inside or outside the Territory) and to Develop (including obtaining and maintaining regulatory approval), make, have made, use, import, export, offer for sale and sell pharmaceutical products containing the Drug Substance for sale anywhere in the world.

## **2.3 Additional Licensing Provisions**

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**2.3.1 Negative Covenant.** Each Party covenants that it will not use or practice any of the other Party's Patents, Know-How or other intellectual property rights licensed (or sublicensed, as applicable) to it under this Article 2 outside the scope of or otherwise not in compliance with the licenses, sublicenses and rights granted to such Party and its Affiliates under this Agreement.

### **2.3.2 Third Party Licenses.**

(a) In the event that, after the Effective Date and prior to any Change of Control of Amarin, Amarin enters into any agreement with a Third Party to in-license any Know-How, physical material, Patent, or other intellectual property right ("**Third Party IP**") that would be deemed Controlled for purposes of the licenses granted to Licensee under Section 2.1.1 [\*\*\*]

(b) [\*\*\*]

**2.3.3** The sublicenses granted to Licensee by Amarin under the Amarin Technology will be granted subject to the terms and conditions of the Amarin In-Licenses, as applicable. [\*\*\*]

**2.3.4 No Implied Licenses; Retained Rights.** Except as explicitly set forth in this Agreement, neither Party grants any right or license, express or implied, under its intellectual property rights to the other Party, whether by implication, estoppel or otherwise.

**2.4** [\*\*\*]

**2.5 Restrictive Covenants**

**2.5.1 Licensee.** Licensee hereby covenants that it shall not, and shall cause its Affiliates and Sublicensees not to [\*\*\*]

**2.5.2** [\*\*\*]

**2.5.3 Jurisdictional Compliance.** It is the desire and intent of the Parties that the restrictive covenants contained in this Section 2.5 be enforced to the fullest extent permissible under the Applicable Laws and public policies applied in each jurisdiction in which enforcement is sought. Amarin and Licensee believe that the restrictive covenants in this Section 2.5 are valid and enforceable. However, if any restrictive covenant should for any reason become or be declared by a competent court or competition authority to be invalid or unenforceable in any jurisdiction, such restrictive covenant shall be deemed to have been amended to the extent necessary in order that such provision be valid and enforceable, such amendment shall apply only with respect to the operation of such provision of this Section 2.5 in the particular jurisdiction in which such declaration is made.

### ARTICLE 3 GOVERNANCE

**3.1 Joint Development Committee**

**3.1.1 Establishment and Responsibilities.** In the event that Development Activities are required to obtain Regulatory Approval for the Product in the Territory [\*\*\*], the Parties shall establish the JDC within a reasonable period following the Effective Date that is mutually acceptable to the Parties (and in any event, within [\*\*\*] of a request by a Party to establish the JDC). The JDC shall perform the following functions:

(a) Review, coordinate, discuss and approve the overall strategy for Developing the Product in the Territory for the Field, including reviewing, coordinating, discussing and approving the overall strategy for seeking Regulatory Approvals for the Product

in the Territory for the Field and approving the Development Plan and each annual update and any material amendments thereto;

(b) Review, coordinate, discuss and approve the design of the clinical trial protocols and endpoints and oversee the conduct of all clinical trials required as set forth in the Development Plan as well as discuss any Territory Development Activities to be conducted with respect to the Product for the Field;

(c) Review any matters related to obtaining and maintaining Regulatory Approvals for the Product in the Territory for the Field, including being informed of the development and contents of all submissions to Regulatory Authorities in the Territory for Regulatory Approvals and all necessary filing and registration activities related thereto;

(d) Review, coordinate, discuss and approve any Phase IV Clinical Trials in the Territory, investigator-sponsored studies in the Territory, and any other clinical studies to be conducted in the Territory that are not described in the Development Plan;

(e) Facilitate the exchange of information between the Parties under this Agreement regarding the strategy for implementing the Development Activities in the Territory, including sharing Development Data created pursuant to this Agreement and establishing procedures for the efficient sharing of information and materials necessary or useful for the Development of the Product in the Territory for the Field;

(f) Review and oversee issues regarding supply of Product for clinical trials and Phase IV Clinical Trials in the Territory under the Development Plan and for anticipated commercial needs;

(g) Review and oversee issues regarding pharmacovigilance and safety both inside and outside the Territory; and

(h) Have such other responsibilities as may be assigned to the JDC pursuant to this Agreement or as may be mutually agreed upon by the Parties in writing from time to time.

**3.1.2 Membership.** The JDC shall consist of an equal number of representatives from each Party, with at least three (3) representatives appointed by each Party. A Party may change any of its representatives on the JDC at any time with a new person (with appropriate expertise to replace the outgoing member) by giving written notice to the other Party; provided, however, that, without limiting the generality of the foregoing, a key objective with respect to membership in the JDC shall be preserving continuity. The JDC shall be co-chaired by a representative of each of Licensee and Amarin. One member of the JDC shall serve as secretary of the JDC at each JDC meeting, and the secretary shall alternate from meeting to meeting between a Licensee JDC member and an Amarin JDC member. The chairpersons shall be responsible for (a) calling meetings, (b) preparing and issuing minutes of each such meeting within thirty (30) days thereafter, and (c) preparing and circulating an agenda for the upcoming

meeting; provided, that the chairpersons shall consider including any agenda items proposed by either Party no less than five (5) days prior to the next scheduled JDC meeting.

**3.1.3 Meetings.** The JDC shall hold [\*\*\*]; provided, that the JDC shall meet more or less frequently as Licensee and Amarin mutually agree upon as appropriate. Meetings of the JDC shall be effective only if at least one (1) representative of each Party is present or participating. The JDC may meet either (a) in person at either Party’s facilities (alternating between the facilities of Licensee and Amarin) or at such locations as the Parties may otherwise agree or (b) by audio or video teleconference; provided, that no less than [\*\*\*] meeting of the JDC during each Calendar Year shall be conducted in person. Other representatives of each Party involved with the Product may attend meetings as non-voting participants, subject to the confidentiality provisions set forth in Article 12. Additional meetings of the JDC may also be held with the consent of each Party, as required to resolve disputes, disagreements or deadlocks in the other Committees or as otherwise required under this Agreement, and neither Party shall unreasonably withhold its consent to hold such additional meetings.

**3.1.4 Decision-Making.** The JDC may make decisions with respect to any subject matter that is subject to the JDC’s decision-making authority and functions as set forth in Section 3.1. All decisions of the JDC shall be made by unanimous vote or written consent, with Licensee and Amarin each having, collectively, among its respective members, one (1) vote in all decisions. The JDC shall use Commercially Reasonable Efforts to resolve the matters within its roles and functions or otherwise referred to it. [\*\*\*]

**3.2 [\*\*\*].**

**3.2.1 [\*\*\*]**

**3.2.2 [\*\*\*]**

**3.2.3 [\*\*\*]**

**3.2.4 [\*\*\*]**

**3.3 Committees**

. From time to time, the Parties may establish and delegate duties to other committees (each, a “**Committee**”) to oversee particular matters. Each such Committee shall be constituted and shall operate as the Parties reasonably and mutually determine as reflected in a written agreement between the Parties; provided, that each Committee shall have equal representation from each Party.

**3.4 Limits on Committee Authority**

. The JDC, [\*\*\*] and any other Committee shall have only the powers assigned expressly to it in this Article 3 and elsewhere in this Agreement, and shall not have any power to amend, modify or waive compliance with this Agreement. In furtherance thereof, each Party shall retain the rights, powers and discretion granted to it under this Agreement and no such rights, powers or discretion shall be delegated or

vested in the JDC, [\*\*\*] and any other Committee unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree in writing. Without limiting the generality of the foregoing, the JDC, [\*\*\*] and any other Committee shall have no decision-making authority with respect to any matters related to (a) approving (or otherwise making decisions with respect to) matters related to obtaining, maintaining or enforcing Patent protection for the Product in the Territory for the Field (which matters shall be governed by Article 9), (b) the Development of the Product outside the Field or outside of the Territory, (c) the Commercialization of the Product outside the Field or outside of the Territory or (d) the Manufacture of the Product.

### 3.5 Disbanding the JDC and [\*\*\*]

. At any time during the Term, and for any reason, Amarin shall have the right to disband the JDC, [\*\*\*] or any Committees existing as of such time upon written notice to Licensee, which notice shall be effective immediately upon receipt (“**Disbanding Notice**”). [\*\*\*]

### 3.6 Actions

. In developing strategies, making decisions and exercising its rights under this Agreement (including acting through its representatives on any of the Committees), each Party shall act in good faith.

### 3.7 Exchange of Information

. Licensee shall keep Amarin fully and promptly informed as to its progress and activities in material aspects relating to the Development and Commercialization of the Product in the Territory, including with respect to regulatory matters and meetings with Regulatory Authorities, by way of updates to appropriate Committees at their meetings or directly in writing in English in the event that the Committees are disbanded and as otherwise specified in this Agreement, or as reasonably requested from time to time by Amarin. In connection therewith, Licensee shall provide Amarin with such information regarding such progress and activities under the Development Plan or Commercialization Plan, or otherwise relating to the Product, as Amarin may reasonably request from time to time. In addition, Licensee shall update the JPCC no less than twice per Calendar Year regarding its significant Commercialization activities involving the Product within the Territory for the Field. Notwithstanding anything to the contrary in this Agreement, nothing in this Section 3.7 shall require Licensee to provide to Amarin any information that Licensee is prohibited from disclosing under Applicable Law.

### 3.8 Minutes of Committee Meetings

. Definitive minutes of all Committee meetings shall be finalized no later than thirty (30) days after each meeting. The minutes shall be approved by each Party not later than the first order of business at the immediately succeeding Committee meeting.

### 3.9 Expenses

. Each Party shall be responsible for all of its own expenses incurred in connection with participating in the JDC, [\*\*\*] or meetings or any of the other Committee meetings.

## ARTICLE 4 DEVELOPMENT

### 4.1 Overview

#### 4.1.1 Overview of Development. [\*\*\*]

**4.1.2 General Development Activities and Development Outside the Territory or Outside the Field; Regulatory Approvals Outside the Territory or Outside the Field.** The Parties hereby agree and acknowledge that nothing contained herein shall limit or otherwise restrict the ability of Amarin or its other licensees or sublicensees, as applicable, to (a) perform the General Development Activities as it sees fit and at its sole discretion and at its cost, (b) Develop the Product for use or sale outside the Territory (whether or not for the Field) and (c) obtain or maintain Regulatory Approvals for the Product outside the Territory (whether or not for the Field). [\*\*\*]

**4.1.3 Manufacturing Related Activities.** The Parties shall agree as to the allocation of responsibility with respect to the performance of the developmental aspects of Territory-Specific Analytical Release Testing [\*\*\*]

**4.1.4 Certain Additional Restrictions.** Licensee agrees and acknowledges that it and its Affiliates shall not conduct any Development of the Product except in accordance with the Development Plan established pursuant to this Agreement.

### 4.2 Objectives Under the Development Plan

#### 4.2.1 Development Activities.

(a) Each of the Parties shall use Commercially Reasonable Efforts to carry out their specific Territory Development Activities set forth in the Development Plan in accordance with the time frames set forth therein [\*\*\*].

(b) Each of the Parties shall use Commercially Reasonable Efforts to carry out the Territory Development Activities for which they are responsible under the Development Plan in accordance with the time frames set forth therein [\*\*\*]

#### 4.2.2 [\*\*\*]

**4.2.3 Compliance.** Each Party shall conduct its Development Activities in accordance with sound and ethical business and scientific practices, and in compliance with all Applicable Laws, GCPs and GLPs. In addition, neither Party shall use in any capacity, in connection with its Development (or Commercialization) of Product hereunder, any Person who has been debarred pursuant to Section 306 of the FD&C Act (or similar Applicable Laws outside of the U.S.), or who is the subject of a conviction described in such section, and:

(a) in the event that a Person who is performing services for a Party hereunder is debarred or is the subject of a conviction described in Section 306 (or similar Applicable Laws outside of the U.S.), or

(b) if any action, suit, claim, investigation or legal administrative proceeding is pending or, to a Party’s knowledge, is threatened, relating to the debarment of a Party or any Person used in any capacity by such Party in connection with its Manufacturing, Development (or Commercialization) of Product hereunder;

such Party shall inform the other Party immediately in writing.

4.3 Development Plan and Development Budget

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4.3.1 General. In connection with the Development of the Product in the Territory for the Field, Licensee shall conduct the Territory Development Activities, if any, that are required pursuant to a comprehensive development plan (the “Development Plan”). The Development Plan shall set forth, among other things, the following (if applicable):

[\*\*\*]

4.3.2 [\*\*\*]

4.3.3 [\*\*\*]

4.4 Development Costs

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4.4.1 [\*\*\*]

4.4.2 [\*\*\*]

4.4.3 [\*\*\*]

4.5 Records, Reports and Information

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4.5.1 General. Licensee shall, and shall cause each of its Affiliates and permitted Third Party subcontractors to, maintain current and accurate records of all work conducted by it under the Development Plan and all data and other information resulting from such work [\*\*\*]. Amarin shall be given an adequate opportunity, in any event not less than [\*\*\*], to comment on and approve the drafts of reports resulting from Territory Development Activities conducted under the Development Plan.

4.5.2 Status Updates. Licensee shall provide the JDC with reports detailing its respective Territory Development Activities and the results thereof at least [\*\*\*] prior to any JDC meeting, but in any event, on at least a Calendar Quarter basis. Without limiting the foregoing, subject to Applicable Law, Licensee shall [\*\*\*] after receipt thereof, provide to



Amarin copies of any material documents or correspondence received from any Regulatory Authority related to Territory Development Activities.

**4.5.3 Access to Records.** Subject to Applicable Law, Amarin shall have the right to review all records under the Development Plan maintained by Licensee at reasonable times, upon written request.

**4.6 Ownership and Transfer of Development Data**

. [\*\*\*]

**4.7 Right to Audit**

. Licensee shall ensure that Amarin’s authorized representatives and any Regulatory Authorities, to the extent permitted by Applicable Laws, may, during regular business hours and upon reasonable advance written notice, no more than once per Calendar Year (unless a previous audit during such Calendar Year revealed an issue) (a) examine and inspect its facilities or, subject to any Third Party confidentiality restrictions and other obligations, the facilities of any subcontractor or any investigator site used by Licensee in the performance of Development of the Product in the Territory for the Field hereunder, and (b) subject to Applicable Laws and any Third Party confidentiality restrictions and other obligations, inspect all data, documentation and work product to the extent reasonably available to Licensee relating to the activities performed by it, the subcontractor or investigator site, including the medical records of any patient participating in any clinical study, in each case generated pursuant to the said Development. This right to inspect all data, documentation, and work product relating to the Product in the Territory for the Field may be exercised at any time during the Term upon reasonable notice, or such longer period as shall be required by Applicable Laws. The audit rights described in this Section 4.7 are without limitation of other audit rights described elsewhere in this Agreement.

**ARTICLE 5  
REGULATORY**

**5.1 Regulatory Data and Regulatory Materials**

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**5.1.1 Regulatory Data Generated by Amarin and Licensee.** [\*\*\*] Amarin shall provide Licensee with the Amarin Know-How, including existing and future (as it may come available during the Term) Regulatory Materials and Regulatory Data for the Product [\*\*\*].

**5.1.2 Use of Data by Licensee.** Licensee may only use the Regulatory Materials and Regulatory Data provided by Amarin hereunder for the purposes of Developing or Commercializing the Product and obtaining and maintaining Regulatory Approval for the Product, in each case in the Territory for the Field pursuant to this Agreement. Amarin and its Affiliates may use the Regulatory Materials and Regulatory Data provided by Licensee hereunder for the purposes of Development, Manufacture and Commercialization of and obtaining and maintaining Regulatory Approval of the Product (a) outside the Territory (whether for the Field or outside Field) and (b) in accordance with Section 2.4, in the Territory in

connection with a New Indication for which Amarin is entitled to Develop or Commercialize the Product.

**5.1.3 Regulatory Materials.** Licensee shall provide assistance to Amarin with the development of the core data sheet. Licensee shall be responsible for providing the approved local prescriber, and patient-directed, labeling that are proposed or approved for the Commercialization of the Product in the Territory for the Field.

## **5.2 Regulatory Filings and Regulatory Approvals**

**5.2.1 General Responsibilities.** Subject to Section 5.2.5, Licensee shall be responsible for the preparation of all Regulatory Materials necessary or desirable for obtaining and maintaining (a) the Regulatory Approvals for the Product in the Territory for the Field (including in connection with patient information leaflets, labeling and packaging for the Product in the Territory for the Field) and (b) Regulatory Exclusivity for the Product in the Territory for the Field. Licensee shall submit such Regulatory Materials, as applicable, to the applicable Governmental Authorities in the Territory for the Field. Without limiting the foregoing, subject to Section 5.2.5, Licensee shall use Commercially Reasonable Efforts to seek and obtain Regulatory Approval and Regulatory Exclusivity for the Product in the Territory for the Field. [\*\*\*]

**5.2.2 Ownership of Regulatory Approvals.** For clarity, to the extent allowed by Applicable Laws, all Regulatory Approvals for the Product in the Territory for the Field (other than those related solely to the Manufacture of the Drug Product or Drug Substance, if any, which it is agreed shall be held and owned by Amarin) shall be held and owned by Licensee in its name. [\*\*\*]

**5.2.3 Cost of Regulatory Activities.** All Regulatory Costs incurred from and after the Effective Date in connection with the preparation by or on behalf of Licensee of Regulatory Materials for, and the obtaining of, Product Approvals or Regulatory Exclusivity for the Product in the Territory for the Field, or other activities performed by Amarin pursuant to this Section 5.2, shall be borne solely by Licensee. [\*\*\*]

**5.2.4 Reporting and Review.** Licensee shall keep Amarin reasonably and regularly informed in connection with the preparation of all Regulatory Materials, Regulatory Authority review of Regulatory Materials, and Regulatory Approvals, in each case with respect to Product for sale in the Territory for the Field. Licensee shall provide Amarin, within [\*\*\*], with copies of all notices, questions, and requests for information in tangible form which it receives from a Regulatory Authority with respect to Product for sale in the Territory for the Field; provided, however, that Licensee shall have the right to redact any information to the extent not related to Product.

**5.2.5 Consultation and Approval Prior to Regulatory Filings.** The Parties shall consult with each other on the strategy for pre-authorization activities (i.e., Regulatory Authority meetings) and post-authorization activities [\*\*\*].

**5.2.6 Pre-Registration Meetings.** Upon Licensee's reasonable request, Amarin and its Affiliates shall provide reasonable support for any pre-registration meetings with Regulatory Authorities for the Product in the Territory for the Field [\*\*\*].

### **5.3 Communications**

. The Parties shall cooperate in communicating with any Regulatory Authority having jurisdiction regarding the Product for the Field [\*\*\*]. All communications with Regulatory Authorities regarding the Product in the Territory for the Field shall be undertaken as provided in this Agreement.

### **5.4 No Other Regulatory Filings**

. Except as otherwise expressly set forth in this Agreement, Licensee (and its Affiliates) shall not file any Regulatory Materials or Regulatory Approvals for the Product or that are otherwise based on any Amarin Technology.

### **5.5 Rights of Reference**

**5.5.1 Licensee's Rights.** Amarin hereby grants to Licensee (and its Affiliates or permitted Sublicensees) rights to reference, access and use, in association with exercising Licensee's rights and performing its obligations under this Agreement, Amarin's Development Data, Regulatory Materials and Regulatory Approvals outside the Territory that are associated with the Product for the Field and any New Indications for which Licensee is a current licensee pursuant to Section 2.4. Amarin shall promptly transmit to the extent accessible to and Controlled by Amarin all necessary and appropriate letters to applicable Regulatory Authorities advising such applicable Regulatory Authorities of such rights of reference and use.

**5.5.2 Amarin's Rights.** Licensee hereby grants to Amarin (and its Affiliates or permitted Sublicensees) rights to reference, access and use Licensee's Development Data, Regulatory Materials and Regulatory Approvals in the Territory to the extent associated with the Product to (a) exercise Amarin's rights and perform its obligations under this Agreement or (b) for the purposes of obtaining or maintaining Regulatory Approvals of the Product outside the Territory or outside the Field. Licensee shall promptly transmit to the extent accessible to and Controlled by Licensee all necessary and appropriate letters to applicable Regulatory Authorities advising such applicable Regulatory Authorities of such rights of reference and use. Such rights of reference shall survive the expiration or termination of this Agreement.

### **5.6 Adverse Event Reporting, Safety Data Exchange and Medical Inquiries**

**5.6.1 Pharmacovigilance.** Subject to the terms of this Section 5.6.1, each Party shall be responsible for its respective pharmacovigilance obligations for the Product under Applicable Laws. Licensee, as the intended beneficiary under this Agreement of the privileges of ownership of the Product Approvals for the Product in the Territory for the Field, (or its

designee) shall be responsible for the collection of information relating to Safety Data or Serious Adverse Events associated with the Product in the Territory for the Field and for forwarding such information to Amarin, who shall be responsible for reviewing, assessment, tracking and filing of such information (whether or not Product Approval has been achieved), in each case in accordance with Applicable Laws and this Agreement. Amarin (or its designee) shall be responsible for the collection, review, assessment, tracking and filing of information related to Safety Data or Serious Adverse Events associated with the Product in the countries outside the Territory, and Licensee (or its designee) shall be responsible for filing with the applicable Regulatory Authorities information related to Safety Data or Serious Adverse Events associated with the Product in the Territory for the Field. The safety units from each of the Parties shall meet and agree upon a written pharmacovigilance agreement for exchanging Safety Data and Serious Adverse Events and other safety information relating to the Product prior to Licensee's first clinical activity or prior to the first Regulatory Approval in the Territory (whichever is first). Such written pharmacovigilance agreement shall ensure that Safety Data and Serious Adverse Events associated with the Product and other safety information is exchanged according to a schedule that will permit each Party (and its designees or, solely with respect to Amarin, its (sub)licensees) to comply with Applicable Laws and regulatory requirements in their respective markets.

**5.6.2 Global Safety Database.** Amarin shall be responsible for maintaining the global safety database for the Product. The written pharmacovigilance agreement prescribed by Section 5.6.1 shall ensure that adverse event and other safety information is exchanged according to a schedule that will permit Amarin (and each of its designees and sublicensees, as applicable) to comply with Applicable Laws and regulatory requirements in their respective markets. Amarin shall provide Licensee with reasonable access to such global safety database without any compensation to Amarin. Amarin shall be responsible for developing and maintaining the Core Safety Data Sheet for the Product.

**5.6.3 Medical Inquiries for the Product.** Following the Effective Date, Licensee, as the intended beneficiary under this Agreement of the privileges of ownership of the Product Approvals in the Territory for the Field, (or its designee) shall be responsible for handling all medical questions or inquiries in the Territory, including all Product Complaints, with regard to any Product sold by or on behalf of Licensee (or any of its Affiliates), in each case in accordance with Applicable Laws and this Agreement. Amarin shall provide a copy of any standardized responses to medical inquiries, and such other information as Licensee may reasonably request, to Licensee for Licensee's use with respect to the Product in the Territory for the Field. Amarin shall [\*\*\*] forward to Licensee any and all medical questions or inquiries which it receives with respect to the Product sold by or on behalf of Licensee (or any of its Affiliates) in the Territory in accordance with all Applicable Laws, and Licensee shall [\*\*\*] forward to Amarin any and all medical questions or inquiries that it receives with respect to the Product (a) not sold by or on behalf of Licensee (or any of its Affiliates) in the Territory or (b) outside of the Territory, in each case in accordance with all Applicable Laws. Notwithstanding the foregoing, Amarin shall be responsible for managing all Product

Complaints related to the Development or Commercialization of the Product in or outside the Territory, and Licensee shall refer all such Product Complaints to Amarin, and Licensee shall reasonably cooperate with the management and resolution of such Product Complaints. The Parties shall specify in the pharmacovigilance agreement detailed processes (including timing) for the periodic reconciliation of Product Complaints between the Parties.

## 5.7 Regulatory Authority Communications Received by a Party

### 5.7.1

**General.** Each Party shall immediately inform the other Party of notification of any action by, or notification or other information which it receives from, any Regulatory Authority whether inside the Territory or outside the Territory which (i) raises any material concerns regarding the safety or efficacy of the Product; (ii) indicates or suggests a potential material liability of either Party to Third Parties in connection with the Product; (iii) is reasonably likely to lead to a recall, market withdrawal or market notification with respect to the Product whether inside the Territory or outside the Territory; or (iv) relates to expedited and periodic reports of adverse events with respect to the Product whether inside the Territory or outside the Territory, or Product Complaints, and which could have an adverse impact on Regulatory Approval or the continued Development or Commercialization of the Product whether inside the Territory or outside the Territory. Licensee shall be solely responsible for responding to any such communications relating to the Product in the Territory for the Field, and the Parties shall reasonably cooperate with and assist each other in complying with regulatory obligations, including by Amarin providing to Licensee such information and documentation which is in Amarin's possession as may be necessary or reasonably helpful for Licensee to prepare a response to an inquiry from a Regulatory Authority with respect to the Product in the Territory for the Field. Each Party shall also promptly provide the other Party with a copy of all correspondence received from a Regulatory Authority whether inside the Territory or outside the Territory specifically regarding the matters referred to above. Amarin (or its designee) shall be solely responsible for any communications relating to the Product outside of the Territory or outside the Field.

### 5.7.2

**Disclosures.** In addition to its obligations under this Agreement and subject to Applicable Law, each Party shall disclose to the other Party (and in the case of Amarin, Amarin shall have the right, acting reasonably, to subsequently disclose to its designees) the following regulatory information:

(a) all material information pertaining to actions taken by Regulatory Authorities, whether inside the Territory or outside the Territory, in connection with the Product for the Field, including any notice, audit notice, notice of initiation by Regulatory Authorities of investigations, inspections, detentions, seizures or injunctions concerning the Product for the Field, notice of violation letter (i.e., an untitled letter), warning letter, service of process or other inquiry; provided, however, that a Party shall be entitled to redact those portions thereof to the extent not related to the Product for the Field. Without limiting the generality of the foregoing, each Party shall promptly, but in any event within [\*\*\*], inform the other Party of any inspections, proposed regulatory actions, investigations or requests for information or a meeting

by any Regulatory Authority with respect to the Product for the Field whether inside the Territory or outside the Territory; and

(b) all information pertaining to notices from Regulatory Authorities, whether inside the Territory or outside the Territory, of non-compliance with Applicable Laws in connection with the Product, including receipt of a warning letter or other notice of alleged non-compliance from any Regulatory Authority relating to the Product; provided, however, that a Party shall be entitled to redact those portions thereof to the extent not related to the Product.

## **5.8 Recall, Withdrawal, or Market Notification of Product**

**5.8.1 Notification and Determination.** In the event that any Governmental Authority threatens or initiates any action to remove the Product from the market for the Field whether inside the Territory or outside the Territory (in whole or in part), the Party receiving notice thereof shall notify the other Party of such communication immediately, but in no event later than one (1) Business Day, after receipt thereof. Before Licensee or Amarin (as the case may be) initiates a recall, withdrawal or market notification for the Product in the Territory, the Parties shall promptly meet and discuss in good faith the reasons therefor; provided, that such discussion shall not delay any action that is required to be taken under Applicable Laws in relation to any recall, withdrawal or market notification for the Product. In all cases Licensee, as the intended beneficiary under this Agreement of the privileges of ownership of the Product Approvals for the Product in the Territory for the Field (and any other New Indication for which Licensee is a current licensee pursuant to Section 2.4), shall determine (and notify Amarin with respect to such determination) whether to initiate any recall, withdrawal or market notification of the Product in the Territory for the Field, and Amarin, acting as the holder of the Product Approval for the Product outside the Territory or outside the Field (and any New Indications for which Licensee is a current licensee pursuant to Section 2.4), shall act on behalf of Licensee in any recall, withdrawal and market notification of the Product outside the Territory or outside the Field (and outside of any New Indications for which Licensee is a current licensee pursuant to Section 2.4). Amarin shall determine whether to initiate any such recall, withdrawal or market notification of the Product outside the Field (and any New Indications for which Licensee is a current licensee pursuant to Section 2.4) in the Territory, or outside the Territory, including the scope of such recall or withdrawal (e.g., a full or partial recall, temporary or permanent recall, or “dear doctor” letter) or market notification. In the event of any such recall, withdrawal or market notification for the Product in the Territory, Licensee or Amarin (as the case may be) shall determine the necessary actions to be taken, and shall implement such action, with the other Party providing reasonable input (which the first Party shall in good faith consider and incorporate into any recall, withdrawal or market notification strategy) and reasonable assistance, to conduct such recall, withdrawal or market notification. [\*\*\*\*] Licensee shall at all times utilize a batch tracing system which will enable the Parties to identify, on a prompt basis, customers within the Territory who have been supplied with Product of any particular batch, and to recall such Product from such customers as set forth in this Section 5.8.1.

**5.8.2 Cost Allocation.** All direct costs and expenses associated with implementing a recall, withdrawal or market notification with respect to the Product in the Territory for the Field shall be allocated [\*\*\*].

## ARTICLE 6 COMMERCIALIZATION

### 6.1 Commercialization in the Territory for the Field

. During the Term, Licensee shall be solely responsible for Commercializing the Product in the Territory for the Field, which Commercialization shall be in accordance with the Commercialization Plan and the terms of this Agreement. Licensee shall be responsible for one hundred percent (100%) of the expenses (including Pre-Marketing and other Commercialization expenses) incurred in connection with the Commercialization of the Product in the Territory for the Field. Without limiting the foregoing, Licensee shall use Commercially Reasonable Efforts to Commercialize the Product in the Territory for the Field.

### 6.2 Commercialization Plan

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**6.2.1 Initial Commercialization Plan.** On an annual basis commencing with the Calendar Year in which the first filing for Regulatory Approval for the Product in the Territory for the Field is expected to be made, Licensee shall prepare a commercialization plan with respect to the Commercialization of the Product in the Territory for the Field pursuant to this Agreement (the “**Commercialization Plan**”). The initial Commercialization Plan (i.e., for the Product for the Calendar Year in which the Regulatory Approval is expected to be received) will be prepared by Licensee (the “**Initial Commercialization Plan**”) at an appropriate and agreed time following the Effective Date [\*\*\*].

**6.2.2 Updates to Commercialization Plan.** Following the creation of the Initial Commercialization Plan in accordance with Section 6.2.1 above [\*\*\*]. Licensee shall conduct all Commercialization of the Product in accordance with the Commercialization Plan and this Agreement.

**6.2.3 Contents of Commercialization Plan.** Each annual Commercialization Plan shall include, among other things, a summary of the following items in connection with the Commercialization of the Product in the Territory for the Field:

[\*\*\*]

### 6.3 Licensee’s Performance

.

**6.3.1 Specific Commercialization Obligations.** Without limiting the generality of the provisions of Section 6.1, in connection with the Commercialization of the Product in the Territory for the Field by Licensee hereunder:

[\*\*\*]

### 6.3.2

**Commercialization Plan.** Without limiting the obligations of Licensee under Sections 6.3.1, Licensee shall use Commercially Reasonable Efforts to carry out the Commercialization activities in the Commercialization Plan in accordance with the time frames set forth in the Commercialization Plan.

### 6.4 Pricing

. Amarin shall provide assistance to Licensee in preparing applications for pricing approvals (including any supportive pharmaco-economic data & analysis available to Amarin) and assist in discussions with government and private insurers on reimbursement matters for the Product in the Territory for the Field (and any New Indications for which Licensee is a current licensee in accordance with Section 2.4). Licensee shall submit to Amarin for its review and comment all relevant documents to be filed with Governmental Authorities in connection with pricing of the Product in the Territory for the Field. [\*\*\*].

### 6.5 [\*\*\*].

### 6.6 Reports

. Without limiting Licensee's quarterly reporting obligations under Section 8.4 with respect to Net Sales, Royalty Payments and Sublicense Revenue, Licensee shall (a) [\*\*\*], provide Amarin a reasonably detailed report regarding its significant Development and Commercialization activities involving Product [\*\*\*]; and (b) [\*\*\*], provide Amarin the number of prescriptions written (aggregated by province) to the extent such number of prescriptions written can be provided by IMS (or a similar internationally recognized information service).

### 6.7 Compliance

#### 6.7.1

**Reporting.** Licensee shall ensure that all government reporting (including price and gift reporting), and sales, marketing and promotional practices, in respect of the Product in the Territory for the Field meet the standards required by Applicable Laws, including Anti-Corruption Laws, the Food and Drugs Act and all regulations and other guidelines concerning the advertising of prescription drug products. Each of Amarin and Licensee shall reasonably cooperate with the other Party to provide the other Party access to any and all information, data and reports required by the other in order to comply with the provisions of Applicable Laws required in the respective jurisdictions in which each Party sells the Product, including reporting requirements, in a timely and appropriate manner. Each Party shall ensure that its reporting under governmental healthcare programs in the Territory related to the Product is true, complete and correct in all material respects; provided, however, that a Party shall not be held responsible for submitting erroneous reports if such deficiencies result from information provided by the other Party which itself was not true, complete and correct. For clarity, Licensee shall not promotionally interact with any U.S. licensed physicians, nor engage in any activity that would result in a transfer of value to any such U.S. licensed physician in connection with the Product; provided that (i) the foregoing restriction shall not apply to dual-licensed physicians practicing within the Territory, and (ii) in the event that the Licensee intends to engage in any non-promotional interactions with U.S. licensed physicians for purposes of supporting the



market for the Product, Licensee shall obtain the prior consent to such interactions from, and conduct such interactions in accordance with any guidance provided by, Amarin. For clarity, Licensee shall use commercially reasonable efforts to report any such interactions to Amarin, and the Parties shall discuss and agree within the JPCC regarding the methodology (if any) that would enable Licensee to meet its obligations under this Section 6.7.1 and which would enable Amarin to comply with Applicable Law.

#### 6.7.2

**Corporate Compliance Program.** Each Party shall maintain a comprehensive corporate compliance program that is compliant with Applicable Laws; provided, however, that, whether or not required by Applicable Laws, such compliance program will include a mechanism for its employees and the public to report, anonymously if they choose, any concerns about potential illegal activity relating to the Commercialization of the Product. Each Party's compliance program will require such Party to investigate any such report of wrongdoing. Subject to Applicable Law, a Party shall provide written copies in English of any reports of any investigations related to the Product initiated by Governmental Authorities in the Territory as to the knowledge of such Party to the other Party upon the other Party's request.

#### 6.7.3

**General Compliance Obligations.** Licensee specifically agrees, on behalf of itself and its Affiliates, and its and their respective officers, directors and employees (together with Licensee, the "**Representatives**"), to, and to use Commercially Reasonable Efforts to cause its subcontractors and Sublicensees to, comply with Applicable Laws and, specifically, in connection with the subject matter of this Agreement:

(a)

To not directly or indirectly pay, offer or promise to pay, authorize the payment of any money or give, offer or promise to give, or authorize the giving of anything else of value, to: (i) any Government Official in order to influence official action; (ii) any individual or entity (whether or not a Government Official) in violation of Anti-Corruption Laws; or (iii) any individual or entity (whether or not a Government Official) while knowing or having reason to know that all or any portion of the money or other thing of value will be paid, offered, promised or given to, or will otherwise benefit, the individuals or entities for the purposes listed in clauses (i) and (ii) above.

(b)

To not, directly or indirectly, solicit, receive or agree to accept any payment of money or anything else of value in violation of the Anti-Corruption Laws.

(c)

To comply with the Anti-Corruption Laws and shall not take any action that will, or would reasonably be expected to, cause either Party or its Affiliates to be in violation of any such laws or policies.

(d)

To the knowledge of Licensee, no Representative, subcontractor or Sublicensee that will participate or support its performance of its obligations hereunder has, directly or indirectly, (i) paid, offered or promised to pay or authorized the payment of any money, (ii) given, offered or promised to give or authorized the giving of anything else of value or (iii) solicited, received or agreed to accept any payment of money or anything else of value, in

each case ((i), (ii) and (iii)), in violation of the Anti-Corruption Laws during the three (3) years preceding the date of this Agreement.

(e) To acquire and maintain all applicable licenses, permits, qualifications, approvals or authorizations by the competent Governmental Authority in each jurisdiction in which it operates, in accordance with Applicable Laws.

(f) Licensee shall promptly provide Amarin with written notice of the following events: (i) upon becoming aware of any actual or alleged breach or violation by Licensee or its Representative or of any obligation in this Section 6.7 or (ii) upon receiving a formal notification that it is the target of an investigation by a governmental authority for a violation of the Anti-Corruption Laws or upon receipt of information from any of the Representatives connected with this Agreement that any of them is the target of an investigation by a governmental authority for a violation of the Anti-Corruption Laws.

As between Amarin and Licensee, Licensee shall be responsible for any breach of any obligation under this Section 6.7 or of the Anti-Corruption Laws by any of its Representatives.

**6.7.4 Non-Compliance.** On the occurrence of any of the following events:

(a) Amarin becomes aware of, whether or not through a Compliance Audit, that Licensee or any of its Representatives is in breach or violation of any obligation in this Section 6.7 or of the Anti-Corruption Laws; or

(b) notification is received under Section 6.7.3(f)(i) relating to any suspected or actual violation of the Anti-Corruption Laws by Licensee or any of its Representatives,

then, in either case ((a) or (b)), Amarin shall have the right, in addition to any other rights or remedies under this Agreement or to which Amarin may be entitled in law or equity, to: (i) take such steps as are reasonably necessary in order to avoid a potential violation or continuing violation by Licensee or any of its Representatives of the Anti-Corruption Laws; and (ii) terminate this Agreement in its entirety immediately upon written notice to Licensee: (A) in the event that the breach or violation by Licensee which is the subject of the notice to Amarin pursuant to Section 6.7.3(f)(i) is material and is confirmed by an internal investigation of the compliance team of Licensee, and has not been cured to the reasonable satisfaction of Amarin within [\*\*\*] after receipt of such notice by Amarin (provided, that Amarin shall have the right, acting reasonably, to challenge the finding of Licensee's internal investigation and, upon exercising such right, the Parties agree to cooperate with, and submit any and all evidence in connection with such investigation to, an internationally recognized law firm mutually selected by the Parties in order to resolve such dispute within [\*\*\*] after such submission and the Parties agree to be bound by the final decision rendered in connection therewith); or (B) in the event that an investigation which is the subject of the notice by Licensee to Amarin pursuant to Section 6.7.3(f)(i) is concluded with a finding that Licensee violated the Anti-Corruption Laws in any material respect.

**6.7.5 Compliance Certification.** Within [\*\*\*] of each anniversary of the Effective Date (i.e., once per Calendar Year on the anniversary of the Effective Date), Licensee shall submit to Amarin a written certification by an appropriate corporate officer of Licensee, in a form acceptable to Amarin, regarding Licensee's (and its Sales Representatives, as applicable) compliance with the terms of this Section 6.7.

**6.7.6 Disclaimer.** Licensee acknowledges that compliance with the Anti-Corruption Laws and other Applicable Laws in the Territory by it and its Representatives is the responsibility of Licensee under this Section 6.7, and Licensee agrees that Amarin shall have no liability to Licensee or any of its Representatives by reason of Amarin's exercise (or failure to exercise) its rights or performance of its obligations under this Section 6.7.

## **6.8 Compliance Audit**

. For the Term, Licensee shall, for the purpose of auditing and monitoring the performance of its compliance with this Agreement and particularly its compliance obligations hereunder, permit Amarin and its Affiliates or its or the auditors of any of them to have once per Calendar Year (or more frequently upon a showing of good reason), upon reasonable notice, access to any premises of Licensee or its Affiliates used in connection with this Agreement ("**Compliance Audit**"). To the extent that any Compliance Audit by or on behalf of Amarin requires access and review of any commercially or strategically sensitive information of Licensee or its Affiliates relating to the business of Licensee or its Affiliates, such activity shall be carried out by a Third Party professional advisor appointed by Amarin that is reasonably acceptable to Licensee and such professional advisor shall only report back to Amarin such information as is directly relevant to informing Amarin on Licensee's compliance with the particular provisions of this Agreement being Compliance Audited (and shall enter into a commercially reasonable confidentiality agreement with Licensee consistent with the foregoing). The costs and fees of any such Compliance Audit [\*\*\*] The audit rights described in this Section 6.8 are without limitation of other audit rights described elsewhere in this Agreement.

## **6.9 Provisions Applicable to Sales Representatives and/or Medical Science Liaisons**

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**6.9.1 General.** Licensee shall, and shall cause its Sales Representatives to, conduct all details with respect to the Product and perform its other Commercialization activities under this Agreement in the Territory in adherence with Applicable Laws and Regulatory Approvals.

**6.9.2 Compensation.** Licensee shall be solely responsible for (a) any compensation that is payable to its Sales Representatives (including with respect to any employee benefit plan), (b) the payment or withholding of any contributions, payroll taxes, or any other payroll-related item by or on behalf of Licensee (or its Affiliates) or any of its Sales Representatives or Medical Science Liaisons, and (c) any failure of Licensee (or its Affiliates) to withhold or pay required taxes or failure to file required forms with regard to compensation and

benefits paid or extended by Licensee (or its Affiliates) to any of its Sales Representatives or Medical Science Liaisons.

**6.9.3 Training.** Licensee shall be solely responsible for training, and all costs associated with such training, its Sales Representatives and Medical Science Liaisons in respect of the Product for use in the Territory for the Field (including any New Indications for which Licensee is a current licensee pursuant to Section 2.4) using Commercially Reasonable Efforts and in all cases in accordance with Applicable Laws, including timely reporting of any adverse events with respect to the Product. Such training will include, among other topics, Health Canada requirements and other national and local regulations and industry guidelines, including those set forth in Section 6.7.1 above. Amarin shall make available upon Licensee's reasonable request medical and sales training materials for the Product for use by Licensee pursuant to this Agreement.

**6.9.4 Acts of Sales Representatives and Medical Science Liaisons.** For the avoidance of doubt, Licensee shall be solely responsible for any act or omission of its Sales Representatives and Medical Science Liaisons while interacting with healthcare professionals or performing any Commercialization activities for and on behalf of Licensee. Licensee shall be solely responsible and liable for all probationary and termination actions taken by it with respect to its Sales Representatives and Medical Science Liaisons, as well as for the formulation, content and dissemination (including content) of all employment policies and rules (including written compliance policies, and probationary and termination policies) applicable to its employees and contractors. Licensee shall ensure that its policies require a clear delineation between the promotional and medical activities, including training both its Sales Representatives and Medical Science Liaisons on the differentiation of their roles under Applicable Laws. [\*\*\*]

## **6.10 Promotional Materials.**

**6.10.1 Creation of Promotional Materials.** Licensee will create and develop Promotional Materials for the Territory in accordance with the Regulatory Approvals and Applicable Laws and at Licensee's sole cost and expense, in each case based (to the extent consistent with such Regulatory Approvals and Applicable Laws) on commercial rationale and on promotional materials used by Amarin in the U.S. (copies of which shall be provided by Amarin to Licensee at Licensee's reasonable request). [\*\*\*], Licensee shall provide samples thereof to Amarin in English for its information and use prior to distributing such Promotional Materials (for clarity, such samples need only be submitted for each different type of Promotional Material, as opposed to each item of Promotional Material needing to be submitted). Any new samples of Promotional Material for the Territory made thereafter will be provided to Amarin for its information and use, subject to the licenses and restrictions granted hereunder. To the extent Licensee includes any Amarin trademarks in the Promotional Materials for the Territory, Licensee shall comply with Amarin's then current guidelines for trademark usage.

**6.10.2 Inclusion of Logos on Packaging and Promotional Materials.** To the extent permitted or required by Applicable Laws and subject to obtaining necessary Regulatory

Authority approvals, with respect to Product to be sold by or on behalf of Licensee (or any of its Affiliates) in the Territory, the Amarin Housemark and the Licensee Housemark shall be given equal prominence on all package inserts utilized by Licensee. Amarin hereby grants to Licensee a non-exclusive, royalty-free right and license during the Term to utilize the Amarin Housemark (including all trademarks, names and logos) in order to perform the Commercialization activities required to be performed by Licensee hereunder in accordance with the terms of this Agreement. Licensee hereby grants to Amarin a non-exclusive, royalty free right and license during the Term to utilize the Licensee Housemark (including all trademarks, names and logos) in order to perform the Manufacturing and other activities to be performed by or on behalf of Amarin under the terms of this Agreement. Each Party shall only use the Housemark of the other Party with the necessary trademark designations, and each Party shall use the other Party's Housemarks in a manner that does not derogate from such Party's rights in its trademarks, names and logos. Each Party shall submit representative samples of its use of the other Party's Housemark for review by the JPCC. Neither Party will take any action that will interfere with or diminish the other Party's rights in its respective trademarks, names and logos, and if a Party reasonably believes that the use of its trademarks, names and logos by the other Party hereunder is interfering with or diminishing its rights, such Party shall notify the other Party thereof in writing and such other Party shall promptly cease use of such trademarks, names or logos in such manner. Each Party agrees that all use of the other Party's trademarks, names and logos will inure to the benefit of such other Party, including all goodwill in connection therewith.

**6.10.3 Licensee Ownership of Promotional Materials.** Subject to Article 14, Licensee shall own all right, title and interest in and to any Promotional Materials created by Licensee hereunder relating to the Product in the Territory for the Field [\*\*\*] including copyrights, but excluding trademarks (including the Licensed Trademarks), names, logos and other marks owned by or on behalf of Amarin or its Affiliates.

**6.10.4 Use of Promotional Materials Exclusively for the Product.** The Promotional Materials, and any aspects of those uniquely tied to the Product, shall be used by Licensee (and its Affiliates, Sublicensees, subcontractors, and Distributors) in connection with the Commercialization of the Product in the Territory for the Field in accordance with the terms of this Agreement, and Licensee shall not use, or allow any other Person to use, any such Promotional Materials except in accordance with this Agreement.

## **6.11 Product Trademark and Product Trade Dress**

**6.11.1 Licensed Trademark.** Licensee shall Commercialize the Product in the Territory for the Field under the Licensed Trademarks. For clarity, the Parties acknowledge and agree that it is their mutual intention that Licensee Commercialize the Product in the Territory for the Field under the Licensed Trademark. Licensee shall not employ any alternative trademarks or trade dress without obtaining Amarin's prior written approval.

**6.11.2 Use and Ownership of Licensed Trademarks.** All uses of the Licensed Trademarks by Licensee (and its Affiliates, Sublicensees, subcontractors, and Distributors) to

identify and/or in connection with the Commercialization of the Product in the Territory for the Field shall be in accordance with Regulatory Approvals and all Applicable Laws, Amarin's quality control guidelines for the Licensed Trademarks, as may be amended from time to time, and shall be subject to the approval of Amarin in its reasonable discretion. Licensee (and its Affiliates) shall only use the Licensed Trademarks pursuant to the terms of this Agreement to identify, and in connection with the Commercialization of, the Product in the Territory for the Field. Licensee shall not (and shall cause its Affiliates, Sublicensees, subcontractors, and Distributors not to) use such Licensed Trademark to identify, or in connection with the marketing of, any other products. Amarin shall own and retain all rights to the Licensed Trademarks (in each case, together with all goodwill associated therewith throughout the Territory), and Licensee shall assign (and shall cause its Affiliates, Sublicensees, subcontractors, and Distributors to assign), and hereby does assign, to Amarin, all of its and their right, title and interest in and to such Licensed Trademarks. [\*\*\*] Amarin shall also own rights to any Internet domain names incorporating the Licensed Trademark or any variation or part of the Licensed Trademark as its URL address or any part of such address. Licensee shall not establish any Internet domain name or URL incorporating the Licensed Trademark without the prior written consent of Amarin, which consent shall not be unreasonably withheld. The Parties hereby agree and acknowledge that nothing contained herein shall limit Amarin's right to use the Licensed Trademark outside the Field or outside the Territory.

**6.11.3 Maintenance of Licensed Trademark.** During the Term, Amarin shall use Commercially Reasonable Efforts to establish, maintain and enforce the Licensed Trademark in the Territory and shall bear all costs and expenses relating thereto.

**6.11.4 Infringement of the Licensed Trademark.** In the event that either Party becomes aware of any infringement of the Licensed Trademark by a Third Party in the Territory, [\*\*\*].

**6.11.5 Trademark Acknowledgments.** Each Party acknowledges the sole ownership by the other Party and validity of all copyright, trademarks, trade dress, logos and slogans owned by the other Party and used or intended to be used in connection with the Commercialization of the Product in the Territory for the Field. Each Party agrees that it will not at any time during or after the Term assert or claim any interest in, or do anything which would reasonably be expected to adversely affect the validity or enforceability of, any copyright, trademark, trade dress, logo or slogan owned by the other Party and used or intended to be used on or in connection with the marketing or sale of the Product. Neither Party will register, seek to register or cause to be registered any copyrights, trademarks, trade dress, logos or slogans owned by the other Party and used or intended to be used on or in connection with the marketing or sale of the Product or any variation thereof, under any Applicable Laws providing for registration of copyrights, trademarks, service marks, trade names or fictitious names (including as an Internet domain name) or similar Applicable Laws, without the other Party's prior written consent (in its reasonable discretion).

. Amarin shall have the right, from time to time during the Term, to implement (and thereafter modify and update) a global branding strategy, including global messaging, for the Product for the Field throughout the world (the “**Global Branding Strategy**”). [\*\*\*] Nothing in this Section 6.12 shall be construed to derogate from Licensee’s ultimate right and responsibility to use Commercially Reasonable Efforts to Commercialize the Product in the Territory for the Field in accordance with the terms and conditions of this Agreement.

**6.13****Commercialization Data****6.13.1**

Licensee shall own all marketing and sales data and information resulting from its Commercialization of the Product in the Territory for the Field [\*\*\*] (the “**Commercialization Data**”). Upon request from Amarin, subject to Applicable Law, Licensee shall provide to Amarin a copy of the Commercialization Data, including promotional materials, marketing strategies, market research data, and lists of Licensee’s customers, in each case, to the extent relating to the Product.

**6.13.2**

Subject to Applicable Law and the confidentiality obligations set forth herein, Licensee hereby grants to Amarin a royalty-free, fully paid-up, perpetual, irrevocable, exclusive right and license to use all such Commercialization Data (and the right to grant its Affiliates and Third Parties the right to use such Commercialization Data) solely in connection with the Development and Commercialization of the Product outside the Territory or outside the Field. Notwithstanding the foregoing, Licensee’s obligation to provide Commercialization Data and Amarin’s right to use such data shall be performed, or exercised, respectively, in all instances in accordance with all Applicable Laws, including, without limiting the foregoing, any data privacy laws.

**ARTICLE 7  
SUPPLY****7.1****General**

. Amarin shall use Commercially Reasonable Efforts to Manufacture (or have Manufactured) and supply, on an exclusive basis, all quantities of the Drug Product, duly forecasted and ordered by Licensee pursuant to this Article 7 for commercial use in the Territory for the Field, in each case in accordance with the terms of this Article 7 and the Quality Agreement.

**7.2****Manufacture**

. Amarin or its designated Third Party shall be responsible [\*\*\*] for the Manufacture of Drug Product to be Commercialized in the Territory for the Field. Amarin or its designated Third Party shall ensure that all such Manufacturing shall comply with Applicable Laws, GMPs and the Regulatory Approvals for the Product in the Territory for the Field, including the Product Specifications. [\*\*\*].

**7.3.1**

**Forecast.** Licensee shall furnish the first forecast under this Section 7.3 no less than [\*\*\*] before the anticipated First Commercial Sale (the “**Initial Forecast Date**”). On the Initial Forecast Date and on the first day of each calendar month thereafter (each a “**Forecast Date**”), Licensee shall furnish Amarin a [\*\*\*] forecasted demand for Drug Product that Licensee expects to be delivered on a monthly basis (each a “**Forecast**”). [\*\*\*] All Purchase Orders for commercial Drug Product and professional samples must be delivered to Amarin [\*\*\*] prior to requested delivery date. In the event that the foregoing Forecasts change over time based on commercial or regulatory developments or other factors, the Parties shall meet to discuss in good faith the reasonable ability of Amarin to accommodate any such change and an equitable allocation between the Parties of any resulting costs and expenses.

**7.3.2**

**Long Range Capacity Planning; Supply Chain Improvements.** Concurrent with the initial Forecast, for the purposes of discussion and planning of manufacturing capacity Licensee shall provide a non-binding forecast of Drug Product needs for the [\*\*\*] following that specified in the then current Forecast as described in Section 7.3.1 (“**Long Range Forecast**”). [\*\*\*]

**7.3.3**

**Orders.** On each Forecast Date, in addition to the Forecast specified in Section 7.3.1, Licensee shall for the Term deliver to Amarin a purchase order or orders specifying the quantities of the Drug Product for delivery on a monthly basis in the [\*\*\*] beginning on the Forecast Date, as well as the location of delivery and desired delivery date for each delivery (each a “**Purchase Order**”). After delivery of the [\*\*\*]Forecasts, each such Purchase Order shall provide for aggregate quantities for delivery in such Calendar Quarter as set forth in the Forecast for such Calendar Quarter given one (1) Calendar Quarter earlier than the Forecast Date on which such Purchase Order is placed (see Schedule 7.3 for Forecast methodology); provided, however, that, to the extent a Purchase Order sets forth quantities that are no less than [\*\*\*], and no more than [\*\*\*], of the quantities contained in such Forecast, then Amarin will use Commercially Reasonable Efforts to accommodate such amounts. Unless agreed separately between the Parties, each Purchase Order shall specify no more than one (1) delivery date for the Drug Product in each calendar month.

**7.3.4**

**Receipt and Acceptance.** Subject to the terms and conditions of this Agreement, Amarin shall use Commercially Reasonable Efforts to supply, and Licensee shall purchase, all Drug Product and professional samples forecasted in the binding period or ordered and specified in a Purchase Order. Purchase Orders may be delivered electronically or by other means to such location as Amarin shall designate and shall be in a form reasonably acceptable to Amarin. Amarin shall provide written confirmation of such Purchase Order to Licensee [\*\*\*] of receipt of such Purchase Order (the date of such written confirmation, the “**Purchase Order Acceptance Date**”). Absent formal confirmation of such Purchase Order [\*\*\*] following delivery of any such Purchase Order to Amarin, such Purchase Order shall be deemed accepted by Amarin. Amarin shall accept any Purchase Order for Drug Product consistent with the most recent Forecast. If a Purchase Order, whether or not accepted, exceeds such applicable



maximum, the Parties shall seek to agree on a reasonable manner of proceeding. Amarin shall use Commercially Reasonable Efforts to supply any amount of Drug Product that Licensee orders pursuant to Section 7.3.3 in excess of the maximum amount deliverable under the ordering and forecasting procedures specified herein, but, in any event, such efforts shall not be construed as an obligation hereunder and in no event shall Amarin be deemed in breach of this Agreement by means of a failure to provide Drug Product in excess of the forecasted amount. Nothing in any such Purchase Order or written acceptance shall supersede the terms and conditions of this Agreement or the Quality Agreement, and in the event of a conflict between the terms such Purchase Order (or written acceptance, as applicable) and the terms of this Agreement (or the Quality Agreement, as applicable), the terms of this Agreement (or the Quality Agreement, as applicable) shall control. All Purchase Orders, written acceptances of Purchase Orders and other notices contemplated under this Section 7.3 shall be sent to the attention of such persons as each Party may identify to the other in writing from time to time in accordance with Section 16.3. In addition, (i) Amarin shall not be liable for any delays related to transportation or customs delays, changes or other matters applicable to any camera-ready artwork or other materials or information provided by Licensee, and (ii) the Parties acknowledge that delivery times for clinical quantities may vary.

7.4                      **Price, Invoicing, and Cost of Goods Audit**

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7.4.1                      **Price.** The “**Price**” per strength for the Product is as follows:

[\*\*\*]

7.4.2                      **Invoice.** Each delivery of Drug Product hereunder for Commercialization shall be accompanied by an invoice setting forth the Standard Price for such shipment. Licensee will make payment against each invoice, within the earlier of (a) [\*\*\*] after obtaining the affirmative drug testing report at the destination port for the Product covered by a given invoice (provided, that Licensee shall deliver a copy of such drug testing report in English to Amarin within such [\*\*\*] time period) or (b) [\*\*\*] after the Product arrives at the destination port.

7.4.3                      **Cost of Goods Variance.** No later than [\*\*\*] after the end of each Calendar Year, Amarin will provide Licensee with its calculation of the variance between the Standard Price and the actual Price for the previous Calendar Year. If there is a variance between the Standard Price and actual Price for such Calendar Year, then Amarin will promptly issue Licensee an invoice or credit memo, as applicable, for the amount of such variance.

7.4.4                      **Cost of Goods and Price Audit.** Licensee shall have the right to audit the calculation of Amarin’s Cost of Goods and Price. Such audit shall be carried out in the same manner as the audit provisions of Section 8.10 which shall apply *mutatis mutandis* to both Parties to facilitate such right of audit; provided that such audits shall not occur at any time during which Amarin is being audited by its external auditors.

7.5                      **Shipping and Delivery**

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**7.5.1 Delivery.** Subject to the terms and conditions of this Agreement, Amarin shall ship (or have shipped) to Licensee in accordance with this Section 7.5 the quantity of the Drug Product specified in each accepted Purchase Order in accordance with the delivery dates specified in the accepted Purchase Order, provided such dates comply with the lead time for such Drug Product. Any shipment delivered that is within [\*\*\*] of the quantity of Drug Product ordered and delivered no later than [\*\*\*] after the delivery date specified in the relevant Purchase Order will be considered as delivered on time. [\*\*\*].

**7.5.2 Shipment Terms.** Drug Product shall be supplied to Licensee EXW (Incoterms 2010) (Amarin's or its designated Third Party's facility). Delivery shall occur, and title and risk of loss will pass to Licensee at Amarin's or its designated Third Party's facility. Drug Product shall be shipped at Licensee's expense via a carrier identified by Licensee in the applicable Purchase Order; provided, that (a) such carrier shall be one that can transport and maintain such Drug Product in accordance with Product Specifications [\*\*\*], and (b) in the event that Licensee fails to identify a carrier, Amarin may choose a carrier at its own reasonable discretion, at Licensee's expense.

**7.5.3 Retention.** Unless the Parties agree otherwise, Amarin will maintain or cause to be maintained analytical samples of each Drug Product in storage for a time period based upon Amarin's sample retention policy and Applicable Law.

## **7.6 Quality and Compliance**

**7.6.1 Quality Agreements.** The Quality Agreements will set forth the Parties' quality and compliance obligations with respect to Manufacture of the Drug Product and Amarin's quality and compliance obligations with respect to Manufacture of the Drug Substance used in the Drug Product. Licensee and Amarin agree to comply with the requirements and provisions set forth in the Quality Agreements. The Quality Agreements will set forth in greater detail many of the responsibilities and obligations set forth herein. In the event of a conflict between the terms of the Quality Agreements and the terms of this Agreement, the terms of this Agreement shall prevail. The Parties shall execute the Quality Agreements [\*\*\*], or such other time-frame as otherwise agreed between the Parties.

### **7.6.2 Notice of Non-Conformance.**

(a) Amarin shall supply to Licensee the applicable batch number for the Drug Product delivered as well as such other information as the Parties may set forth in the Quality Agreement with respect to the Manufacture of the Product (a "**Manufacturing Certificate of Analysis and Compliance**") for all Drug Product shipped to Licensee hereunder. Licensee shall promptly on receipt of each shipment of Drug Product hereunder inspect, or cause to have inspected, each shipment of such Product for any damage, Defect or shortage, and cause to be tested by the qualified drug testing institution at the destination port in the Territory of each shipment of such Product for any quality issues, within a reasonable period of time and give Amarin written notice of any such damaged, defective or short shipment or any shipment of such

Product with quality issues (a “**Notice of Non-Conformance**”). All testing shall be conducted in accordance with the Product Specifications, Applicable Law and the Quality Agreement. “**Defect**” and “**Defective**” refer to Drug Product that fails to meet the representations and warranties set forth in Section 10.2.1(k) as of the date of delivery.

(b) Latent Defects shall be communicated to Amarin, together with appropriate detail, via a Notice of Non-Conformance, without undue delay after such Latent Defect is first discovered by Licensee (or Licensee otherwise is notified of such Latent Defect), but in all cases within [\*\*\*], and thereafter such Latent Defect shall be handled as set forth in the remainder of this Section 7.6 and/or the Quality Agreement, as applicable. For purposes of this Section 7.6.2(b), “**Latent Defects**” shall mean those defects that could not reasonably be expected to be discovered by inspection or testing by Licensee or its designee as described in Section 7.6.2(a). Notwithstanding the foregoing, Licensee must submit a Notice of Non-Conformance, if at all, with respect to Drug Product no later than [\*\*\*] from the date of delivery of such Drug Product.

**7.6.3 Notification of Significant Quality Issues.** As set forth in the Quality Agreements, the Parties shall notify each other of the occurrence of a confirmed out-of-specification or out-of-trend (“**OOS**”) result or major process deviation relating to the Product and/or Drug Substance in the Territory. The Parties agree to consult on all quality decisions regarding any OOS result or major process deviations involving the Drug Product and/or Drug Substance that is intended for the Territory.

**7.6.4 Audits.** Licensee, together with any Regulatory Authorities having jurisdiction over Licensee or the Product, shall have access to Amarin’s manufacturing facilities associated with the Drug Product or Drug Substance at a mutually agreeable time (or as otherwise required by Applicable Law) for the sole purpose of auditing the facilities for operational compliance with GMPs and Applicable Law, the terms of this Agreement, and the content of the respective Quality Agreement for Drug Product and Drug Substance. The audit rights described in this Section 7.6.4 are without limitation of other audit rights described elsewhere in this Agreement. Unless otherwise required by Applicable Law or a Regulatory Authority, the audit rights described herein may be exercised by Licensee only one time each Calendar Year in the country where the manufacturing facility being audited is located.

## **7.7 Disputes and Remedies**

**7.7.1 Disputes.** If Licensee timely delivers a Notice of Non-Conformance in respect of all or any part of a shipment of the Drug Product and Amarin does not agree with Licensee’s determination that the Drug Product fails to meet the Product Specifications (or there is a short shipment), the Parties shall in good faith attempt to resolve such dispute. Amarin and Licensee shall [\*\*\*] to resolve such dispute regarding whether all or any part of such shipment of Drug Product was Manufactured in conformance with the Product Specifications (or there is otherwise a short shipment). In the event of such a dispute, Licensee shall retain samples of such Drug Product and make such samples available to Amarin at Amarin’s reasonable request. If the

dispute regarding whether all or any part of a shipment of Drug Product rejected by Licensee was Manufactured in conformance with the Product Specifications (or there is a short shipment) is not resolved in such [\*\*\*] period, then the Parties shall submit the samples of such Drug Product to the drug testing institution in the Territory used by Licensee for re-testing. The results of such drug testing qualified institution's re-testing shall be final and binding on the Parties, and if such Drug Product is determined to meet the Product Specifications (or is otherwise determined not to be a short shipment, as applicable), then Licensee shall pay for the costs of such drug re-testing; otherwise Amarin shall pay for such costs.

#### **7.7.2 Remedies.**

(a) In the event any shipment of Drug Product is timely rejected pursuant to this Section 7.7 solely as a result of such Drug Product being Defective, then (a) Licensee shall, at the direction of Amarin, either [\*\*\*]. For clarity, a shipment of Drug Product that is a short shipment shall not be subject to return by Licensee.

(b) [\*\*\*]

#### **7.8 Shortages**

. In the event that Amarin anticipates the materials and/or Manufacturing capacity of Amarin or its Third Party manufacturer required to Manufacture and deliver the Drug Product to Licensee is to be in short supply, Amarin shall promptly notify Licensee of such shortage and the Parties shall promptly meet to discuss the shortage. [\*\*\*] Amarin shall use its Commercially Reasonable Efforts to minimize the duration of any shortage. Licensee shall maintain reasonable safety stock of Drug Product of at least [\*\*\*] of safety stock of the Product based on the [\*\*\*] portion of the most recent Forecast.

#### **7.9 Product Specification and Manufacturing Changes**

. Neither Party shall make any Product Specification changes and/or Drug Product or Drug Substance Specification changes as it pertains to the Product to be supplied in the Territory for the Field without prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed. In the event of such consent, the Parties shall enter into a written supplemental agreement with respect to the division of responsibilities for obtaining Regulatory Approvals for the Product with respect to such changes and the cost to be assumed by each Party in connection therewith. [\*\*\*] Each Party shall provide the other Party with all necessary documentation and information required for preparing the applicable Regulatory Materials with Health Canada; provided that all applicable Regulatory Materials shall be prepared and filed by the Parties in accordance with the provisions of Article 3. [\*\*\*] Notwithstanding the foregoing and the forecasting and ordering provisions under Section 7.3, Amarin shall use Commercially Reasonable Efforts to ensure the sufficient supply of Product to Licensee during the transitional period for the changes set forth in this Section 7.9. Amarin and Licensee shall discuss means to ensure supply throughout this transition period and the Parties may be required to hold a safety stock of Product at each of their respective sites to mitigate any supply shortages that may occur as a result of such changes. For clarity, changes made with respect to the facilities or other sites that are applicable to the supply of Product outside the Field or outside the Territory, or otherwise not applicable to the

Regulatory Materials filed with Health Canada with respect to the supply of the Product in the Territory for the Field, will not be subject to this Section 7.9. The Quality Agreement shall further set out the Parties’ respective rights and obligations in respect of changes to the Product, Product Specifications, Drug Product, Drug Substance Specifications and manufacturing facilities.

## 7.10 Supply Obligations

. Notwithstanding anything to the contrary contained herein, the obligations of Amarin under this Article 7, including the obligations to Manufacture and supply Drug Product to Licensee hereunder, and Licensee’s obligations to purchase solely from Amarin, shall continue during the Royalty Term and, so long as Licensee desires to continue purchasing the Drug Product, shall continue after the end of the Royalty Term, in accordance with Section 8.3.2.

## ARTICLE 8 PAYMENTS

### 8.1 Upfront Payment

. Licensee shall pay to Amarin an upfront amount equal to Five Million Dollars (\$5,000,000) (the “**Upfront Payment**”) in two (2) installments of Two Million Five Hundred Thousand Dollars (\$2,500,000) each for the grant of Commercialization rights for the Product in the Territory for the Field and other services provided by Amarin (outside of the Territory) hereunder. The first such installment shall be paid on the Effective Date and the second such installment shall be paid on the six (6) month anniversary of the Effective Date. Each such installment shall be paid by wire transfer of immediately available funds into an account designated in writing by Amarin. The Upfront Payment shall be nonrefundable and noncreditable against any other payments due hereunder.

### 8.2 Milestone Payments

. Licensee shall pay to Amarin the milestone payments described in this Section 8.2 following achievement (first occurrence) of the corresponding milestone event. A Party shall promptly notify the other Party in writing of, but in no event later than [\*\*\*] after, the achievement (first occurrence) of each such milestone event (each, a “**Milestone Notification Notice**”) achieved by it. Licensee shall pay the applicable milestone payment by wire transfer of immediately available funds into an account designated by Amarin [\*\*\*] after the date of the Milestone Notification Notice; provided, however, that in no event shall a failure to deliver a Milestone Notification Notice relieve Licensee of its obligation to pay Amarin the milestone payments described in this Section 8.2. Each such milestone payment shall be payable only once regardless of how many times the milestone event is achieved. Each such milestone payment is nonrefundable and noncreditable against any other payments due hereunder.

**8.2.1 Regulatory Milestones.** Licensee shall make the following payments to Amarin upon achievement of any of the milestone events set forth in the table directly below with respect to the Product:

[\*\*\*]

**8.2.2 Sales Milestones.** Licensee shall make the following additional payments to Amarin for the exclusive rights and use of Amarin Technology in the Territory as shown in the table directly below the first time that annual Net Sales in the Territory reach the indicated Net Sales thresholds (the “**Annual Net Sales Threshold**”).

[\*\*\*]

### **8.3 Royalty Payments; Sublicense Revenue**

**8.3.1 Royalty Payments.** As further consideration for the exclusive license to the Amarin Technology granted to Licensee under this Agreement, Licensee shall pay to Amarin tiered payments (“**Royalty Payments**”) at the following rates (the “**Royalty Rates**”) based on aggregate annual Net Sales of Product in the Territory for all or any portion of the Calendar Year falling within the Royalty Term for such Product:

[\*\*\*]

**8.3.2 Expiration of Royalty Term.** If Licensee continues to Commercialize the Product following expiration of the Royalty Term, then in consideration of the continuing value of the Amarin Know-How, the Licensee will pay Amarin a royalty on aggregate annual Net Sales of the Product by Licensee at a royalty rate of [\*\*\*].

**8.3.3 Sublicense Revenue.** In addition to other amounts due under this Section 8.3, Licensee will pay Amarin [\*\*\*] (“**Sublicense Revenue Payment**”).

### **8.4 Royalty Reports and Payment Procedures**

. Licensee shall calculate all (a) Royalty Payments with respect to Net Sales, and (b) Sublicense Revenue, payable to Amarin pursuant to Section 8.3 at the end of each Calendar Quarter, which amounts shall be converted to U.S. Dollars at such time in accordance with Section 8.6. Licensee shall provide a written estimate of Sublicense Revenue received and Net Sales during the just ended Calendar Quarter within [\*\*\*] of the end of such Calendar Quarter. Thereafter, Licensee shall pay to Amarin the Royalty Payment due for Net Sales, and Sublicense Revenue Payment due for Sublicense Revenue, during a given Calendar Quarter within [\*\*\*] following the end of such Calendar Quarter. Each Royalty Payment and Sublicense Revenue Payment due to Amarin shall be accompanied by (i) a statement of the amount of gross sales of the Product in the Territory, and gross Sublicense Revenue received, during the applicable Calendar Quarter (such amounts expressed in local currency and in U.S. Dollars converted at the relevant time in accordance with Section 8.6), (ii) a summary calculation of Net Sales in the Territory, showing each deduction provided for in the definition of “Net Sales” during such Calendar Quarter, and (iii) a calculation of the amount of the Royalty Payment due on such Net Sales, and the Sublicense Revenue Payment due on such Sublicense Revenue, for such Calendar Quarter. Without limiting the generality of the foregoing, Licensee shall require its Affiliates and Sublicensees (if any) to

account for its Net Sales and to provide such reports with respect thereto as if such sales were made by Licensee.

## 8.5 Taxes

**8.5.1** Each of the Parties, respectively, shall pay and/or withhold taxes in accordance with Applicable Laws.

**8.5.2** **VAT.** The Parties agree to cooperate with one another and use reasonable efforts to ensure that value added tax or similar payment (“**VAT**”) in respect of any payments made by Licensee to Amarin under this Agreement does not represent an unnecessary cost in respect of payments made under this Agreement. For purposes of clarity, all sums payable under this Agreement shall be exclusive of VAT. In the event that any VAT is owing in any jurisdiction in respect of any such payment, Licensee shall pay such VAT, and the payment in respect of which such VAT is owing shall be made without deduction for or on account of such VAT to ensure that Amarin receives a sum equal to the sum which it would have received had such VAT not been due. In the event that any VAT is owing in any jurisdiction in respect of any such payment, Amarin will provide to Licensee tax invoices showing the correct amount of VAT in respect of such payments hereunder.

## 8.6 Withholding Tax

**8.6.1** **Tax Cooperation.** To the extent Licensee is required to deduct and withhold taxes on any payments to Amarin, Licensee shall pay the amounts of such taxes to the proper Governmental Authority in a timely manner and promptly transmit to Amarin an official tax certificate or other evidence of such withholding sufficient to enable Amarin to claim such payment of taxes. [\*\*\*] Each Party shall provide the other with reasonable assistance to enable the recovery, as permitted by Applicable Laws, of withholding taxes, VAT, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding tax or VAT.

**8.6.2** [\*\*\*].

**8.6.3** [\*\*\*].

**8.6.4** **Indirect Tax.** All payments to be made by Licensee to Amarin pursuant to the terms of this Agreement are stated exclusive of Indirect Taxes. If any Indirect Taxes are chargeable in respect of such payments, Licensee shall pay such Indirect Taxes.

## 8.7 Currency Conversion

. All payments hereunder shall be made in U.S. Dollars. For the purpose of calculating any sums due under, or otherwise reimbursable pursuant to, this Agreement (including the calculation of Net Sales expressed in currencies other than U.S. Dollars), any amount expressed in a foreign currency shall be converted into U.S. Dollars based on Licensee’s usual accounting systems and processes consistently applied and IFRS as of the

last day of the relevant Calendar Quarter or the date that a milestone is achieved. For the avoidance of doubt, unless expressly referencing Canadian Dollars (CAD), all statements of or references to monetary amounts in this proposal are U.S. dollars.

## 8.8 General Payment Procedures

. Unless otherwise expressly payable in certain time frames as provided in this Agreement (including Section 7.4.1), the receiving Party shall invoice the paying Party for all amounts due to such receiving Party under this Agreement, and such payments shall be made within [\*\*\*] following the receipt by the paying Party of an invoice from the receiving Party specifying the amount due.

## 8.9 Late Payments

. Any amount required to be paid by a Party hereunder which is not paid within [\*\*\*] shall bear interest at a rate equal to the thirty (30) day Dollar LIBOR rate effective for the date that payment was first due as reported by The Wall Street Journal, eastern edition, [\*\*\*]. Such interest shall be computed on the basis of a year of three hundred sixty (360) days for the actual number of days payment is delinquent. Interest charged and paid with respect to any late payments will not limit any other remedies that may be available to a Party.

## 8.10 Financial Records and Audit

. Licensee (and its Affiliates and Sublicensees) shall keep full, true and accurate records and books of account containing all particulars that may be reasonably necessary for the purpose of confirming the accuracy of, and calculating, as applicable, all Royalty Payments, Sublicense Revenue Payments and other amounts payable to Amarin hereunder (including records of Net Sales and Sublicense Revenue), for a minimum period of [\*\*\*] or such longer period as required by Applicable Laws. Amarin shall have a right to request an audit of Licensee by an independent, internationally recognized accounting firm in order to confirm the accuracy of the foregoing (a “**Financial Audit**”) no more than [\*\*\*]. Upon the written request by Amarin to Licensee to conduct a Financial Audit, Amarin shall have the right to engage an independent, internationally recognized accounting firm to perform a review as is reasonably necessary to enable such accounting firm to calculate or otherwise confirm the accuracy of any of the foregoing for the Calendar Year in which the Financial Audit is requested by Amarin [\*\*\*]; provided, that (a) such accountants shall be given access to, and shall be permitted to examine and copy such books and records of Licensee [\*\*\*], (b) prior to any such examination taking place, such accountants shall enter into a confidentiality agreement with Licensee reasonably acceptable to Licensee in order to keep all information and data contained in such books and records strictly confidential and shall not disclose such information or copies of such books and records to any third person including Amarin, but shall only use the same for the purpose of the reviews and/or calculations which they need to perform in order to determine any amounts being reviewed, and (c) such accountants shall use reasonable efforts to minimize any disruption to Licensee’s business. Licensee shall make personnel reasonably available during regular business hours to answer queries on all such books and records required for the purpose of the Financial Audit. The accountants shall deliver a copy of their findings to each of the Parties within [\*\*\*] of the completion of the review, and, in the absence of fraud or manifest error, the findings of such accountant shall be final and binding on each of the Parties. Any underpayments by Licensee shall be paid to Amarin within [\*\*\*] of notification of the results of



such inspection. Any overpayments made by Licensee shall be refunded by Amarin within [\*\*\*] of notification of the results of such inspection. [\*\*\*] Without limitation of the foregoing, Licensee shall have the right to audit the calculation of any costs incurred by Amarin and with respect to which Amarin is seeking reimbursement from Licensee hereunder, on the same terms and conditions as Amarin may audit Licensee's records under this Section 8.10 (substituting references to "Amarin" for "Licensee", and vice versa, and substituting references to "Development Costs", "Regulatory Costs", "Price" or other costs or expenses for which Amarin is entitled to reimbursement hereunder, for "Net Sales"). The audit rights described in this Section 8.10 are without limitation of other audit rights described elsewhere in this Agreement.

## ARTICLE 9 INTELLECTUAL PROPERTY MATTERS

### 9.1 Ownership of Intellectual Property

**9.1.1 General.** Subject to the provisions of this Section 9.1.1 and except as expressly set forth otherwise in this Agreement, (a) Amarin shall solely own, and it alone shall have the right to apply for, Amarin Patents within and outside of the Territory, and (b) Licensee shall solely own, and it alone shall have the right to apply for, Licensee Patents within and outside of the Territory. With respect to any Patents Covering any Joint Inventions ("**Joint Patents**"), each Party will co-own such Joint Patents in accordance with determination of inventorship as provided below. Any Confidential Information contained in such Joint Inventions shall be deemed "Confidential Information" of each Party. Each Party shall promptly disclose to the other Party all Amarin Inventions, Licensee Inventions and Joint Inventions, as applicable, made by it in respect of the Product during the Term to determine whether patent protection shall be sought. The determination of inventorship and subsequent ownership for such Inventions shall be made in accordance with Applicable Laws relating to inventorship as set forth in the Patent Statute of the United States (Title 35, United States Code), and case law construing such determination. Licensee agrees that it shall not grant any license or other right with respect to Licensee Inventions or Joint Inventions to any Third Party without the prior written consent of Amarin.

**9.1.2 Employees.** Each Party will require all of its and its Affiliates' employees to assign all Inventions relating to the Product that are developed, made or conceived by such employees to the applicable Party according to the ownership principles described in Section 9.1.1 free and clear of all liens, encumbrances, charges, security interests, mortgages or other similar restrictions. Each Party will also use its Commercially Reasonable Efforts to require any agents or independent contractors performing an activity pursuant to this Agreement to assign all Inventions relating to the Product that are developed, made or conceived by such agents or independent contractors to Amarin and/or Licensee according to the ownership principles described in Section 9.1.1 free and clear of all liens, encumbrances, charges, security interests, mortgages or other similar restrictions.

. Each Party shall, before filing a new Patent application (including provisionals and continuations-in-part) claiming or covering an Invention relating to the Product, promptly disclose such Invention to the other Party and shall provide the other Party with a copy of the proposed patent application at [\*\*\*] before filing such application or such shorter time as may be required to preserve Patent rights, including the avoidance of a statutory bar or prior publication. If the non-filing Party believes that the filing Party's proposed Patent application discloses Confidential Information of the non-filing Party, the non-filing Party shall so notify the filing Party within such [\*\*\*] after receipt thereof, and the filing Party shall amend its proposed application to comply with the confidentiality provisions of this Agreement. If the Parties are in agreement as to the designation of the Invention as an Amarin Invention, Joint Invention or Licensee Invention, as applicable, they can continue as set forth in Section 9.3. If the Parties disagree as to whether an Invention is an Amarin Invention, Joint Invention or Licensee Invention, and are unable to reach agreement [\*\*\*] after commencing discussions, then the provisions of Article 15 shall apply to such dispute.

### **9.3 Patent Filings, Prosecution and Maintenance**

#### **9.3.1 Amarin Patents.**

(a) Subject to, and without limiting Licensee's rights under, Section 9.4 of this Agreement, Amarin [\*\*\*] all Amarin Patents, at its own cost and expense, and Amarin, in its sole discretion, shall make all determinations with respect to such activities as it deems in the best interest of Amarin's global intellectual property interests. Amarin shall keep Licensee informed of the status of Amarin Patents and will provide Licensee with copies of all substantive documentation submitted to, or received from, the patent offices in connection therewith. [\*\*\*].

(b) If, during the Term, Amarin, in its sole discretion, (i) intends to allow any Amarin Patent to which Licensee has a license under this Agreement to expire or intends to otherwise abandon any such Amarin Patent, or (ii) decides not to prepare or file patent applications covering Amarin Inventions in the Territory to which Licensee would otherwise have a license under this Agreement, Amarin shall notify Licensee of such intention or Patent decision [\*\*\*] prior to any filing or payment due date, or any other date that requires action, in connection with such Amarin Patent or Amarin Inventions. In such event, Licensee shall have the right to take or not take such actions with respect to such Amarin Patent as Licensee may reasonably deem necessary to protect the Product in the Territory; [\*\*\*].

#### **9.3.2 Joint Patents. [\*\*\*].**

#### **9.3.3 Licensee Patents.**

(a) Licensee shall have the first right, but not the obligation, to prepare, file, prosecute and maintain all Licensee Patents, at its own cost and expense. Licensee shall keep Amarin informed of the status of Licensee Patents and will provide Amarin with copies of all substantive documentation submitted to, or received from, the patent offices in connection

therewith. With respect to any substantive submissions that Licensee is required to or otherwise intends to submit to a patent office with respect to a Licensee Patent, Licensee shall provide a draft of such submission to Amarin at least [\*\*\*] prior to the deadline for, or the intended filing date of, such submission, whichever is earlier [\*\*\*]. Amarin shall have the right to review and comment upon any such submission by Licensee to a patent office, [\*\*\*]. Licensee shall consider in good faith any suggestions or recommendations of Amarin concerning the preparation, filing, prosecution and maintenance thereof.

(b) With respect to the Licensee Patents outside of the Territory, Licensee shall notify Amarin before entering such Licensee Patent into national phase filings, and if Amarin notifies Licensee that Amarin desires to file, prosecute and maintain (at its own expense), such Licensee Patent, said patent will be licensed, after completion of national phase filing, to Amarin, and Amarin shall have the right at Amarin’s expense to file, prosecute and maintain such Licensee Patent as licensed to Amarin. If Amarin does not notify Licensee that Amarin desires to do so, then Licensee may file, prosecute and maintain such Licensee Patent outside of the Territory at its discretion.

(c) If, during the Term, Licensee (i) intends to allow any Licensee Patent to which Amarin has a license under this Agreement to expire or intends to otherwise abandon any such Licensee Patent, or (ii) decides not to prepare or file patent applications covering Licensee Know-How or Licensee Inventions to which Amarin would otherwise have a license under this Agreement, Licensee shall notify Amarin of such intention or decision at least [\*\*\*] prior to any filing or payment due date, or any other date that requires action, in connection with such Licensee Patent or Licensee Inventions, and Amarin shall thereupon have the right, but not the obligation, to assume responsibility for the preparation, filing, prosecution or maintenance thereof [\*\*\*], and, to the extent such Licensee Patent Covers a Licensee Invention, Licensee shall assign to Amarin Licensee’s entire right, title and interest in and to any such Licensee Patents (rendering, for clarity, such Licensee Patent an Amarin Patent hereunder).

**9.3.4 Cooperation.** The Parties agree to reasonably cooperate in the preparation, filing, prosecution and maintenance of all Patents under this Section 9.3, including obtaining and executing necessary powers of attorney and assignments by the named inventors, providing relevant technical reports to the filing Party concerning the Invention disclosed in such Patent, obtaining execution of such other documents which are needed in the filing and prosecution of such Patent, and, as requested by a Party, updating each other regarding the status of such Patent, and shall cooperate with the other Party so far as reasonably necessary with respect to furnishing all information and data in its possession reasonably necessary to obtain or maintain such Patents.

**9.3.5 Patent Expenses.** Any expenses incurred by a Party in connection with the preparation, filing, prosecution and maintenance of any Amarin Patents, Joint Patents or Licensee Patents, as applicable, shall be borne by the Party incurring such expenses.

**9.4 Defense and Enforcement of Patents**

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#### 9.4.1

**Infringement of Third Party Patents.** Each of the Parties shall promptly, but in any event no later than ten (10) Business Days after receipt of notice thereof, notify the other Party in writing in the event of any claims by a Third Party of alleged patent infringement by Licensee or Amarin or any of their respective Affiliates or sublicensees (in the case of Amarin) or Sublicensees (in the case of Licensee) with respect to the research, development, manufacture, use, sale, offer for sale or importation of the Product in the Territory (each, an “**Infringement Claim**”). With respect to any Infringement Claim in the Territory for the Field, the Parties shall attempt to negotiate in good faith a resolution with respect thereto. If the Parties cannot settle such Infringement Claim with the appropriate Third Parties within thirty (30) days after the receipt of the notice pursuant to this Section 9.4.1, then the following shall apply:

(a) In the case of any such Infringement Claim, in respect of [\*\*\*], then [\*\*\*] shall be deemed to be the “**Controlling Party**” for purposes of such Infringement Claim, [\*\*\*]. In the case of any Infringement Claim, in respect of [\*\*\*], then [\*\*\*] shall be deemed to be the “**Controlling Party**” for purposes of such Infringement Claim, [\*\*\*]. Each Party shall reasonably assist the other in its role as the Controlling Party.

(b) The Controlling Party shall assume control of the defense of such Infringement Claim. The non-Controlling Party, upon request of the Controlling Party, agrees to join in any such litigation at the Controlling Party’s expense, and in any event to reasonably cooperate with the Controlling Party at the Controlling Party’s expense. The non-Controlling Party will have the right to consult with the Controlling Party concerning such Infringement Claim and to participate in and be represented by independent counsel in any litigation in which such non-Controlling Party is a party at its own expense. The Controlling Party shall have the right to settle any Infringement Claim without the consent of the other Party, unless (i) such settlement shall have a material adverse impact on the other Party (in which case the consent of such other Party shall be required to settle the Infringement Claim); or (ii) such settlement may, in Amarin’s sole discretion, adversely impact Amarin’s global intellectual property interests, in which case Amarin shall have the right to settle such Infringement Claim. For purposes of this Section 9.4.1(b), any settlement that would involve the waiver of rights (including the rights to receive payments) of such other Party shall be deemed a material adverse impact and shall require the consent of such other Party, such consent not to be unreasonably withheld, conditioned or delayed.

(c) If a Party shall become engaged in or participate in any suit described in this Section 9.4.1, the other Party shall cooperate, and shall cause its and its Affiliates’ employees to cooperate, with such Party in all reasonable respects in connection therewith, including giving testimony and producing documents lawfully requested, and using its reasonable efforts to make available to the other. The Controlling Party will reimburse the other Party and its employees who may be helpful with respect to such suit, investigation, claim or other proceeding for their time in complying with such cooperation and for actually incurred, reasonable Out-of-Pocket Costs associated with travel and lodging, and work disruption.

(a) **Notice.** If either Party (i) receives notice of any patent nullity actions, Notice of Allegation (“**NOA**”) (pursuant to the Patented Medicine Notice of Compliance (“**PM NOC**”) regulations), any declaratory judgment actions or any alleged or threatened infringement of patents or patent applications or misappropriation of intellectual property in the Territory comprising the (A) Joint Inventions or Joint Patents, (B) Amarin Patents, Amarin Inventions or Amarin Know-How or (C) Licensee Patents, Licensee Inventions or Licensee Know-How, or (ii) learns that a Third Party is infringing or allegedly infringing any Patent within the Amarin Patents, Joint Patents or Licensee Patents in each case, in the Territory, or if any Third Party claims that any such Patent is invalid or unenforceable, in each case, with respect to the Territory for the Field, it shall promptly (within ten (10) days of receiving an NOA or other action) notify the other Party thereof, including providing evidence of infringement or the claim of invalidity or unenforceability reasonably available to such Party.

(b) **Enforcement of Patents.** [\*\*\*].

(c) **Cooperation; Damages.**

(i) If one Party brings any suit, action or proceeding under Section 9.4.2(b), the other Party agrees [\*\*\*].

(ii) Any settlements, damages or other monetary awards (a “**Recovery**”) recovered pursuant to a suit, action or proceeding brought pursuant to Section 9.4.2(b) [\*\*\*].

#### 9.5 Patent Term Extensions

. [\*\*\*].

#### 9.6 Patent Marking

. Licensee shall mark the Product marketed and sold by Licensee (or its Affiliates, Sublicensees or Distributors) hereunder with appropriate patent numbers or indicia, as long as it is required by Applicable Laws.

9.7 [\*\*\*].

### ARTICLE 10 REPRESENTATIONS, WARRANTIES AND COVENANTS

#### 10.1 Mutual Representations and Warranties

. Each Party hereby represents, warrants, and covenants (as applicable) to the other Party as follows, as of the Effective Date:

(a) It has the corporate power and authority to execute and deliver this Agreement and to perform its obligations hereunder, and the execution, delivery and performance of this Agreement has been duly and validly authorized and approved by proper corporate action on the part of such Party. Assuming due authorization, execution and delivery

on the part of the other Party, this Agreement constitutes a legal, valid and binding obligation of such Party, enforceable against such Party, in accordance with its terms.

(b) The execution and delivery of this Agreement by it and the performance by it contemplated hereunder will not violate any Applicable Laws, and, to its knowledge, it is in compliance in all material respects with all material Applicable Laws applicable to the subject matter of this Agreement.

(c) It is not a party to any agreement or arrangement with any Third Party or under any obligation or restriction (including any outstanding order, judgment or decree of any court or administrative agency) which in any way limits or conflicts with its ability to fulfill any of its obligations under this Agreement.

(d) Except with respect to Regulatory Approvals for the Development, Manufacturing or Commercialization of the Product or as otherwise described in this Agreement, (i)all necessary consents, approvals and authorizations of, and (ii)all notices to, and filings by such Party with, all Governmental Authorities and other Persons required to be obtained or provided by such Party as of the Effective Date in connection with the execution, delivery and performance of this Agreement have been obtained and provided, except for those approvals, if any, not required at the time of execution of this Agreement.

(e) In the course of the Development of Products, such Party has not used prior to the Effective Date and shall not use, during the Term, any employee, agent or, to its knowledge, independent contractor who has been debarred by any Regulatory Authority, or, to such Party's knowledge, is the subject of debarment proceedings by a Regulatory Authority.

## **10.2 Additional Representations, Warranties and Covenants of Amarin**

. Except as set forth on Schedule 10.2, Amarin hereby represents, warrants and covenants (as applicable) to Licensee that:

(a) As of the Effective Date, Amarin is solvent and has the ability to pay and perform all of its obligations as and when such obligations become due, including payment obligations and other obligations under this Agreement.

(b) As of the Effective Date, Amarin has not filed any application for Product Approval in the Territory for the sale of the Product in the Territory, and, to the knowledge of Amarin, no application for Product Approval for any Competing Product has been filed with Health Canada by any Third Party which would block the application for Product Approval for the Product in the Territory.

(c) As of the Effective Date, Amarin is the owner or licensee of, and has the right to license, the Amarin Patents, Amarin Know-How, necessary to Develop, Manufacture and Commercialize the Product in the Territory for the Field; in each case, free and clear of any lien or encumbrance.

(d) As of the Effective Date, neither Amarin nor its Affiliates, nor, to the knowledge of Amarin, its subcontractors nor sublicensees, has received written notice of any proceedings pending before or threatened by any Regulatory Authority with respect to the Product or any Facility where the Drug Product is Manufactured, nor does Amarin have knowledge of any reasonable basis for such a proceeding.

(e) As of the Effective Date, to the knowledge of Amarin, no Third Party (i) is infringing any Amarin Patents or has misappropriated any Amarin Technology or (ii) has challenged the scope, duration, validity, enforceability, priority, or Amarin's right to use or license any Amarin Technology.

(f) As of the Effective Date, Amarin (or its Affiliate) is the exclusive owner of the trademark registrations for VASCEPA® as displayed on Schedule 6.11.1.

(g) As of the Effective Date, neither Amarin nor any of its Affiliates have received any written warning that any Patent, trademark or other intellectual property right owned by a Third Party would be infringed by the research, Development, Manufacture, Commercialization, use or import of the Product in the Territory for the Field.

(h) As of the Effective Date, Amarin has obtained assignments from the inventors of all inventorship rights relating to the Amarin Patents which are owned by Amarin, and, to the knowledge of Amarin, all such assignments of inventorship rights relating to such Amarin Patents are valid and enforceable.

(i) As of the Effective Date, Amarin has complied with all Applicable Laws, in all material respects.

(j) As of the Effective Date, Amarin has maintained, and during the Term, Amarin shall use Commercially Reasonable Efforts to maintain, valid Regulatory Approvals in compliance with Regulatory Authority requirements, along with support programs, such as pharmacovigilance systems, for the Product in the U.S.

(k) During the Term, the Drug Product furnished by Amarin to Licensee under this Agreement:

(i) shall be manufactured, handled, stored and shipped by Amarin, in accordance with, and shall conform to, the applicable Product Specifications;

(ii) shall be manufactured, handled and stored by or on behalf of Amarin in compliance with all Applicable Laws, including GMPs; and

(iii) shall be manufactured using Drug Substance which is manufactured, handled, stored and shipped by or on behalf of Amarin in accordance with, and

conforms to, the applicable Drug Substance Specifications and in compliance with all Applicable Laws, including GMPs.

### 10.3 Additional Representations, Warranties and Covenants of Licensee

. Licensee hereby represents, warrants and covenants (as applicable) to Amarin that:

(a) As of the Effective Date, Licensee is solvent and has the ability to pay and perform all of its obligations as and when such obligations become due, including payment obligations and other obligations under this Agreement.

(b) As of the Effective Date, Licensee's compensation programs for its Sales Representatives do not, and during the Term will not with respect to the Product, provide financial incentives for the promotion, sales, and marketing in violation of any Applicable Laws or any professional requirements.

(c) During the Term, Licensee's medical, regulatory or legal teams will review all training materials and programs prior to use by Licensee to ensure that such training materials and programs are in accordance with the Commercialization Plan and the Regulatory Approvals and in compliance with Applicable Laws.

(d) During the Term, all Product used in Development Activities or Commercialized, by, or under authority of, Licensee:

(i) shall be handled, stored and shipped by Licensee, in accordance with the applicable Product Specifications;

(ii) shall be handled, stored and shipped by Licensee in compliance with all Applicable Laws, including GMPs; and

(iii) shall, during the time such Product is under the care or Control of Licensee or any of its Affiliates, not cause the Product to be adulterated or misbranded within the meaning of Applicable Laws.

(e) As of the Effective Date, no claim or demand of any Person has been asserted in writing to Licensee arising out of Licensee's development, regulatory or commercialization activities with respect to any other products that would reasonably be expected to adversely affect Licensee's ability to perform any of its obligations under this Agreement, and no investigations are pending or, to the knowledge of Licensee, threatened relating to such activities.

(f) As of the Effective Date, Licensee has complied with all Applicable Laws, in all material respects.

(g) As of the Effective Date, Licensee has obtained assignments from the inventors of all inventorship rights relating to the Licensee Patents which are owned by Licensee,



and, to the knowledge of Licensee, all such assignments of inventorship rights relating to such Licensee Patents are valid and enforceable.

#### **10.4**                      Disclaimer

. Subject to the regulatory and commercial status of the Product in the U.S. as of the Effective Date, Licensee understands that the Product is the subject of ongoing clinical research and development and that Amarin cannot ensure the safety or usefulness of the Product or that the Product will receive Regulatory Approvals. In addition, Amarin makes no warranties except as set forth in this Article 10 concerning the Amarin Technology.

#### **10.5**                      No Other Representations or Warranties

. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, ARE MADE OR GIVEN BY OR ON BEHALF OF A PARTY. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.

### **ARTICLE 11 INDEMNIFICATION**

#### **11.1**                      Indemnification by Amarin

. Amarin hereby agrees to save, indemnify, defend and hold Licensee, its Affiliates and Sublicensees, and their respective directors, officers, agents and employees harmless from and against any and all losses, damages, liabilities, costs and expenses (including reasonable attorneys' fees and expenses) (collectively, "**Losses**") arising in connection with any and all charges, complaints, actions, suits, proceedings, hearings, investigations, claims, demands, judgments, orders, decrees, stipulations or injunctions by a Third Party (each a "**Third Party Claim**") to the extent resulting or otherwise arising from (a) any breach by Amarin or its Affiliates, sublicensees or subcontractors of Applicable Law or any of Amarin's representations, warranties, covenants or obligations pursuant to this Agreement, (b) the negligence or willful misconduct by Amarin or its Affiliates, sublicensees or subcontractors or their respective officers, directors, employees, agents or consultants in performing any obligations under this Agreement or (c) any matter related to the Development or Manufacturing of the Product hereunder (including, for clarity, product liability Losses resulting therefrom) by or on behalf of Amarin or its Affiliates, sublicensees or subcontractors or their respective officers, directors, employees, agents or consultants.

#### **11.2**                      Indemnification by Licensee

. Licensee hereby agrees to save, indemnify, defend and hold Amarin, its Affiliates, and their respective directors, agents and employees harmless from and against any and all Losses arising in connection with any and all Third Party Claims to the extent resulting or otherwise arising from (a) any breach by Licensee (or by any of its Affiliates, Sublicensees, subcontractors, or Distributors) or any of Licensee's representations, warranties, covenants or obligations pursuant to this Agreement, (b) any breach by Licensee (or

by any of its Affiliates or Sublicensees or subcontractors) of Applicable Law, (c) the negligence or willful misconduct by Licensee (or by any of its Affiliates, Sublicensees or subcontractors) or their respective officers, directors, employees, agents or consultants in performing any obligations under this Agreement, (d) the Development or Commercialization of the Product hereunder (including, for clarity, any product liability Losses to the extent resulting therefrom) by or on behalf of Licensee (or by any of its Affiliates, Sublicensees or subcontractors, or their respective officers, directors, employees, agents or consultants), or (e) the failure by Licensee to initiate a Product recall, withdrawal or market notification that is proposed by Amarin under Section 5.8.1.

### 11.3 Indemnification Procedures

. The obligations to indemnify and defend set forth in Sections 11.1 and 11.2 shall be contingent upon the Party seeking indemnification (the “**Indemnatee**”): (a) notifying the indemnifying Party of a claim, demand or suit within fifteen (15) Business Days of receipt of same (provided, however, that Indemnatee’s failure or delay in providing such notice shall not relieve the indemnifying Party of its indemnification obligation except to the extent the indemnifying Party is prejudiced thereby), (b) allowing the indemnifying Party and/or its insurers the right to assume direction and control of the defense of any such Third Party Claim (subject to the limitations set out in this Section 11.3), (c) using its Commercially Reasonable Efforts to cooperate with the indemnifying Party and/or its insurers in the defense of such Third Party Claim at the indemnifying Party’s expense, and (d) agreeing not to settle or compromise any Third Party Claim without prior written authorization of the indemnifying Party. Indemnatee shall have the right to participate in the defense of any such claim referred to in this Section 11.3 utilizing attorneys of its choice, at its own expense; provided, however, that the indemnifying Party shall have full authority and control to handle any such claim. The indemnifying Party shall have the right to settle or compromise any action or otherwise seek to terminate any pending or threatened action for which indemnity may be sought hereunder (whether or not any indemnified Party is a party thereto) as long as such settlement, compromise or termination includes an unconditional release of, and does not include an admission of liability by, each indemnified Party from all liability in respect of such Third Party Claim.

### 11.4 Limitation of Liability

. EXCEPT WITH RESPECT TO LOSSES AWARDED TO A THIRD PARTY IN A THIRD PARTY CLAIM FOR WHICH A PARTY IS OBLIGATED TO INDEMNIFY THE OTHER PARTY UNDER SECTION 11.1 or 11.2, OR DAMAGES AVAILABLE FOR A PARTY’S BREACH OF SECTIONS 2.1, 2.5.1, OR 6.5 OR CONFIDENTIALITY OBLIGATIONS UNDER Article 12, NEITHER PARTY SHALL, EXCEPT IN THE CASE OF FRAUDULENT ACTIVITY, BE LIABLE TO THE OTHER FOR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT OR EXPECTATION DAMAGES ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES.

### 11.5 Insurance

. Each Party shall procure and maintain insurance that is available on commercially reasonable terms, including general liability, clinical trial insurance, product

liability insurance and other insurance as necessary, adequate to cover its obligations hereunder and which is consistent with normal business practices of prudent companies similarly situated at all times during which Product is being clinically tested in human subjects or commercially distributed or sold by a Party pursuant to this Agreement. It is understood that such insurance shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under this Article 11. Each Party shall provide the other Party with written evidence of such insurance upon request of the other Party and upon expiration of any such coverage. Each Party shall provide the other Party with written notice at least thirty (30) days prior to the cancellation, nonrenewal or material change in such insurance which materially adversely affects the rights of the other Party hereunder. Without limiting the foregoing, each Party shall cause its insurance policies to name the other Party as an additional insured without cost to such other Party.

## ARTICLE 12 CONFIDENTIALITY

### 12.1 Confidential Information

. As used in this Agreement, the term “**Confidential Information**” means all information, whether it be written or oral, including all production schedules, lines of products, volumes of business, processes, new product developments, product designs, formulae, technical information, patent information, Know-How, trade secrets, financial and strategic information, marketing and promotional information and data, and other material relating to any products, projects or processes of one Party (the “**Disclosing Party**”) that is provided to, or otherwise obtained by, the other Party (the “**Receiving Party**”) in connection with this Agreement (including information exchanged prior to the date hereof in connection with the transactions set forth in this Agreement, including any information disclosed by either Party pursuant to the Confidentiality Agreement between the Parties dated January 30, 2017 (the “**Confidentiality Agreement**”)). Notwithstanding the foregoing sentence, Confidential Information shall not include any information or materials that:

(a) were already known to the Receiving Party (other than under an obligation of confidentiality), at the time of disclosure by the Disclosing Party, to the extent such Receiving Party has documentary evidence to that effect;

(b) were generally available to the public or otherwise part of the public domain at the time of disclosure thereof to the Receiving Party;

(c) became generally available to the public or otherwise part of the public domain after disclosure or development thereof, as the case may be, and other than through any act or omission of a Party in breach of such Party's confidentiality obligations under this Agreement; or

(d) were independently discovered or developed by or on behalf of the Receiving Party without the use of the Confidential Information belonging to the other Party, to the extent such Receiving Party has documentary evidence to that effect.

. Each of Licensee and Amarin shall keep all Confidential Information received from or on behalf of the other Party with the same degree of care with which it maintains the confidentiality of its own Confidential Information, but in all cases no less than a reasonable degree of care. Neither Party shall use such Confidential Information for any purpose other than in performance of this Agreement, or exercise of rights under this Agreement, or disclose the same to any other Person other than to such of its and its Affiliates' directors, managers, employees, independent contractors, agents, consultants or, solely with respect to Amarin, its sublicensees, who have a need to know such Confidential Information to implement the terms of this Agreement or enforce its rights under this Agreement; provided, however, that a Receiving Party shall advise any of its and its Affiliates' directors, managers, employees, independent contractors, agents, consultants or, solely with respect to Amarin, its sublicensees, who receives such Confidential Information of the confidential nature thereof and of the obligations contained in this Agreement relating thereto, and the Receiving Party shall ensure (including, in the case of a Third Party, by means of a written agreement with such Third Party having terms at least as protective as those contained in this Article 12) that all such directors, managers, employees, independent contractors, agents, consultants or, solely with respect to Amarin, its sublicensees comply with such obligations. Upon termination of this Agreement, the Receiving Party shall return or destroy all documents, tapes or other media containing Confidential Information of the Disclosing Party that remain in the possession of the Receiving Party or its directors, managers, employees, independent contractors, agents, consultants or, solely with respect to Amarin, its sublicensees, except that the Receiving Party may keep one copy of the Confidential Information in the legal department files of the Receiving Party, solely for archival purposes, and shall not be required to destroy any automatically generated back-up files for disaster or business recovery purposes provided access to such files is limited. Such archival or other copies shall be deemed to be the property of the Disclosing Party, and shall continue to be subject to the provisions of this Article 12.

### 12.3

#### Permitted Disclosure and Use

. Notwithstanding Section 12.2, (a) either Party may disclose Confidential Information belonging to the other Party only to the extent such disclosure is reasonably necessary to: (i) comply with or enforce any of the provisions of this Agreement; or (ii) comply with Applicable Laws; and (b) Amarin may disclose Confidential Information belonging to Licensee related to the Product only to the extent such disclosure is reasonably necessary to obtain or maintain Regulatory Approval of the Product, as applicable, to the extent such disclosure is made to a Governmental Authority. If a Party deems it necessary to disclose Confidential Information of the other Party pursuant to this Section 12.3, such Party shall give reasonable advance written notice of such disclosure to the other Party to permit such other Party sufficient opportunity to object to such disclosure or to take measures to ensure confidential treatment of such information, including seeking a protective order or other appropriate remedy. Notwithstanding Section 12.2, Amarin may also disclose Confidential Information belonging to Licensee related to the Product to Third Parties in connection with the development or commercialization of the Product outside of the Field or outside of the Territory (provided that: (i) such Third Parties are bound by written agreements having terms at least as protective as those contained in this Article 12 with respect to keeping such Confidential

Information confidential; and (ii) Amarin shall be liable to Licensee in respect of a breach of such confidentiality obligations by any such Third Party).

#### **12.4 Notification**

. The Receiving Party shall notify the Disclosing Party promptly upon discovery of any unauthorized use or disclosure of the Disclosing Party's Confidential Information, and will cooperate with the Disclosing Party in any reasonably requested fashion to assist the Disclosing Party to regain possession of such Confidential Information and to prevent its further unauthorized use or disclosure.

#### **12.5 Publicity; Filing of this Agreement**

**12.5.1 Publicity.** The press release to be issued in connection with this Agreement and the transactions described herein is set forth on Schedule 12.5.1. Except as otherwise provided in this Section 12.5, each Party shall maintain the confidentiality of all provisions of this Agreement, and without the prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed, neither Party nor its respective Affiliates shall make any press release or other public announcement of or otherwise disclose the provisions of this Agreement to any Third Party, except for: (a) disclosure to those of its directors, officers, employees, accountants, attorneys, underwriters, lenders and other financing sources, potential and actual strategic partners, advisors, and agents; provided, that such directors, officers, employees, accountants, attorneys, underwriters, lenders and other financing sources, potential and actual strategic partners, advisors, or agents are required to maintain the confidentiality of this Agreement; (b) disclosures required by The NASDAQ Stock Market or any securities exchanges, in which case the disclosing Party shall provide the non-disclosing Party with at least sixty (60) hours' notice (to the extent not prohibited by Applicable Law), but in any event no later than the time the disclosure required by such NASDAQ Stock Market or any securities exchange is made; (c) disclosures as may be required by Applicable Laws, in which case the disclosing Party shall provide the non-disclosing Party with prompt advance notice of such disclosure (unless otherwise prohibited by Applicable Law) and cooperate with the non-disclosing Party to seek a protective order or other appropriate remedy, including a request for confidential treatment in the case of a filing with the U.S. Securities and Exchange Commission; (d) the report on Form 8-K, which may be filed by Amarin or an Affiliate of Amarin setting forth the press release referred to above, and/or this Agreement in redacted form (i.e., Redacted Agreement) as provided in Section 12.5.2 and/or a summary thereof; (e) disclosures that are consistent with or complementary to those described in clause (d) but which do not contain any Confidential Information of the other Party; and (f) other disclosures for which consent has previously been given. A Party may publicly disclose without regard to the preceding requirements of this Section 12.5 any information that was previously publicly disclosed pursuant to this Section 12.5, so long as the context of such disclosure is substantially similar to the context in which the initial disclosure was made.

**12.5.2 Required Filings.** Notwithstanding Section 12.5.1, either Party may publicly disclose without violation of this Agreement, such terms of this Agreement as are, on the advice of such Party's counsel, required by the rules and regulations of the SEC or The

NASDAQ Stock Market, Inc. or any other recognized stock exchange or Regulatory Authority (“**Redacted Agreement**”); provided, that such Party shall advise the other Party of such intended disclosures and provide the other Party with reasonable opportunity to request that the Party required to make such disclosure seek confidential treatment of such disclosures to be filed with the applicable stock exchange or Regulatory Authority. Subject to the immediately preceding sentence, the Party so required to disclose the Redacted Agreement shall consult with the other Party, and the other Party shall have the right to review and comment with respect to the Redacted Agreement or such other Party’s Confidential Information as part of the confidential treatment request to the stock exchange or Regulatory Authority, as applicable. After release of the press release announcing this Agreement and excluding any public disclosures of the terms of this Agreement that are authorized by the preceding sentences or Section 12.5.1, if a Party desires to make a public announcement concerning the material terms of this Agreement, milestones achieved under this Agreement or the other Party’s Confidential Information, then such Party shall give reasonable prior advance notice of the proposed text of such announcement to the other Party for its prior review and approval (except as otherwise provided herein), such approval not to be unreasonably withheld, conditioned or delayed; provided, that the other Party shall provide its comments, if any, within [\*\*\*] (or [\*\*\*] in the event a Party is required to make such disclosure pursuant to Applicable Laws or stock exchange rules) after receiving the public announcement for review (and failure for the other Party to provide comments within such time period shall be deemed to constitute such other Party’s consent to such public announcement). In relation to a Party’s review of such an announcement, such Party may make specific, reasonable comments on such proposed press release or other public disclosure within the prescribed time for commentary. A Party shall not be required to seek the permission of the other Party to disclose any information already disclosed or otherwise in the public domain, provided such information remains accurate.

## 12.6 Publication

. Licensee shall submit copies in English of each proposed academic, scientific, medical and other publication or presentation that contains or refers to [\*\*\*] in advance of submitting such proposed publication or presentation to a publisher or other Third Party. Amarin shall have the right to review, comment on and consent to each such proposed publication or presentation at its sole discretion. Amarin shall have the right to remove any of its Confidential Information prior to submission for publication or presentation. Licensee shall redact or otherwise modify the proposed publication or presentation to remove any such Confidential Information of Amarin. In addition, in the event that the document includes data, information or material generated by Amarin’s scientists, and professional standards for authorship would be consistent with including Amarin’s scientists as co-authors of the document, the names of such scientists will be included as co-authors.

## 12.7 Use of Names

. Except as otherwise set forth in this Agreement, neither Party shall use the name of the other Party in relation to this transaction in any public announcement, press release or other public document without the written consent of such other Party, which consent shall not be unreasonably withheld, conditioned or delayed; provided, however, that subject to Section 12.5, either Party may use the name of the other Party in any document filed

with any Regulatory Authority or Governmental Authority, including the Securities and Exchange Commission.

## 12.8 Survival

. The obligations and prohibitions contained in this Article 12 as they apply to Confidential Information shall survive the expiration or termination of this Agreement for a period of five (5) years.

## ARTICLE 13 TERM AND TERMINATION

### 13.1 Term

. This Agreement shall become effective on the Effective Date and, unless earlier terminated pursuant to this Article 13, shall remain in effect on a Product-by-Product basis until the later of [\*\*\*].

### 13.2 Termination for Breach

. Except as set forth in Section 13.4, in the event that either Party reasonably anticipates the occurrence of an event which may result in a material breach in the performance of its obligations under this Agreement, the Parties shall first consult with each other in good faith and use Commercially Reasonable Efforts to amicably resolve the disputed subject matter prior to the other Party invoking its termination rights under this Section 13.2. Subject to the foregoing and the right to remedy a default in accordance with the immediately following sentence, either Party may, without prejudice to any other remedies available to it at law or in equity, terminate this Agreement upon written notice to the other Party in the event that the other Party (the “**Breaching Party**”) shall have materially breached or defaulted in the performance of its obligations under this Agreement. The Breaching Party shall have ninety (90) days (thirty (30) days in the event of payment) after written notice thereof was provided to the Breaching Party by the non-breaching Party to remedy such default. Unless the Breaching Party has cured any such breach or default prior to the expiration of such ninety (90) day period (thirty (30) days in the event of payment), such termination shall become effective upon the end of the ninety (90) day period (thirty (30) days in the event of payment). In the event of any dispute as to whether or not a material breach has been committed under this Section 13.2, the Parties shall first consult with each other and use Commercially Reasonable Efforts to settle such dispute. Should the Parties fail to agree on the settlement of any such dispute, the matter shall be submitted to and finally resolved by arbitration in accordance with Section 15.3 (provided, however, that referral to the Executive Officers shall not be applicable, and the time period for a decision under Section 15.3.2 shall be three (3) months following selection of the arbitrators). For the avoidance of doubt, if Licensee is entitled to terminate this Agreement in accordance with the foregoing, it is agreed that Licensee shall also have the right not to terminate this Agreement. In the case that Licensee chooses not to terminate this Agreement, Licensee shall have the right to claim damages arising out of Amarin’s material breach; provided, however, that it is understood and agreed that Licensee shall remain subject to its payment obligations as set forth in Article 8.

### 13.3 Termination as a Result of Bankruptcy

. Each Party shall have the right to terminate this Agreement upon written notice as a result of the filing or institution of bankruptcy,

reorganization, liquidation or receivership proceedings, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party; provided, that such termination shall be effective only if such proceeding is not dismissed within ninety (90) days after the filing thereof.

**13.4 Termination for Breach of License Grant or Parallel Importation**

. In the event that Licensee breaches the scope of its rights or obligations in Sections 2.1, 2.5.1 or 6.5, Amarin has the right, without prejudice to any other remedies available to it at law or in equity, terminate this Agreement upon written notice to Licensee in the event that Licensee does not remedy such breach within [\*\*\*] after written notice thereof was provided to the Licensee by Amarin. Unless Licensee has cured any such breach or default prior to the expiration of such [\*\*\*] period, such termination shall become effective upon the end of the [\*\*\*] period.

**ARTICLE 14  
EFFECTS OF TERMINATION AND EXPIRATION**

**14.1 Termination Not Involving Amarin’s Fault**

. Without limiting any other legal or equitable remedies that a Party may have, if this Agreement is terminated by either Party and for any reason prior to its natural expiration, then the following provisions shall apply:

**14.1.1 Termination of Licenses.** All rights and licenses granted to Licensee hereunder shall immediately terminate and be of no further force and effect and Licensee shall cease Developing and Commercializing the Product (except as otherwise set forth in Section 14.1.3).

**14.1.2 Assignments.** Licensee will promptly, [\*\*\*].

**14.1.3** [\*\*\*].

**14.1.4** [\*\*\*].

**14.1.5** [\*\*\*].

**14.1.6** [\*\*\*].

**14.2 Expiration of this Agreement**

.  
**14.2.1** Upon expiration of this Agreement pursuant to Section 13.1 (as opposed to termination of this Agreement), the licenses granted to Licensee under Section 2.1 shall become fully paid-up, royalty-free, perpetual and non-exclusive licenses; provided, however, that if, pursuant to Section 7.10, Amarin is not continuing to supply the Product for Licensee, then such license shall not include any rights with respect to the Licensed Trademarks.

**14.2.2** Licensee may use the Regulatory Materials and Regulatory Data provided by Amarin hereunder or generated by Licensee hereunder, and any other Development Data or



#### 14.3 Accrued Rights

. Termination or expiration of this Agreement for any reason will be without prejudice to any rights that will have accrued to the benefit of a Party prior to the effective date of such termination. Such termination will not relieve a Party from obligations that are expressly indicated to survive the termination or expiration of this Agreement.

#### 14.4 Survival

. Notwithstanding anything to the contrary contained herein, the following provisions shall survive any expiration or termination of this Agreement: Article 1, 8 (for all accrued but unpaid payments), 11, 12, 14, 15 and 16, and Sections 2.2.2, 2.2.3, 2.3.4, 5.5.2, 6.13.2, 9.1.1, 9.1.2, 9.2, 9.3, 10.4 and 10.5. Except as set forth in this Article 14 or otherwise expressly set forth herein, upon termination or expiration of this Agreement all other rights and obligations of the Parties shall cease.

#### 14.5 Rights in Bankruptcy

. All rights and licenses granted under or pursuant to this Agreement by Amarin and Licensee are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code (and of any similar provisions of Applicable Laws under any other jurisdiction), licenses of right to “intellectual property” as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that each Party, as licensee of certain rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code and under any similar provisions of Applicable Laws under any other jurisdiction. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against a Party (such Party, the “**Bankrupt Party**”) under the U.S. Bankruptcy Code or under any similar provisions of Applicable Laws under any other jurisdiction, the Bankrupt Party shall not unreasonably interfere with the other Party’s rights to intellectual property and all embodiments of intellectual property, and shall assist and not unreasonably interfere with the other Party in obtaining intellectual property and all embodiments of intellectual property from another entity. The “embodiments” of intellectual property includes all tangible, intangible, electronic or other embodiments of rights and licenses hereunder, including all compounds and products embodying intellectual property, Products, filings with Regulatory Authorities and related rights and Amarin Know-How in the case that Amarin is the Bankrupt Party and Licensee Know-How in the case Licensee is the Bankrupt Party.

### ARTICLE 15 DISPUTE RESOLUTION

#### 15.1 Disputes

. The Parties recognize that, from time to time during the Term, disputes may arise as to certain matters which relate to either Party’s rights and/or obligations hereunder. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the Parties agree to follow the procedures set forth in

this Article 15 to resolve any controversy or claim arising out of, relating to or in connection with any provision of this Agreement (other than a dispute addressed in Section 3.1.4 or 3.2.4).

## 15.2 Arising Between the Parties

. With respect to all disputes arising between the Parties, including any alleged failure to perform, or breach, of this Agreement, or any issue relating to the interpretation or application of this Agreement, if the Parties are unable to resolve such dispute within thirty (30) days after such dispute is first identified by either Party in writing to the other, the Parties shall refer such dispute to the Chief Executive Officers of each of the Parties, or a designee from senior management with decision-making authority (the Chief Executive Officer or such designee, the “**Executive Officer**”) for attempted resolution by good faith negotiations within thirty (30) days after such notice is received by the Executive Officers of each of the Parties.

## 15.3 Dispute Resolutions

. If the Executive Officers are not able to resolve such dispute referred to them under Section 15.2 within such thirty (30) day period, then either Party shall have right to refer such dispute for binding arbitration administered in New York in accordance with the Rules of Arbitration of the International Chamber of Commerce (“**Rules**”) by one or more arbitrators appointed in accordance with said Rules. The language of the arbitration shall be English. Any situation not expressly covered by this Agreement shall be decided in accordance with the Rules. Notwithstanding the foregoing, any dispute, controversy or claim relating to the scope, validity, enforceability or infringement of any patent rights covering the manufacture, use or sale of any Product or of any trademark rights relating to any Product shall be subject to Section 15.4 and not this Section 15.3.

**15.3.1 Arbitrator.** The tribunal shall consist of three (3) arbitrators. Each Party shall appoint one (1) arbitrator respectively and the third arbitrator shall be appointed by the Chairman of the ICC. The arbitrators may, in the award, allocate all or part of the costs of the arbitration, including the fees of the arbitration and the reasonable attorneys’ fees of the prevailing Party.

**15.3.2 Decision.** A written decision shall be rendered by the arbitrators following a full comprehensive hearing, no later than twelve (12) months following the selection of the arbitrators as provided for in Section 15.3.1.

**15.3.3 Award.** Any award rendered by the arbitrators may be entered in any court having jurisdiction thereof. Such award shall be promptly paid in U.S. Dollars free of any tax, deduction or offset; and any costs, fees or taxes incident to enforcing the award shall, to the maximum extent permitted by Applicable Laws, be charged against the Party resisting enforcement. Such award may include an appropriate allocation of the prevailing Party’s attorneys’ fees. Each Party agrees to abide by the award rendered in any arbitration conducted pursuant to this Section 15.3. The award shall include interest from the date of the award until paid in full, at a rate fixed by the arbitrators and the arbitrators may, in their discretion, award pre-judgment interest. With respect to money damages, nothing contained herein shall be construed to permit the arbitrators or any court or any other forum to award punitive or

exemplary damages. Pursuant to this Agreement, the Parties expressly waive any claim for punitive or exemplary damages.

**15.3.4 Costs.** Except as set forth in Section 15.3.3, each Party shall bear its own legal fees. The arbitrators shall assess their costs, fees and expenses against the Party losing the arbitration unless he or she believes that neither Party is the clear loser, in which case the arbitrators shall divide his or her fees, costs and expenses according to their sole discretion.

**15.3.5 Injunctive Relief.** Provided a Party has made a sufficient showing under the rules and standards set forth in Applicable Laws, the arbitrators shall have the freedom to invoke, and the Parties agree to abide by, injunctive measures after either Party submits in writing for arbitration claims requiring immediate relief. Additionally, nothing in this Section 15.3 will preclude either Party from seeking equitable relief or interim or provisional relief from a court of competent jurisdiction, including a temporary restraining order, preliminary injunction or other interim equitable relief, concerning a dispute either prior to or during any arbitration if necessary to protect the interests of such Party or to preserve the status quo pending the arbitration proceeding.

**15.3.6 Confidentiality.** The arbitration proceeding shall be confidential and the arbitrators shall issue appropriate protective orders to safeguard each Party's Confidential Information. Except as required to comply with Applicable Laws, including rules and regulations promulgated by the U.S. Securities Exchange Commission, The NASDAQ Stock Market or any securities exchanges or Regulatory Authorities, no Party shall make (or instruct the arbitrators to make) any public announcement with respect to the proceedings or decision of the arbitrators without prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed. The existence of any dispute submitted to arbitration, and the award, shall be kept in confidence by the Parties and the arbitrators, except as required in connection with the enforcement of such award or as otherwise required by Applicable Laws.

**15.3.7 Survivability.** Any duty to arbitrate under this Agreement shall remain in effect and be enforceable after termination of this Agreement for any reason.

#### **15.4 Patent and Trademark Dispute Resolution**

. Any dispute, controversy or claim relating to the scope, validity, enforceability or infringement of any patent rights covering the manufacture, use or sale of any Product or of any trademark rights relating to any Product shall be submitted to a court of competent jurisdiction in the region in which such patent or trademark rights were granted or arose.

#### **15.5 Injunctive Relief**

. Nothing herein may prevent either Party from seeking a preliminary injunction or temporary restraining order, in any court of competent jurisdiction, so as to prevent any Confidential Information from being disclosed in violation of this Agreement.

**ARTICLE 16**  
**MISCELLANEOUS**

**16.1**                      Entire Agreement; Amendment

. This Agreement, together with the Quality Agreement and pharmacovigilance agreement contemplated hereunder, and all Schedules attached hereto and thereto, shall constitute the entire agreement between the Parties relating to the subject matter hereof and thereof and shall supersede all previous writings and understandings including the Confidentiality Agreement. No terms or provisions of this Agreement shall be varied or modified by any prior or subsequent statement, conduct or act of either of the Parties, except that the Parties may amend this Agreement by written instruments specifically referring to and executed in the same manner as this Agreement.

**16.2**                      Force Majeure

. If the performance of any part of this Agreement by either Party, or of any obligation under this Agreement, is prevented, restricted, interfered with or delayed by reason of a Force Majeure affecting the Party liable to perform, unless conclusive evidence to the contrary is provided, the Party so affected shall, upon giving written notice to the other Party, be excused from such performance to the extent of such Force Majeure; provided, that the affected Party shall use its Commercially Reasonable Efforts to avoid or remove such causes of nonperformance and shall continue performance with the utmost dispatch whenever such Force Majeure ceases. When such circumstances arise, the Parties shall discuss what, if any, modification of the terms of this Agreement may be required in order to arrive at an equitable solution.

**16.3**                      Notices

. Any notice, request, approval or other document required or permitted to be given under this Agreement shall be in writing and shall be deemed to have been given when delivered in person, or sent by overnight courier service, postage prepaid, or sent by certified or registered mail, return receipt requested, or by facsimile transmission, to the following addresses of the Parties and to the attention of the persons identified below (or to such other address, addresses or persons as may be specified from time to time in a written notice). Any notices given pursuant to this Agreement shall be deemed to have been given and delivered upon the earlier of (a) if sent by overnight courier service, on the date when received at the address set forth below as proven by a written receipt from the delivery service verifying delivery, or (b) if sent by facsimile transmission, on the day when sent by facsimile as confirmed by automatic transmission report coupled with overnight courier service receipt proving delivery, or (c) if delivered in person, on the date of delivery to the address set forth below as proven by written signature of the recipient.

<b>If to Licensee:</b> Name: HLS Therapeutics Inc. Street: 10 Carlson Court, Suite 410 City: Etobicoke, Ontario Country: Canada Attn: Chief Executive Officer Facsimile: 416 213 0045	<b>With a copy to:</b> Name: Blake, Cassels & Graydon LLP Street: 199 Bay Street, Suite 4000 City: Toronto, Ontario Country: Canada Attn: Cheryl L. Satin Facsimile: 416-863-2653
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<b>If to Amarin Pharma:</b> Name: Amarin Pharma, Inc. Street: 1430 Route 206, Suite 101 City/State: Bedminster, NJ 07921 Country: U.S.A. Attn: Chief Executive Officer Facsimile: 1-908-719-3012	<b>With a copy to:</b> Name: Amarin Pharma, Inc. Street: 1430 Route 206, Suite 101 City/State: Bedminster, NJ 07921 Country: U.S.A. Attn: General Counsel Facsimile: 1-908-719-3012
<b>If to Amarin Ireland:</b> Name: Amarin Pharmaceuticals Ireland Limited Street: 88 Harcourt Street, Dublin 2, Co City/State: Dublin Country: Ireland Attn: Chief Executive Officer Facsimile: Not valid notice	<b>With a copy to:</b> Name: Amarin Pharma, Inc. Street: 1430 Route 206, Suite 101 City/State: Bedminster, NJ 07921 Country: U.S.A. Attn: Chief Executive Officer and General Counsel, respectively Facsimile: 1-908-719-3012

**16.4** No Strict Construction; Interpretation

. This Agreement has been prepared jointly and shall not be strictly construed against either Party. Ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision. The headings of each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section.

**16.5** Assignment

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**16.5.1** Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other, such consent not to be unreasonably withheld, conditioned or delayed, except that either Party may make such assignment or transfer without the other Party’s consent to an Affiliate or a successor to all or substantially all of the assets or business of such Party to which this Agreement relates (whether by sale, merger, reorganization, consolidation or otherwise). Any permitted assignment or transfer shall be binding on the successors of the assigning Party. Any assignment or transfer or attempted assignment or transfer by either Party in violation of the terms of this Section 16.5 shall be null, void and of no legal effect.

**16.5.2** Notwithstanding anything to the contrary in this Agreement (including in Section 2.5.2), [\*\*\*].

**16.5.3** [\*\*\*].

**16.5.4** [\*\*\*].

**16.5.5** [\*\*\*].

**16.6****Severability**

. In the event that any portion of this Agreement is held illegal, void or ineffective, the remaining portions of this Agreement shall remain in full force and effect. If any of the terms or provisions of this Agreement are in conflict with any Applicable Laws, then such terms or provisions shall be deemed to be modified to conform with such Applicable Laws to the extent necessary in order that such terms or provisions be valid and enforceable and such amendment shall apply only with respect to the operation of such terms or provisions in the particular jurisdiction in which such declaration is made or, if such modification is not feasible, then such terms and provisions shall be deemed to be inoperative to the extent that such terms or provisions conflict with Applicable Laws. In the event that the terms and conditions of this Agreement are materially altered as a result of this Section 16.6, the Parties shall renegotiate the terms and conditions of this Agreement to resolve any inequities and to achieve the original intent of the Parties.

**16.7****No Waiver of Breach**

. The failure of either Party at any time or times to require performance of any provision hereof shall in no manner affect its rights at a later time to enforce the same. No waiver by either Party of any condition or term in any one or more instances shall be construed as a further or continuing waiver of such condition or term or of another condition or term.

**16.8****Partnership or Joint Venture**

. Amarin and Licensee shall be independent contractors and the relationship between the Parties hereunder shall not constitute a partnership, joint venture or agency. Neither Amarin nor Licensee shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other, without the prior written consent of such other Party to do so.

**16.9****English Language; Governing Law**

. This Agreement was prepared in the English language, which language shall govern the interpretation of, and any dispute regarding, the terms of this Agreement. All notices, reports and other documents contemplated by this Agreement to be delivered by a Party to the other Party shall be in the English language. This Agreement and all disputes arising out of or related to this Agreement or any breach hereof shall be governed by and construed under the laws of the State of New York, without giving effect to any choice of law principles that would require the application of the laws of a different jurisdiction.

**16.10****Execution in Counterparts**

. This Agreement may be executed in counterparts, each of which shall be deemed an original but which together shall constitute one and the same instrument. A facsimile or a portable document format (PDF) copy of this Agreement, including the signature pages, will be deemed an original.

*[No Further Text on This Page]*

**IN WITNESS WHEREOF**, the Parties, through their authorized representatives, have executed this Agreement as of the Effective Date.

**HLS THERAPEUTICS INC.**

**AMARIN PHARMACEUTICALS IRELAND LIMITED**

[\*\*\*]

By: /s/ Patrick O’Sullivan

Name: Patrick O’Sullivan

Title: Director

[\*\*\*]

**AMARIN PHARMA, INC.**

By: /s/ John F. Thero

Name: John F. Thero

Title: President & CEO

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH “[\*\*\*]”. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT UNDER RULE 24b-2 OF THE SECURITIES EXCHANGE ACT OF 1934.

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CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH “[\*\*\*]”. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT UNDER RULE 24b-2 OF THE SECURITIES EXCHANGE ACT OF 1934.

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For the United States:



**Amarin and HLS Therapeutics Announce Agreement to Commercialize Vascepa® in Canada**

BEDMINSTER, N.J., and DUBLIN, Ireland, TORONTO, Canada, September 25, 2017 -- Amarin Corporation plc (NASDAQ:AMRN) and HLS Therapeutics Inc. ("HLS"), announced today an exclusive agreement between the parties to register, commercialize and distribute Vascepa® (icosapent ethyl) capsules in Canada. Amarin and HLS anticipate submitting an application to Canadian regulatory authorities to seek approval to commercialize Vascepa in Canada.

"We are excited to enter into a collaboration with HLS to seek regulatory approval and commercialize Vascepa in Canada," stated John F. Thero, president and chief executive officer of Amarin. "The proven track record of HLS's leadership in commercializing pharmaceutical products in Canada, along with our shared vision and commitment, bestow confidence that we will provide Vascepa as a treatment option for millions of Canadians."

"HLS is delighted to work with Amarin, as we expect Vascepa to be the first **highly pure, omega-3 fatty acid product available by prescription in Canada**," stated Greg Gubitz, chief executive officer of HLS Therapeutics. "Amarin's \$200+ million cardiovascular outcomes study, REDUCE-IT, has a significant number of Canadian key opinion leaders and clinical sites involved. As cardiovascular disease is the number one killer in the world<sup>1</sup>, HLS is proud to be associated with Amarin's mission to improve cardiovascular health."

Heart disease is a leading cause of death in Canada<sup>1</sup>. Twenty-five percent of Canadians have high triglycerides<sup>2</sup>, a key comorbidity associated with cardiovascular disease, and about 2.4 million Canadians live with heart disease<sup>3</sup>. HLS and Amarin believe Vascepa has the potential to become an important part of the physician's armamentarium in the treatment of the millions of Canadians dealing with these conditions.

Under the agreement, HLS will be responsible for regulatory and commercialization activities and associated costs. Amarin is responsible for providing assistance towards local filings, supplying finished

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product, maintaining intellectual property and continuing the development and funding of REDUCE-IT. Terms of the agreement include upfront and milestone payments to Amarin of up to US\$65.0 million. These payments include a non-refundable upfront payment of US\$5.0 million, as well as development, regulatory and sale-based milestones totaling up to an additional US\$60.0 million. The agreement also provides for HLS to pay Amarin tiered double digit royalties on net sales of Vascepa in Canada. Amarin is obligated to supply finished product to HLS under negotiated supply terms. The agreement for supply and commercialization is for Canada only and includes all Canadian provinces.

### **About Vascepa® (icosapent ethyl) capsules**

Vascepa® (icosapent ethyl) capsules are a single-molecule prescription product consisting of the omega-3 acid commonly known as EPA in ethyl-ester form. Vascepa is not fish oil, but 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. Vascepa is known in scientific literature as AMR101. Amarin has been issued multiple patents internationally based on the unique clinical profile of Vascepa, including the drug's ability to lower triglyceride levels in relevant patient populations without raising LDL-cholesterol levels.

#### FDA-Approved Indication and Usage

- Vascepa (icosapent ethyl) is indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe ( $\geq 500$  mg/dL) hypertriglyceridemia.
- The effect of Vascepa on the risk for pancreatitis and cardiovascular mortality and morbidity in patients with severe hypertriglyceridemia has not been determined.

#### Important Safety Information for Vascepa

- Vascepa is contraindicated in patients with known hypersensitivity (e.g., anaphylactic reaction) to Vascepa or any of its components.
  - Use with caution in patients with known hypersensitivity to fish and/or shellfish.
  - The most common reported adverse reaction (incidence  $> 2\%$  and greater than placebo) was arthralgia (2.3% for Vascepa, 1.0% for placebo). There was no reported adverse reaction  $> 3\%$  and greater than placebo.
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- Patients receiving treatment with Vascepa and other drugs affecting coagulation (e.g., anti-platelet agents) should be monitored periodically.
- In patients with hepatic impairment, monitor ALT and AST levels periodically during therapy.
- Patients should be advised to swallow Vascepa capsules whole; not to break open, crush, dissolve, or chew Vascepa.
- Adverse events and product complaints may be reported by calling 1-855-VASCEPA or the FDA at 1-800-FDA-1088.

FULL VASCEPA PRESCRIBING INFORMATION CAN BE FOUND AT [WWW.VASCEPA.COM](http://WWW.VASCEPA.COM).

Vascepa has been approved for use by the United States Food and Drug Administration (FDA) as an adjunct to diet to reduce triglyceride levels in adult patients with severe ( $\geq 500$  mg/dL) hypertriglyceridemia. Vascepa is under various stages of development for potential use in other indications that have not been approved by the FDA. Vascepa is not approved for use in Canada. Nothing in this press release should be construed as promoting the use of Vascepa where not approved.

#### **About Amarin**

Amarin Corporation plc is a biopharmaceutical company focused on the commercialization and development of therapeutics to improve cardiovascular health. Amarin's product development program leverages its extensive experience in lipid science and the potential therapeutic benefits of polyunsaturated fatty acids. Amarin's clinical program includes a commitment to an ongoing outcomes study. Vascepa® (icosapent ethyl), Amarin's first FDA-approved product, is a highly pure omega-3 fatty acid product available by prescription. For more information about Vascepa, visit [www.vascepa.com](http://www.vascepa.com). For more information about Amarin, visit [www.amarincorp.com](http://www.amarincorp.com).

#### **About HLS Therapeutics**

HLS Therapeutics Inc. is a specialty pharmaceutical company acquiring and distributing commercial stage and legacy, branded pharmaceutical drugs for the North American markets. HLS's management team is comprised of seasoned pharmaceutical executives with a strong track record of success. Building on the expertise of the founders, HLS is focused on treatment products for the central nervous system, and cardiovascular specialties. For more information about HLS, visit [www.hlstherapeutics.com](http://www.hlstherapeutics.com).

#### **Forward-looking statements**

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This press release contains forward-looking statements, including expectations regarding regulatory submissions and approvals and commercialization of Vascepa in Canada, as well as timing related thereto; future expectation regarding timing and continuation of Amarin's REDUCE-IT cardiovascular outcomes study; statements regarding the potential and therapeutic benefits of Vascepa; and potential milestone and other payments to be paid to Amarin, an obligation of Amarin, under this agreement. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. In particular, as disclosed in filings with the U.S. Securities and Exchange Commission, Amarin's ability to effectively develop and commercialize Vascepa will depend in part on its ability to continue to effectively finance its business, efforts of third parties, its ability to create market demand for Vascepa through education, marketing and sales activities, to achieve increased market acceptance of Vascepa, to receive adequate levels of reimbursement from third-party payers, to develop and maintain a consistent source of commercial supply at a competitive price, to comply with legal and regulatory requirements in connection with the sale and promotion of Vascepa and to maintain patent protection for Vascepa. Among the factors that could cause actual results to differ materially from those described or projected herein include the following: uncertainties associated generally with research and development, clinical trials and related regulatory approvals; the risk that clinical data and regulatory reviews may alter current expectations related to anticipated prospects for approval; the risk that future legal determinations and interactions with regulatory authorities may impact Vascepa marketing and sales rights and efforts; the risk that Vascepa may not show clinically meaningful effects in REDUCE-IT or support regulatory approvals for cardiovascular risk reduction; and the risk that patents may not be obtained or upheld in patent litigation. A further list and description of these risks, uncertainties and other risks associated with an investment in Amarin can be found in Amarin's filings with the U.S. Securities and Exchange Commission, including its most recent Quarterly Report on Form 10-Q. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Amarin undertakes no obligation to update or revise the information contained in this press release, whether as a result of new information, future events or circumstances or otherwise.

#### **Availability of other information about Amarin**

Investors and others should note that we communicate with our investors and the public using our company website ([www.amarincorp.com](http://www.amarincorp.com)), our investor relations website (<http://investor.amarincorp.com>), including but not limited to investor presentations and investor FAQs, Securities and Exchange Commission filings, press releases, public conference calls and webcasts. The information that we post on these channels and websites could be deemed to be material information. As a result, we encourage investors, the media, and others interested in Amarin to review the information that we post on these channels, including our investor relations website, on a regular basis. This list of channels may be updated from time to time on our investor relations website and may include social media channels. The contents of our website or these channels, or any other website that

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may be accessed from our website or these channels, shall not be deemed incorporated by reference in any filing under the Securities Act of 1933.

## References

- 1 [https://www.medpagetoday.com/PublicHealthPolicy/PublicHealth/67946?xid=nl\\_mpt\\_DHE\\_2017-09-16&eun=g811140d0r&pos=0](https://www.medpagetoday.com/PublicHealthPolicy/PublicHealth/67946?xid=nl_mpt_DHE_2017-09-16&eun=g811140d0r&pos=0)
- 2 <http://www.statcan.gc.ca/pub/82-625-x/2010001/article/11136-eng.htm>
- 3 <https://www.canada.ca/en/public-health/services/diseases/heart-disease-heart-health.html>

## Amarin contact information:

### *Investor Relations:*

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Investor Relations and Corporate Communications  
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### *Media Inquiries:*

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[Ovidio.torres@finnpartners.com](mailto:Ovidio.torres@finnpartners.com)

## HLS contact information:

### *Business and Media Contact:*

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Phone: +1 (484) 232-3400 ext101

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**FOR RELEASE IN CANADA ONLY**



HLS Therapeutics®

**HLS Therapeutics and Amarin Announce Agreement to Commercialize Vascepa® in Canada**

Toronto, Canada, BEDMINSTER, N.J., and DUBLIN, Ireland, September 25, 2017 -- HLS Therapeutics Inc. (“HLS”) and Amarin Corporation plc (“Amarin”) announced today an exclusive agreement between the parties to register, commercialize and distribute Vascepa® (icosapent ethyl) capsules in Canada. Amarin and HLS anticipate submitting an application to Canadian regulatory authorities to seek approval to commercialize Vascepa in Canada.

“HLS is delighted to work with Amarin, as we expect Vascepa to be the first highly pure, omega-3 fatty acid product available by prescription in Canada,” stated Greg Gubit, chief executive officer of HLS Therapeutics. “Amarin’s \$200+ million cardiovascular outcomes study, REDUCE-IT, has a significant number of Canadian key opinion leaders and clinical sites involved. As cardiovascular disease is the number one killer in the world<sup>1</sup>, HLS is proud to be associated with Amarin’s mission to improve cardiovascular health.”

“We are excited to enter into a collaboration with HLS to seek regulatory approval and commercialize Vascepa in Canada,” stated John F. Thero, president and chief executive officer of Amarin. “The proven track record of HLS’s leadership in commercializing pharmaceutical products in Canada, along with our shared vision and commitment, bestow confidence that we will provide Vascepa as a treatment option for millions of Canadians.”

Heart disease is a leading cause of death in Canada<sup>2</sup>. Twenty-five percent of Canadians have high triglycerides<sup>3</sup>, a key comorbidity associated with cardiovascular disease, and about 2.4 million Canadians live with heart disease<sup>2</sup>. HLS and Amarin believe Vascepa has the potential to become an important part of the physician’s armamentarium in the treatment of the millions of Canadians dealing with these conditions.

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Under the agreement, HLS will be responsible for regulatory and commercialization activities and associated costs. Amarin is responsible for providing assistance towards local filings, supplying finished product, maintaining intellectual property and continuing the development and funding of REDUCE-IT. Terms of the agreement include up-front and milestone payments to Amarin, as well as development, regulatory and sale-based milestones. The agreement also provides for HLS to pay Amarin tiered double digit royalties on net sales of Vascepa in Canada. Amarin is obligated to supply finished product to HLS under negotiated supply terms. The agreement for supply and commercialization is for Canada only and includes all Canadian provinces.

### **About Vascepa® (icosapent ethyl) capsules**

Vascepa® (icosapent ethyl) capsules are a single-molecule prescription product consisting of the omega-3 acid commonly known as EPA in ethyl-ester form. Vascepa is not fish oil, but 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. Vascepa is known in scientific literature as AMR101. Amarin has been issued multiple patents internationally based on the unique clinical profile of Vascepa, including the drug's ability to lower triglyceride levels in relevant patient populations without raising LDL-cholesterol levels.

- While the safety and efficacy for Canada are still under investigation and the Canadian market authorization has not yet been obtained, the proposed indication would be the same as that approved by the United States Food and Drug Administration, being: Vascepa (icosapent ethyl) is indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe ( $\geq 500$  mg/dL) hypertriglyceridemia.

FULL VASCEPA UNITED STATES FDA APPROVED PRESCRIBING INFORMATION CAN BE FOUND AT [WWW.VASCEPA.COM](http://WWW.VASCEPA.COM).

Vascepa is also under various stages of development for potential use in other indications. Vascepa is not approved for use in Canada. Nothing in this press release should be construed as promoting the use of Vascepa where not approved.

### **About HLS Therapeutics**

HLS Therapeutics Inc. is a specialty pharmaceutical company acquiring and distributing commercial stage and legacy, branded pharmaceutical drugs for the North American markets. HLS's management team is comprised of seasoned pharmaceutical executives with a strong track record of success. Building on the expertise of the founders, HLS is focused on treatment products for the central nervous system, and cardiovascular specialties. For more information about HLS, visit [\*\*www.hlstherapeutics.com\*\*](http://www.hlstherapeutics.com).

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## **About Amarin**

Amarin Corporation plc is a biopharmaceutical company focused on the commercialization and development of therapeutics to improve cardiovascular health. Amarin's product development program leverages its extensive experience in lipid science and the potential therapeutic benefits of polyunsaturated fatty acids. Amarin's clinical program includes a commitment to an ongoing outcomes study. Vascepa® (icosapent ethyl), Amarin's first FDA-approved product, is a highly pure omega-3 fatty acid product available by prescription. For more information about Vascepa, visit [www.vascepa.com](http://www.vascepa.com). For more information about Amarin, visit [www.amarincorp.com](http://www.amarincorp.com).

## **Forward-looking statements**

This press release contains forward-looking statements, including expectations regarding regulatory submissions and approvals and commercialization of Vascepa in Canada, as well as timing related thereto; future expectation regarding timing and continuation of Amarin's REDUCE-IT cardiovascular outcomes study; statements regarding the potential and therapeutic benefits of Vascepa; and potential milestone and other payments to be paid to Amarin, an obligation of Amarin, under this agreement. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. In particular, as disclosed in filings with the U.S. Securities and Exchange Commission, Amarin's ability to effectively develop and commercialize Vascepa will depend in part on its ability to continue to effectively finance its business, efforts of third parties, its ability to create market demand for Vascepa through education, marketing and sales activities, to achieve increased market acceptance of Vascepa, to receive adequate levels of reimbursement from third-party payers, to develop and maintain a consistent source of commercial supply at a competitive price, to comply with legal and regulatory requirements in connection with the sale and promotion of Vascepa and to maintain patent protection for Vascepa. Among the factors that could cause actual results to differ materially from those described or projected herein include the following: uncertainties associated generally with research and development, clinical trials and related regulatory approvals; the risk that clinical data and regulatory reviews may alter current expectations related to anticipated prospects for approval; the risk that future legal determinations and interactions with regulatory authorities may impact Vascepa marketing and sales rights and efforts; the risk that Vascepa may not show clinically meaningful effects in REDUCE-IT or support regulatory approvals for cardiovascular risk reduction; and the risk that patents may not be obtained or upheld in patent litigation. A further list and description of these risks, uncertainties and other risks associated with an investment in Amarin can be found in Amarin's filings with the U.S. Securities and Exchange Commission, including its most recent Quarterly Report on Form 10-Q. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Amarin undertakes no obligation to update or revise the information contained in this press release, whether as a result of new information, future events or circumstances or otherwise.

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## References

<sup>1</sup> [https://www.medpagetoday.com/PublicHealthPolicy/PublicHealth/67946?xid=nl\\_mpt\\_DHE\\_2017-09-16&eun=g811140d0r&pos=0](https://www.medpagetoday.com/PublicHealthPolicy/PublicHealth/67946?xid=nl_mpt_DHE_2017-09-16&eun=g811140d0r&pos=0)

<sup>2</sup> <https://www.canada.ca/en/public-health/services/diseases/heart-disease-heart-health.html>

<sup>3</sup> <http://www.statcan.gc.ca/pub/82-625-x/2010001/article/11136-eng.htm>

## HLS contact information:

### *Business and Media Contact:*

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Phone: +1 (484) 232-3400 ext101

### **Amarin contact information:**

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**Subsidiaries of the Registrant as of December 31, 2017**

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

**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),
- (7) Registration Statement (Form S-3 No. 333-203312) of Amarin Corporation plc,
- (8) Registration Statement (Form S-3 No. 333-205861) of Amarin Corporation plc,
- (9) Registration Statement (Form S-3 No. 333-216384) of Amarin Corporation plc, and
- (10) Registration Statement (Form S-3 No. 333-216385) of Amarin Corporation plc;

of our reports dated February 27, 2018, 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, 2017.

/s/ Ernst & Young LLP

Iselin, New Jersey  
February 27, 2018

## 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 27, 2018

/s/ John F. Thero

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

## 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 27, 2018

/s/ Michael W. Kalb

Michael W. Kalb

Senior Vice President and Chief Financial Officer  
(Principal Financial Officer and Principal Accounting Officer)

## 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, 2017, 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.

Date: February 27, 2018

/s/ John F. Thero

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

Date: February 27, 2018

/s/ Michael W. Kalb

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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.