

AMARIN CORP PLC\UK  
Form 10-K  
February 27, 2014  
Table of Contents

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**Form 10-K**

þ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended December 31, 2013

OR

· TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the transition period from to

Commission File No. 0-21392

**Amarin Corporation plc**

(Exact name of registrant as specified in its charter)

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

2 Pembroke House

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

Edgar Filing: AMARIN CORP PLC\UK - Form 10-K

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:

Title of Each Class	Name of Each Exchange on Which Registered
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

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  Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company) Smaller reporting company

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, 2013 was approximately \$785 million, based upon the closing price on the NASDAQ Capital Market reported for such date.

172,440,210 shares held as American Depositary Shares (ADS), each representing one Ordinary Share, 50 pence par value per share, and 465,853 Ordinary Shares, were outstanding as of February 20, 2014.

DOCUMENTS INCORPORATED BY REFERENCE

## Edgar Filing: AMARIN CORP PLC\UK - Form 10-K

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.

**Table of Contents****Table of Contents**

	<b>Page</b>
<b><u>PART I</u></b>	
Item 1. <u>Business</u>	2
Item 1A. <u>Risk Factors</u>	23
Item 1B. <u>Unresolved Staff Comments</u>	54
Item 2. <u>Properties</u>	54
Item 3. <u>Legal Proceedings</u>	54
Item 4. <u>Mine Safety Disclosures</u>	55
<b><u>PART II</u></b>	
Item 5. <u>Market For Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	56
Item 6. <u>Selected Financial Data</u>	60
Item 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	61
Item 7A. <u>Quantitative and Qualitative Disclosures about Market Risk</u>	80
Item 8. <u>Financial Statements and Supplementary Data</u>	80
Item 9. <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	80
Item 9A. <u>Controls and Procedures</u>	80
Item 9B. <u>Other Information</u>	83
<b><u>PART III</u></b>	
Item 10. <u>Directors, Executive Officers and Corporate Governance</u>	84
Item 11. <u>Executive Compensation</u>	84
Item 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	84
Item 13. <u>Certain Relationships and Related Transactions, and Director Independence</u>	84
Item 14. <u>Principal Accountant Fees and Services</u>	84
<b><u>PART IV</u></b>	
Item 15. <u>Exhibits and Financial Statement Schedules</u>	85
<u>SIGNATURES</u>	94

**Table of Contents**

**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 terms. These statements include but are not limited to statements regarding the commercial success of Vascepa in its first approved indication, the MARINE indication, the potential for, and timing of, approval of the Vascepa Supplemental New Drug Application, or sNDA, by the United States Food and Drug Administration, or FDA, in its potential second indication, the ANCHOR indication; the safety and efficacy of our product candidates; the scope of our intellectual property protection and the likelihood of securing additional patent protection; estimates of the potential markets for our product candidates; the likelihood of qualifying additional third party manufacturing suppliers and 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.

---

## **Table of Contents**

### **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 (formerly Ethical Holdings 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 registered office is located at One New Change, London EC4M 9AF, England. Our principal offices are located at 2 Pembroke House, Upper Pembroke Street 28-32, Dublin 2 Ireland. 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  $\geq$ 500mg/dL) hypertriglyceridemia. We refer to this approved indication for Vascepa as the MARINE indication. We began marketing and selling Vascepa in the United States in January 2013. Vascepa is available in the United States by prescription only. We market Vascepa through our sales force of approximately 150 sales professionals, including sales representatives and their managers.

Triglycerides are fats in the blood. Hypertriglyceridemia refers to a condition in which patients have high levels of triglycerides in the bloodstream. It is estimated that over 40 million adults in the United States have elevated triglyceride levels (TG  $\geq$ 200mg/dL) and approximately 4.0 million people in the United States have severely high triglyceride levels (TG  $\geq$ 500mg/dL), commonly known as very high triglyceride levels. According to *The American Heart Association Scientific Statement on Triglycerides and Cardiovascular Disease* (2011), triglycerides also 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.

The potential efficacy and safety of Vascepa (known in its development stage as AMR 101) was studied in two Phase 3 clinical trials, the MARINE trial and the ANCHOR trial. At a daily dose of 4 grams of Vascepa, the dose at which Vascepa is FDA approved, these trials showed favorable clinical results in their respective patient populations 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

---

**Table of Contents**

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).

We are also developing Vascepa for the treatment of patients with high (TG <sup>3</sup> 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 which we refer to as mixed dyslipidemia. We refer to this second proposed indication for Vascepa as the ANCHOR indication. The FDA views the proposed ANCHOR indication as ostensibly and impliedly an indication to reduce cardiovascular risk. In addition, in December 2011, we announced commencement of patient dosing in our cardiovascular outcomes study of Vascepa, titled REDUCE-IT (Reduction of Cardiovascular Events with EPA Intervention Trial). The REDUCE-IT study is designed to evaluate the efficacy of Vascepa in reducing major cardiovascular events in a high risk patient population on statin therapy.

We have a pending supplemental new drug application, or sNDA, with the FDA that seeks marketing approval of Vascepa for use in the ANCHOR indication. On October 16, 2013, the FDA convened an advisory committee to review our sNDA. This advisory committee was not asked by the FDA to evaluate whether Vascepa is effective in lowering triglycerides in the studied population, the ANCHOR indication as specified in the sNDA. Rather, the advisory panel was asked whether Vascepa has been demonstrated to improve cardiovascular outcomes or whether approval of the ANCHOR indication should wait for successful completion of the REDUCE-IT study, the first prospective study of cardiovascular outcomes in patients who have high triglyceride levels despite statin therapy. The advisory committee voted 9 to 2 against recommending approval of the ANCHOR indication based on information presented at the meeting. The FDA considers the recommendation of advisory committees, but final decisions on the approval of new drug applications are made by the FDA.

The ANCHOR trial clinical study was conducted under a special protocol assessment, or SPA, agreement with the FDA. The law governing SPA agreements requires that if the results of the trial conducted under the SPA substantiate the hypothesis of the protocol covered by the SPA, the FDA must use the data from the protocol as part of the primary basis for approval of the product. A SPA agreement is not a guarantee of FDA approval of the related new drug application. 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 of the drug after the study begins that rises to the level of a public health concern, or if the study sponsor fails to follow the protocol that was agreed upon with the FDA. On October 29, 2013, the FDA 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. As a basis for this determination, the FDA communicated that it determined that the cumulative results from outcome studies of other triglyceride-lowering drugs failed to support the hypothesis that a triglyceride-lowering drug significantly reduces the risk for cardiovascular events among the population studied in the ANCHOR trial. Thus, the FDA stated that while information we submitted supports testing the hypothesis that Vascepa 4 grams/day versus placebo reduces major adverse cardiovascular events in statin-treated subjects with residually high triglyceride levels, as is being studied in the Vascepa REDUCE-IT cardiovascular outcomes study, the FDA no longer considers a change in serum triglyceride levels as sufficient to establish the effectiveness of a drug intended to reduce cardiovascular risk in subjects with serum triglyceride levels below 500 mg/dL. In November 2013, we submitted to the FDA a request for reconsideration of its decision to rescind the ANCHOR SPA agreement. On January 17, 2014, we were notified by the FDA that it does not intend to reinstate the ANCHOR SPA agreement. Our plan is to continue appealing the rescission decision to successively higher administrative levels within the FDA in accordance with FDA dispute resolution guidance.

The FDA did not take action on the ANCHOR sNDA by the Prescription Drug User Fee Act, or PDUFA, goal date for completion of FDA's review, December 20, 2013. Instead, the FDA notified us on December 19, 2013 that it would first consider our appeal of the ANCHOR SPA agreement rescission. No new PDUFA goal date for the ANCHOR sNDA was established. Based on information available to us, we do not expect a determination on the ANCHOR sNDA while our appeal of the January 17, 2014 FDA decision to uphold the

---

**Table of Contents**

ANCHOR SPA rescission is in process. We are also continuing our efforts toward a positive determination on the pending ANCHOR sNDA. There also can be no assurance that the FDA will not communicate the results of its review of the ANCHOR sNDA prior to the timing expected.

Based on our communications with the FDA, we currently expect that final positive results from the REDUCE-IT outcomes study will be required for FDA approval of Vascepa for the ANCHOR indication. There can be no assurance that we will be successful in our effort to reinstate the ANCHOR SPA agreement or obtain a label expansion reflecting the ANCHOR clinical trial. Such label expansion could include FDA approval of the addition of an ANCHOR indication statement and/or the addition of the ANCHOR clinical trial data to our currently approved labeling.

On October 22, 2013, in an effort to reduce operating expenses following the recommendation of the advisory committee to the FDA against approval of the ANCHOR indication, we implemented a worldwide reduction in force of approximately 50% of our staff positions. The majority of affected staff members were sales professionals who supported the initial commercial launch of Vascepa. We incurred approximately \$2.8 million in charges related to the reduction in force, all of which includes cash expenditures for one-time termination benefits and associated costs. The charges were recorded in the fourth quarter of 2013 and the related payments will be made by the first half of 2014. As part of the reduction in force, we retained approximately 130 sales representatives, excluding sales management, in the United States in sales territories that we believe have demonstrated the greatest potential for Vascepa sales growth. We plan to have this team cover the target base of physicians responsible for the majority of Vascepa prescription volume and growth since its launch in early 2013. With these changes and resulting target base coverage, we anticipate continued Vascepa revenue growth over time. We also anticipate that such sales growth may be inconsistent from period to period.

We have over 6,500 patients enrolled in the REDUCE-IT study. We currently estimate that we will complete patient enrollment in this study in the first half of 2015. However, if we do not receive an expansion of Vascepa labeling for the ANCHOR indication, we plan to re-evaluate continuation of the REDUCE-IT study in its present form and re-evaluate whether it is advisable to continue the study. If continued, the REDUCE-IT study will be completed after reaching an aggregate number of cardiovascular events. Based on event rates in other outcomes studies, we estimate completing the REDUCE-IT study in or about 2017 with results expected to be available in 2018. 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 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 resolution of the ANCHOR sNDA with the FDA. If we do not receive FDA approval for the ANCHOR indication, we may discontinue development of AMR102.

*Commercialization of Vascepa*

Vascepa became commercially available in the United States by prescription in early 2013, when we commenced sales and shipments to our network of U.S.-based wholesalers. On January 28, 2013, we commenced our full commercial launch of Vascepa in the United States for use in the MARINE indication. In preparation for our commercial launch, we hired and trained a direct sales force of approximately 275 sales representatives. In October 2013, we reduced our number of sales representatives to approximately 130, excluding sales management, in the United States to focus on the sales territories that we believe have demonstrated the greatest potential for Vascepa sales growth. We now market Vascepa in the United States through our sales force of approximately 150 sales professionals and their managers. We also employ various marketing and medical affairs personnel to support our commercialization of Vascepa. Our clinical and commercial supply is provided to us under agreements with various third-party suppliers. As of February 1, 2014, over 16,000 clinicians had written prescriptions for Vascepa.



## **Table of Contents**

In December 2013, we completed our eleventh full calendar month of marketing and selling Vascepa. Based on monthly compilations of data provided by a third party, Symphony Health Solutions, the estimated number of normalized total Vascepa prescriptions for the year ended December 31, 2013 was approximately 225,000. According to data from another third party, IMS Health, the estimated number of normalized total Vascepa prescriptions was approximately 195,000 for that same period. Normalized total prescriptions represent the estimated total number of Vascepa prescriptions shipped to patients, calculated on a normalized basis (i.e., total capsules shipped divided by 120 capsules, or one month's supply). 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. We recorded revenue of \$26.4 million during the year ended December 31, 2013, all from sales of Vascepa in the U.S.

Although we believe these third-party-provided data are prepared on a period-to-period basis in a manner that is generally consistent and that such results are generally indicative of current prescription trends, these data are based on estimates and should not be relied upon as definitive. In addition, because of our limited selling history, during the year ended December 31, 2013, we only recognized revenue on product that was resold for purposes of filling prescriptions. Those prescription data may differ from data reported by other third parties.

Prior to commencing our U.S. commercial launch of Vascepa in January 2013, we had no revenue from Vascepa. Because of our limited selling history, changes in the size of our sales force and uncertainty regarding resolution of the ANCHOR sNDA with the FDA, we do not believe that we can provide a reasonably accurate forecast of Vascepa prescriptions or revenues. While we expect to be able to grow Vascepa revenues, we provide no quantified guidance regarding anticipated levels of Vascepa prescriptions or revenues and no such guidance should be inferred from the operating metrics described above. 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 and other factors. We believe investors should consider our results over several quarters, or longer, before making an assessment about potential future performance.

The commercial launch of a new pharmaceutical product is a complex undertaking, and our ability to effectively and profitably launch 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*.

We believe that our sales and marketing teams are well positioned to support the commercialization of Vascepa for the MARINE indication. We also believe that a larger sales effort will be required to best support the commercialization of Vascepa for the ANCHOR indication, if the FDA approves such indication. To support the continued commercialization of Vascepa, we intend to consider strategic opportunities with larger pharmaceutical companies. From time to time we have held discussions with larger pharmaceutical companies on potential collaborations and other strategic opportunities, and we intend to continue having discussions regarding such opportunities in the future. These strategic opportunities may include licensing or similar transactions, joint ventures, partnerships, strategic alliances, business associations, or a sale of the company. However, we cannot estimate the timing of any such potential strategic transaction, and no assurance can be given that we will enter into any such strategic transaction. Until such time when we enter into such a strategic transaction, if ever, we plan to continue to execute on our plans to market and sell Vascepa on our own.

The U.S. market is currently our primary focus for Vascepa. Opportunities to seek regulatory approval and to market and sell Vascepa outside of the United States are also under evaluation.

### *Financial Position*

We believe that our cash balance of \$191.5 million at December 31, 2013 is sufficient to fund our projected operations for at least the next twelve months, including continued commercialization of Vascepa in the United

---

## **Table of Contents**

States for the MARINE indication, preparations for commercialization of Vascepa in the United States for the ANCHOR indication, if approved, and the advancement of the REDUCE-IT cardiovascular outcomes study.

### **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 2014 Update from the American Heart Association, more than 1 out of every 3 adults in the U.S. (approximately 84 million) currently lives with one or more types of cardiovascular disease; an estimated 915,000 heart attacks and 795,000 strokes occur each year; an estimated 32 million adults <sup>≥</sup>20 years of age have high total serum cholesterol levels (<sup>≥</sup>240 mg/dL), and an estimated 71 million adults <sup>≥</sup>20 years of age have borderline high or high low-density lipoprotein ( bad ) cholesterol, or LDL-C, levels (<sup>≥</sup>130 mg/dL).

In addition to cholesterol, lipoproteins such as LDL 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 recognized as 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 (<sup>≥</sup>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, very low density lipoprotein cholesterol (VLDL-C), and HDL-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 >200mg/dL and approximately 3 to 4 million people in the United States have very high triglyceride levels (<sup>≥</sup>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 <sup>≥</sup>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 treatments to lower triglyceride levels are fibrates (fenofibrate and gemfibrozil), statins and a prescription only omega-3 fatty acid, known as Lovaza<sup>®</sup> in the United States, and as Omacor<sup>®</sup> 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 eicosapentanoic acid, or EPA, docosahexaenoic acid, or DHA, and other fatty acids. We believe that DHA may increase LDL-C levels

---

## **Table of Contents**

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.

### **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, as well as removing the fishy taste and smell that is sometimes associated with 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. In addition, currently no omega-3 based product is approved in the United States for lowering high triglycerides in patients with mixed dyslipidemia. If approved in that indication, Vascepa has the potential to become first-in-class in the prescription-only omega-3 market for lowering triglycerides in patients with mixed dyslipidemia.

We believe the potential market for Vascepa is large and growing. We estimate that drug treatment for hypercholesterolemia patients exceeds \$59 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 \$3.8 billion in 2013 with generic fenofibrate and gemfibrozil leading the class. U.S. gross sales of Lovaza in 2013 were over \$1.4 billion.

### **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 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.

**Table of Contents**

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

The MARINE trial results also included statistically significant reductions compared to placebo in several important lipid and inflammatory biomarkers, including apo B (apolipoprotein B) (8.5%), Lp-PLA2 (lipoprotein-phospholipase A2) (13.6%), VLDL-C (very low-density lipoprotein cholesterol) (28.6%), Total Cholesterol (16.3%), and hsCRP (high-sensitivity C-reactive protein) (36.0%) at the 4-gram dose. For these achieved endpoints, p-values were <0.01 for most and <0.05 for all. Apo B (apolipoprotein B) is believed to be a sensitive biomarker of cardiovascular risk and may be a better predictor of cardiovascular risk than LDL-C. Lp-PLA2 is an enzyme found in blood and atherosclerotic plaque; high levels have been implicated in the development and progression of atherosclerosis.

In 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 grams 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 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 (basis for sNDA submitted to FDA seeking expanded indication for Vascepa)***

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

**Table of Contents**

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. In addition to the previously reported favorable lipid effects of Vascepa on hypertriglyceridemic patients in the MARINE and ANCHOR studies, a recently published analysis of these studies showed that the Vascepa 4-gram daily dose also significantly decreased levels of the inflammatory marker oxidized low-density lipoprotein relative to 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.

We have a pending sNDA with the FDA that seeks marketing approval of Vascepa for use in the ANCHOR indication. On October 16, 2013, the FDA convened an advisory committee to review our sNDA. This advisory committee was not asked by the FDA to evaluate whether Vascepa is effective in lowering triglycerides in the studied population, the ANCHOR indication as specified in the sNDA. Rather, the advisory panel was asked whether Vascepa has been demonstrated to improve cardiovascular outcomes or whether approval of the ANCHOR indication should wait for successful completion of the REDUCE-IT study, the first prospective study of cardiovascular outcomes in patients who have high triglyceride levels despite statin therapy. The advisory committee voted 9 to 2 against recommending approval of the ANCHOR indication based on information presented at the meeting. The FDA considers the recommendation of advisory committees, but final decisions on the approval of new drug applications are made by the FDA.

The ANCHOR trial clinical study was conducted under an SPA agreement with the FDA. The law governing SPA agreements requires that if the results of the trial conducted under the SPA substantiate the hypothesis of the protocol covered by the SPA, the FDA must use the data from the protocol as part of the primary basis for approval of the product. A SPA agreement is not a guarantee of FDA approval of the related new drug application. 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 of the drug after the study begins that rises to the level of a public health concern, or if the study sponsor fails to follow the protocol that was agreed upon with the FDA. On October 29, 2013, the FDA rescinded the ANCHOR study SPA.

## **Table of Contents**

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. As a basis for this determination, the FDA communicated that it determined that the cumulative results from outcome studies of other triglyceride-lowering drugs failed to support the hypothesis that a triglyceride-lowering drug significantly reduces the risk for cardiovascular events among the population studied in the ANCHOR trial. Thus, the FDA stated that while information we submitted supports testing the hypothesis that Vascepa 4 grams/day versus placebo reduces major adverse cardiovascular events in statin-treated subjects with residually high triglyceride levels, as is being studied in the Vascepa REDUCE-IT cardiovascular outcomes study, the FDA no longer considers a change in serum triglyceride levels as sufficient to establish the effectiveness of a drug intended to reduce cardiovascular risk in subjects with serum triglyceride levels below 500 mg/dL. In November 2013, we submitted to the FDA a request for reconsideration of its decision to rescind the ANCHOR SPA agreement. On January 17, 2014, we were notified by the FDA that it does not intend to reinstate the ANCHOR SPA agreement. Our plan is to continue appealing the rescission decision to successively higher administrative levels within the FDA in accordance with FDA dispute resolution guidance.

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

In Japan, ethyl-EPA is marketed under the product name of Epadel by Mochida Pharmaceutical Co. and is indicated for hyperlipidemia and peripheral vascular disease. Clinical data from Japan suggests that Epadel is effective in reducing triglycerides. In addition, in an outcomes study called the Japan EPA Lipid Intervention Study, or JELIS study, which consisted of more than 18,000 patients followed over multiple years, Epadel, when used in conjunction with statins, was shown to reduce cardiovascular events by 19% compared to the use of statins alone. In this study, cardiovascular events decreased by approximately 53% compared to statins alone in the subset of patients with triglyceride levels of  $\geq 150$  mg/dL (average 269 mg/dL at entry) and HDL-C  $< 40$  mg/dL. Epadel has been approved and available by prescription in Japan for over a decade. In 2013, the Japan Ministry of Health approved Epadel for over-the-counter sales.

### ***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).

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 an SPA for the design of the REDUCE-IT (Reduction of Cardiovascular Events with EPA Intervention Trial) cardiovascular outcomes study. In May 2013, we amended the patient enrollment criteria within the SPA agreement with the FDA. An SPA is an evaluation by the FDA of a protocol with the goal of reaching an agreement that the Phase 3 trial protocol design,

## **Table of Contents**

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. An 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 an 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 study duration is dependent on the rate of clinical events in the study which rate may be affected by the number of patients enrolled in the study and the epidemiology of the patients enrolled in the study. Based on preliminary assumptions for patient enrollment rates and the clinical profile of these patients, it is assumed that fewer than 10,000 patients will be required to complete the study with an optimized target in which the study is completed in approximately six years of 8,000 patients.

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 multi-center, 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.

We currently expect that final positive results of the REDUCE-IT study will be required for FDA approval of Vascepa for the ANCHOR indication based on communications from the FDA. Based on the results of REDUCE-IT, we may seek additional indications for Vascepa beyond the indication studied in the ANCHOR and MARINE trials such as a potential indication 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 resolution of the ANCHOR sNDA with the FDA. If we do not receive FDA approval for the ANCHOR indication, we may discontinue development of AMR102.

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 clinic developments are in formulative or pre-clinical stages.

### **Manufacturing and Supply for Vascepa**

We currently use third party manufacturers and suppliers to manufacture clinical and commercial quantities of ethyl-EPA, which constitutes the only active pharmaceutical ingredient, or API, within Vascepa, to encapsulate, bottle and package Vascepa and to maintain inventory of Vascepa. The FDA approval of Vascepa in

## **Table of Contents**

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 Europe BV). Nisshin and Patheon are the API manufacturer and API encapsulator, respectively, with which we have had the longest working relationships. Their facilities were inspected by regulatory authorities as part of the process that led to the FDA's July 2012 approval of Vascepa, and we believe that the facilities are qualified to continue to support our commercialization of Vascepa.

We currently rely exclusively on Patheon for the encapsulation of Vascepa. We have encapsulation agreements with two other commercial API encapsulators. These companies are working to qualify their processes and to prove that the Vascepa capsules they produce meet the same quality standards as the capsules produced by Patheon.

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 suppliers. In April 2013, the FDA approved our sNDAs covering Chemport and BASF as additional Vascepa API suppliers. BASF is working to complete validation of their facility for the manufacture of Vascepa. 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. BASF is entitled to a 60-day cure period. In December 2012, we announced an agreement with an exclusive consortium of companies led by Slanmhor Pharmaceutical, Inc., or Slanmhor. Slanmhor was spun-out from Ocean Nutrition Canada, or ONC, prior to the May 2012 acquisition of ONC by Royal DSM N.V. We are working with Slanmhor to pursue FDA approval for this supplier to manufacture Vascepa API and we submitted a sNDA in August 2013. Slanmhor is working to complete construction and validation of their facility for the manufacture of Vascepa. The regulatory approval and facility validation of Slanmhor as an API supplier would give us an additional qualified worldwide supplier of API for Vascepa to utilize in supporting the global commercialization of Vascepa.

The API material that constitutes ethyl-EPA is a naturally occurring substance which is sourced from qualified producers of fish oil. A limited number of other manufacturers have the ability, know-how and suitable facilities to produce ethyl-EPA to a similar 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 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 an ongoing basis. In complying 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 requirements.

Our agreements with our API suppliers include minimum purchase commitments. During 2013 we fully met the aggregate minimum purchase requirements for metric tons of API contained in our supply agreements with Nisshin and Chemport. We may purchase more than the minimum requirements. We have not purchased any commercial supply from BASF as they have not completed the validation of their manufacturing process. If the manufacturing process is validated, there will be annual minimum purchase commitments under that supply agreement. If the sNDA for Slanmhor is approved and their manufacturing facility is validated, there will be annual minimum purchase commitments under that supply agreement. Certain of these agreements also contain provisions under which the cost of supply to us decreases as we purchase increased product volume and provisions under which the cost of supply to us changes based on increases or decreases in certain production costs. Certain of these agreements also contemplate phased capacity expansion aimed at creating sufficient capacity to meet anticipated demand for API material for Vascepa. Accordingly, certain of these suppliers are currently working to expand their production capabilities to manufacture the API for Vascepa. These API suppliers are self-funding these expansion and qualification plans with contributions from Amarin. There can be no assurance that additional suppliers will fully fund the capital costs of our engagement or that these additional suppliers will successfully qualify with the FDA. These contracts contain provisions for making lesser payments to these suppliers in lieu of purchasing the full minimum purchase requirements.



## **Table of Contents**

### **Our Marketing Plans**

In January 2013, we commenced our full commercial launch of Vascepa in the United States for use in the MARINE indication. In preparation for our commercial launch, we hired and trained a direct sales force of approximately 275 sales representatives. In October 2013, we reduced our number of sales representatives to approximately 130, excluding sales management, in the United States to focus on the sales territories that we believe have demonstrated the greatest potential for Vascepa sales growth. We now market Vascepa in the United States through our sales force of approximately 150 sales professionals and managers. We also employ various marketing and medical affairs personnel to support our commercialization of Vascepa. We currently target clinicians who are top prescribers of lipid regulating therapies. Our current sales team covers clinicians responsible for greater than 90% of Vascepa prescriptions fulfilled in 2013.

### **Historical Product Development Programs**

Prior to October 2009, the majority of Amarin's product development activities were focused on central nervous system and other non-cardiovascular disorders. In October 2009, we completed a private placement resulting in gross proceeds of \$70.0 million. These proceeds were used primarily to fund the MARINE and ANCHOR studies for Vascepa. In connection with this private placement, our board of directors and executive management changed significantly, and our research and development activities, as well as certain executive functions, were consolidated from multiple offices to our research and development headquarters in the United States. In connection with these changes, we re-focused our efforts on developing improved treatments for cardiovascular disease and ceased development of all product candidates outside of our cardiovascular disease focus. In particular, this decision resulted in our ceasing all direct development of product candidates on central nervous system disorders, which included product candidates for the treatment of Huntington's disease, Myasthenia gravis and Parkinson's disease.

### **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 potential competitors both in the United States and Europe include large, well-established pharmaceutical companies, specialty pharmaceutical sales and marketing companies, and specialized cardiovascular treatment companies. These companies include GlaxoSmithKline plc, which currently markets Lovaza, a prescription-only omega-3 fatty acid indicated for patients with severe hypertriglyceridemia, and AbbVie, Inc., which currently markets Tricor and Trilipix for the treatment of severe hypertriglyceridemia and mixed dyslipidemia and Niaspan, which is primarily used to raise HDL-C, but is also used to lower triglycerides. In March 2011, Pronova BioPharma Norge AS, now owned by BASF, which owns the patents for Lovaza, entered into an agreement with Apotex Corp. and Apotex Inc., or Apotex, to settle their patent litigation in the United States related to Lovaza. Pursuant to the terms of the settlement agreement, Pronova/BASF granted Apotex a license to enter the United States market with a generic version of Lovaza in the first quarter of 2015, or earlier depending on circumstances. In addition, Pronova /BASF recently lost an appeal in its patent infringement lawsuit against Teva Pharmaceuticals USA Inc., or Teva, and Par Pharmaceutical Inc., or Par, which would have prevented Teva and Par from launching generic versions of Lovaza. Apotex, Teva, and Par must obtain FDA approval of generic versions of Lovaza before they are permitted to sell such products in the

## **Table of Contents**

United States. Other companies are also seeking to introduce generic versions of Lovaza. Each of these competitors has greater resources than we do, including financial, product development, marketing, personnel and other resources.

In addition, we are aware of other pharmaceutical companies that are developing products that, if approved and marketed, would compete with Vascepa. These include a free fatty acid form of omega-3 (comprised of 55% EPA and 20% DHA) developed by Omthera Pharmaceuticals, now owned by AstraZeneca PLC. In July 2013, an NDA was submitted to the FDA seeking approval of this drug candidate for the treatment of severe hypertriglyceridemia. AstraZeneca has announced that the scheduled goal date for FDA approval of its product is May 5, 2014. We expect AstraZeneca will utilize its substantial commercial resources to market Omthera Pharmaceuticals' product, if approved. We also understand that another company, Trygg Pharma AS, has completed a Phase 3 study of an omega-3 based drug candidate for severe hypertriglyceridemia, but we do not believe Trygg has announced results from that study. It is possible that Trygg Pharma has filed for FDA approval of its product candidate. In addition, Acasti Pharma, a subsidiary of Neptune Technologies & Bioresources Inc., announced in late 2012 that it intends to conduct a Phase 3 clinical program to assess the safety and efficacy of its omega-3 prescription drug candidate derived from krill oil for the treatment of hypertriglyceridemia. We believe Catabasis Pharmaceuticals, or Catabasis, Resolvix Pharmaceuticals, or Resolvix, and Sancilio & Company, or Sancilio, are also developing potential treatments for hypertriglyceridemia based on omega-3 fatty acids and, to our knowledge, Catabasis initiated a Phase 2 clinical trial of its product in December 2013; Resolvix's compound remains in Phase 1 clinical testing; and Sancilio has recently filed an Investigational New Drug Application (IND) and is preparing to commence Phase 3 clinical trials. In addition, we are aware that Matinas BioPharma, Inc. is developing an omega-3-based therapeutic for the treatment of severe hypertriglyceridemia and mixed dyslipidemia. Matinas BioPharma, Inc. has reported that it is preparing to file an IND with the FDA and to conduct a human study in the first half of 2014. Isis Pharmaceuticals announced favorable Phase 2 results of ISIS-APOCIII<sub>Rx</sub>, a drug candidate administered through weekly subcutaneous injections, in patients with high triglycerides and type 2 diabetes and in patients with moderate to severe high triglycerides. Finally, Madrigal Pharmaceuticals has completed Phase 1 clinical testing of MGL-3196 for the treatment of high triglycerides and various lipid parameters in patients.

Vascepa also faces competition from dietary supplement companies marketing omega-3 products as nutritional supplements. 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 supplements.

In addition, we expect that generic drug companies will seek to challenge the validity and enforceability of our patents and work toward FDA approval for 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. Our drugs must be approved by the FDA through the NDA process before they may be legally marketed in the United States. For new chemical entities, the pre-clinical development stage generally involves synthesizing the active component, developing the formulation and determining the manufacturing process, as well as carrying out non-human toxicology, pharmacology and drug metabolism studies which support subsequent clinical testing.

## **Table of Contents**

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, they may suspend or terminate the study at any time. Studies must be conducted in accordance with good clinical practice 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 marketing a drug in the United States.

The FDA will likely re-analyze the clinical trial data, which could result in extensive 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 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

## **Table of Contents**

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.

### ***European Union Drug Development***

In the European Union, or E.U., our future products may also be subject to extensive regulatory requirements. As in the United States, the marketing of medicinal products has been subject to the granting of marketing authorizations by regulatory agencies. Particular emphasis is also being placed on more sophisticated and faster procedures for reporting of adverse events to the competent authorities.

Similar to the United States, the various phases of pre-clinical and clinical research in the E.U. are subject to significant regulatory controls. Although the regulatory controls on clinical research are currently undergoing a harmonization process following the adoption of the Clinical Trials Directive 2001/20/EC, there are currently significant variations in the member state regimes. However, all member states currently require independent institutional review board approval of interventional clinical trials. With the exception of U.K. Phase 1 studies in healthy volunteers, all clinical trials require either prior governmental notification or approval. Most regulators also require the submission of adverse event reports during a study and a copy of the final study report.

### ***European Union Drug Review and Approval***

In the E.U., approval of new medicinal products can be obtained through one of three processes: the mutual recognition procedure, the centralized procedure and the decentralized procedure.

#### **Mutual Recognition Procedure**

An applicant submits an application in one E.U. member state, known as the reference member state. Once the reference member state has granted the marketing authorization, the applicant may choose to submit applications in other concerned member states, requesting them to mutually recognize the marketing authorizations already granted. Under this mutual recognition process, authorities in other concerned member states have 55 days to raise objections, which must then be resolved by discussions among the concerned member states, the reference member state and the applicant within 90 days of the commencement of the mutual recognition procedure. If any disagreement remains, all considerations by authorities in the concerned member states are suspended and the disagreement is resolved through an arbitration process. The mutual recognition procedure results in separate national marketing authorizations in the reference member state and each concerned member state.

#### **Centralized Procedure**

This procedure is currently mandatory for products developed by means of a biotechnological process and optional for new active substances and other innovative medicinal products with novel characteristics. Under this procedure, an application is submitted to the European Agency for the Evaluation of Medical Products. Two European Union member states are appointed to conduct an initial evaluation of each application. These countries each prepare an assessment report that is then used as the basis of a scientific opinion of the Committee on Proprietary Medical Products. If this opinion is favorable, it is sent to the European Commission, which drafts a decision. After consulting with the member states, the European Commission adopts a decision and grants a marketing authorization, which is valid throughout the European Union and confers the same rights and obligations in each of the member states as a marketing authorization granted by that member state.

#### **Decentralized Procedure**

The most recently introduced of the three processes for obtaining approval of new medicinal processes in the E.U., the decentralized procedure is similar to the mutual recognition procedure described above, but with

## **Table of Contents**

differences in the timing that key documents are provided to concerned member states by the reference member state, the overall timing of the procedure and the possibility of clock stops during the procedure, among others.

### ***Post-Marketing Requirements***

Following approval of a new product, a pharmaceutical company generally must engage in numerous specific monitoring and recordkeeping activities and continue to submit periodic and other reports to the applicable regulatory agencies, including any cases of adverse events and appropriate quality control records. 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 U.S. Federal Food, Drug, and Cosmetic Act.

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 current good manufacturing practices, or 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. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making or using, or causing to be made or used, a false statement to get a false claim paid. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false

## **Table of Contents**

claims to be submitted because of the company's marketing of the product for unapproved, and thus non-reimbursable, uses. 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.

Because of the breadth of these laws and the narrowness of the 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. The laws that may affect our ability to operate include:

the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information; and

state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations, any of which 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.

## **Table of Contents**

The American Recovery and Reinvestment Act of 2009 provides funding for the federal government to compare the effectiveness of different treatments for the same illness. A plan for the research will be developed by the Department of Health and Human Services, the Agency for Healthcare Research and Quality and the National Institutes for Health, and periodic reports on the status of the research and related expenditures will be made to Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payers, it is not clear what effect, if any, the research will have on the sales of any product, if any such product or the condition that it is intended to treat is the subject of a study. It is also 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.

Most recently, 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;

new requirements to report certain financial arrangements with physicians and others, including reporting any transfer of value made or distributed to prescribers and other healthcare providers and reporting any investment interests held by physicians and their immediate family members;

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.

Many of the details regarding the implementation of the PPACA are yet to be determined, and at this time, it remains unclear the full effect that the PPACA would have on our business.

### ***Other Regulatory Matters***

Manufacturing, sales, promotion, and other activities following product approval are also subject to regulation by numerous regulatory authorities in addition to the FDA, including, in the United States, 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 also comply with the U.S. Medicare-Medicaid Anti-Fraud and Abuse 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. The handling of any controlled substances must comply with the U.S. Controlled





## **Table of Contents**

Substances Act and Controlled Substances Import and Export Act. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities are also potentially subject to federal and state consumer protection and unfair competition laws.

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***

The Food Drug and Cosmetic Act, or 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. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity, or NCE. A drug is an NCE if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement.

The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application (for example, for new indications, dosages, or strengths of an existing drug). Such three-year exclusivity protection would preclude the FDA from approving a marketing application for a duplicate of a pioneer drug, a product candidate that the FDA views as having the same conditions of approval as the pioneer drug (for example, the same indication and/or other conditions of use), or a 505(b)(2) NDA submitted to the FDA with the pioneer drug as the reference product, for a period of three years from the date of FDA approval, although the FDA may accept and commence review of such applications during the exclusivity period. This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Such three-year exclusivity grant would also not prevent a company from challenging the validity of patents covering the pioneer drug at any time. In this case, the pioneer drug company may be afforded the benefit of a 30-month stay against the launch of such a competitive product that would extend from the period that it responds to a pending patent challenge, and may also be afforded other extensions under applicable regulations, including a six-month pediatric exclusivity

## **Table of Contents**

extension or a judicial extension if applicable requirements are met. 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.

Five-year and three-year exclusivity will not delay the submission or tentative approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

The FDA typically makes a determination on marketing exclusivity in connection with, or soon after, an NDA approval of a drug for a new indication. 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 NCE marketing exclusivity to Vascepa and granted three-year marketing exclusivity. Such three-year exclusivity extends through July 25, 2015 and can be supplemented by a 30-month stay triggered after patent infringement litigation initiated by Amarin following a valid notice to Amarin of the filing of an application to the FDA seeking approval of a generic version of Vascepa.

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 also plan to seek regulatory exclusivity for Vascepa in Europe. There can be no assurance that we will be successful in securing marketing approval or regulatory exclusivity in the United States or in Europe.

### **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.

Amarin has prosecuted, and is currently prosecuting, multiple patent applications to protect the intellectual property developed during the Vascepa cardiovascular program. As of the date of this Annual Report, we had 40 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. Of such 40 allowed and issued applications, we currently have:

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,

## Edgar Filing: AMARIN CORP PLC\UK - Form 10-K

29 U.S. patents covering the use of Vascepa in either the MARINE or anticipated ANCHOR indication that have terms that expire in 2030,

6 additional patent applications for which the United States Patent and Trademark Office, or USPTO, has issued a Notice of Allowance each of which with terms that expire in 2030 and are related to the use of Vascepa in either the MARINE or anticipated ANCHOR indication,

## **Table of Contents**

1 additional patent related to the use of a pharmaceutical composition comprised of free fatty acids to treat the ANCHOR patient population that expires in 2030, and

1 additional patent application for which the United States Patent and Trademark Office, or USPTO, has issued a Notice of Allowance with a term that expires in 2030 and is related to the use of a pharmaceutical composition comprised of free fatty acids to treat the MARINE patient population.

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. 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. 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 20, 2014 we had 185 full-time employees employed in sales, marketing, general and administrative and research and development functions. We believe our relations with our employees are good.

**Table of Contents****Organizational Structure**

At February 20, 2014, 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 Ltd	Ireland	100%
Ester Neurosciences Limited	Israel	100%

Our registered office is located at One New Change, London EC4M 9AF, England. Our principal offices are located at 2 Pembroke House, Upper Pembroke Street 28-32, Dublin 2 Ireland. Our primary offices in the United States are located at 1430 Route 206, Bedminster, NJ 07921, USA. Our telephone number at that location is (908) 719-1315. Our website address is [www.amarincorp.com](http://www.amarincorp.com). No information contained on, or accessible through, our website is incorporated by reference into this Annual Report on Form 10-K.

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 Ltd, or Ester Neurosciences Limited.

On January 9, 2012, Amarin, through its wholly-owned subsidiary Corsicanto Limited, a private limited 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 notes are the senior unsecured obligations of Corsicanto and are guaranteed by Amarin Corporation plc. Corsicanto was formed in November 2011 and was subsequently acquired by Amarin in January 2012 for the sole purpose of facilitating this financing transaction.

**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.

**Where You Can Find More Information**

You are advised to read this Annual Report on Form 10-K in conjunction with other reports and documents that we file from time to time with the Securities and Exchange Commission, or SEC. You may obtain copies of these reports after the date of this annual report directly from us or from the SEC at the SEC's Public Reference Room at 100 F Street, N.E. Washington, D.C. 20549. In addition, the SEC maintains information for electronic filers (including Amarin) at its website at [www.sec.gov](http://www.sec.gov). The public may obtain information regarding the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. We make our periodic and current reports, as well as any amendments to such reports, available on our internet website, free of charge, as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC.

**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 capital resources, our ability to successfully launch Vascepa, 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*

---

## **Table of Contents**

*candidates, commercial market estimates, future development efforts, patent protection, effects of healthcare reform, reliance on third parties, and other risks set forth below.*

### **Risks Related to the Commercialization and Development of Vascepa**

***Our ability to generate increased revenue over the next few years depends, in part, on FDA approval for the use of Vascepa in the ANCHOR indication in the United States and we may be delayed in obtaining, or never obtain, such approval. In October 2013 an advisory committee convened by the FDA voted 9 to 2 against recommending approval of Vascepa in the ANCHOR indication and the FDA has rescinded our ANCHOR clinical trial Special Protocol Assessment Agreement, as a result of which there is a significant risk that FDA will not approve Vascepa for this indication.***

While we are currently marketing Vascepa for use in the MARINE indication in the United States, our ability to commercialize Vascepa in the ANCHOR indication in the United States or market Vascepa for either indication outside of the United States is dependent upon receiving additional regulatory approvals. In April 2013, the FDA accepted our Supplemental New Drug Application, or sNDA, which seeks 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 for elevated LDL-C levels, which we refer to as the ANCHOR indication. The FDA originally assigned the sNDA a Prescription Drug User Fee Act, or PDUFA, date of December 20, 2013 for the completion of its review. The PDUFA date is the goal date for the FDA to complete its review of the sNDA. On December 19, 2013, the FDA notified us it did not expect to take action on our sNDA on December 20, 2013 because our request to re-instate the ANCHOR special protocol assessment, or SPA, agreement remained under consideration with the FDA. Our request to reinstate the ANCHOR SPA was denied and we are in the process of appealing that decision. No new PDUFA date has been established.

On October 16, 2013 the FDA convened an advisory committee meeting to review the sNDA for the ANCHOR indication. At the meeting, the advisory committee voted 9 to 2 against recommending approval of Vascepa, based on the following question:

Taking into account the described efficacy and safety data for Vascepa, do you believe that its effects on the described lipid/lipoprotein parameters are sufficient to grant approval for co-administration with statin therapy for the treatment of patients with mixed dyslipidemia and CHD or CHD risk equivalent prior to the completion of REDUCE-IT?

During the advisory committee meeting, based in part on the briefing materials prepared by the FDA for the meeting, the advisory committee reviewed the safety and efficacy data observed in the ANCHOR trial. This included a discussion regarding observed nominally statistically significant changes from baseline in an adverse direction, while on background statin therapy, in certain lipid parameters, including TGs, in the placebo group, raising the possibility that the mineral oil placebo used in the ANCHOR trial (and in the REDUCE-IT trial) was not biologically inert and might be viewed as artificially exaggerating the clinical effect of Vascepa when measured against placebo in the ANCHOR trial. Because no strong evidence for biological activity of mineral oil was identified by the FDA in the MARINE trial, ultimately it was 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. Following this discussion at the advisory committee meeting, while no formal vote was taken related to the inert nature of the placebo, we believe that the consensus of the advisory committee, although not unanimous, and the FDA was that, based on the information made available to the advisory committee and FDA at the meeting, Vascepa appeared to be safe and effective for the reduction of TGs in patients with mixed dyslipidemia on statin therapy.

However, there was also extensive discussion during the advisory committee meeting regarding the expected clinical benefit of a reduction in TGs in this patient population. That is, whether the clinical data derived from the ANCHOR trial was a sufficient basis for approval. In particular, the advisory committee and

---

**Table of Contents**

FDA noted the lack of prospective, controlled clinical trial data demonstrating that pharmacological reduction of TGs in patients with mixed dyslipidemia on statin therapy significantly reduces residual cardiovascular risk in these patients. The FDA noted that prior clinical outcomes studies conducted by others, albeit in different patient populations, evaluating different drugs with different mechanisms of action, failed to demonstrate a statistically significant reduction in cardiovascular events following concomitant use of drug therapy in patients on statin therapy. We believe that the negative vote of the advisory committee was principally due to the lack of recent conclusive data in these clinical outcomes studies in favor of the hypothesis that TG reduction will result in reduced cardiovascular risk. The FDA is not bound by the recommendations of the advisory board, but it generally follows such recommendations.

A Special Protocol Assessment, or SPA, agreement is an agreement with the FDA that Phase 3 trial protocol design, clinical endpoints, and planned statistical analyses are acceptable to support regulatory approval. A SPA 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. On October 29, 2013, the FDA notified us that it rescinded the SPA agreement we entered into for the ANCHOR trial protocol 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. As a basis for this determination, the FDA communicated that, consistent with discussion at the advisory committee meeting, it determined that results from outcome studies of other triglyceride-lowering drugs failed to support the hypothesis that a triglyceride-lowering drug significantly reduces the risk for cardiovascular events among the population studied in the ANCHOR trial. Thus, the FDA stated that it no longer considers a change in serum triglyceride levels as sufficient to establish the effectiveness of a drug intended to reduce cardiovascular risk in subjects with serum triglyceride levels below 500 mg/dL. On November 7, 2013, we submitted to the FDA a formal appeal of its decision to rescind the SPA including documents outlining why we believe the SPA was wrongfully rescinded.

On November 21, 2013, we received notification from the dispute resolution group of the Office of New Drugs at the FDA that it had not accepted for review, on procedural grounds, our appeal regarding the rescission of the SPA. We were also notified by the FDA that our request for a meeting at a high level within the FDA regarding the appeal was not granted and that we would first need to address the matter at the division level within the FDA. On December 19, 2013, the FDA notified us it did not expect to take action on our sNDA on December 20, 2013 because our request to re-instate the ANCHOR SPA agreement remained under consideration with the FDA. The FDA also communicated to us that, as of December 19, 2013, it viewed our appeal of the ANCHOR SPA agreement rescission and the ANCHOR sNDA as separate administrative decisions worthy of separate consideration and that it FDA planned to complete its review of our request to re-instate the ANCHOR SPA agreement. The FDA provided no additional information on when it expects to complete its review of the ANCHOR sNDA. On January 17, 2014, the Division of Metabolism and Endocrinology Products, or DMEP, within the FDA notified Amarin in connection with Amarin's request for reconsideration of the October 2013 decision to rescind the ANCHOR SPA agreement that the DMEP does not plan to re-instate the ANCHOR SPA agreement. Our plan is to continue appealing the rescission decision to successively higher administrative levels within the FDA in accordance with FDA dispute resolution guidance. Neither the DMEP nor FDA provided additional information on when it expects to complete its review of the ANCHOR sNDA. There can be no assurance that we will be successful in the reinstatement of the ANCHOR SPA agreement or in approval of the ANCHOR indication sNDA.

Based on our communications with the FDA, we currently expect that final positive results from the REDUCE-IT outcomes study will be required for FDA approval of Vascepa for the ANCHOR indication. If we do not receive FDA approval of the ANCHOR indication, we plan to re-evaluate the REDUCE-IT study, including the likelihood of REDUCE-IT providing clinically and commercially useful results, the likelihood of FDA approval for an expanded indication for Vascepa based on these results and whether it is best to continue or discontinue the study. We anticipate that in any such re-evaluation we will seek further feedback from the FDA. The aggregate cost to complete REDUCE-IT, excluding amounts previously expensed, is estimated to

---

## **Table of Contents**

exceed \$100 million, which is a significant financial burden given our current financial position. To the extent the FDA conditions approval of Vascepa for the ANCHOR indication on its review of the data from the REDUCE-IT trial, Vascepa may never be approved for this indication. Any delay in obtaining, or an inability to obtain, marketing approval in this indication would prevent us from growing revenue and could 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 the ANCHOR indication takes too long, we may miss market opportunities and give other companies the ability to develop competing products or establish market dominance. Additionally, the terms of any approvals, including 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 SPA agreement for ANCHOR has been 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 ANCHOR trial was, and the REDUCE-IT trial is, being conducted under an 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 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.

On October 29, 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. Specifically, consistent with discussion at the advisory committee meeting, the FDA determined that results from outcome studies of other triglyceride-lowering drugs failed to support the hypothesis that a triglyceride-lowering drug significantly reduces the risk for cardiovascular events among the population studied in the ANCHOR trial. In response to our appeal of the decision to rescind the ANCHOR SPA agreement, on January 17, 2014, the DMEP within the FDA notified Amarin in connection with Amarin's request for reconsideration of the October 2013 decision to rescind the ANCHOR SPA agreement that the DMEP does not plan to re-instate the ANCHOR SPA agreement. Thus, the DMEP stated that it no longer considers a change in serum triglyceride levels as sufficient to establish the effectiveness of a drug intended to reduce cardiovascular risk in subjects with serum triglyceride levels below 500 mg/dL. We are in the process of appealing this decision.

Thus, even though we have received regulatory approval of Vascepa for the MARINE indication under an SPA agreement, our ANCHOR SPA agreement was rescinded and there is no assurance that the FDA will not rescind our REDUCE-IT SPA agreement. Any delay in obtaining, or an inability to obtain, marketing approval in either the ANCHOR or REDUCE-IT indications would prevent us from growing revenue and could have a material adverse effect on our operations and financial condition, including our ability to reach profitability.

***If we do not obtain FDA approval of the ANCHOR indication, we may choose to discontinue our ongoing REDUCE-IT outcome study of Vascepa, which is designed to determine whether Vascepa is effective in reducing major cardiovascular events in a high risk patient population on statin therapy and our development of AMR102, a fixed dose combination of Vascepa and a leading statin product.***

Our ongoing REDUCE-IT cardiovascular outcome study was designed to determine whether Vascepa, when added to statin therapy, would reduce the risk of major cardiovascular events in an at-risk patient population. We



---

**Table of Contents**

expect the ongoing incremental cost of the REDUCE-IT study to us over the next several years will exceed \$100 million as the study currently involves over 400 clinical trial sites in eleven countries. The timing of completion of the REDUCE-IT study is based on the rate of cardiovascular events for patients in the study. If it takes longer for such events to accrue than we expect, the trial could take longer to complete and cost more than we currently expect. AMR102, a fixed dose combination of Vascepa and a leading statin product, is in early stage development with relatively minimal current expenses associated with ongoing development, but significant expense associated with development over the next several years. We have not been profitable in any of the last five fiscal years. Our cash and cash equivalents at December 31, 2013 was \$191.5 million. For the fiscal year ended December 31, 2013, we reported a loss of \$166.2 million and we had an accumulated deficit of \$913.9 million. For the twelve months ended December 31, 2013, net revenue from the sale of Vascepa based on the MARINE indication was \$26.4 million. Given the substantial ongoing cost of the REDUCE-IT cardiovascular outcome study, our current capital resources and the current sales of Vascepa resulting from FDA approval of Vascepa for use in the MARINE indication, we may not be able to continue the study with our current financial resources and anticipated revenues from Vascepa without the additional revenues that may be available to us from the sale of Vascepa following an FDA approval of the ANCHOR indication. If we do not receive FDA approval of the ANCHOR indication, we plan to re-evaluate the REDUCE-IT study, including the likelihood of REDUCE-IT providing clinically and commercially useful results, the likelihood of FDA approval for an expanded indication for Vascepa based on these results and whether it is advisable to continue or discontinue the study. We anticipate that in any such re-evaluation we will seek further feedback from the FDA. If we do not receive FDA approval of the ANCHOR indication and do not continue the ongoing REDUCE-IT trial or our development of AMR102, our ability to generate revenue now and over the next several years will be substantially dependent on sales of Vascepa resulting from FDA approval of Vascepa for use in the MARINE indication. Accordingly, our prospects for substantially increasing future revenue from sales of Vascepa beyond what might be expected from the MARINE indication labeling alone will be substantially diminished.

*We are dependent upon the success of Vascepa, which we launched commercially in the MARINE indication in early 2013.*

As a result of our reliance on a single product 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, which we launched in January 2013. If commercialization efforts for Vascepa in the MARINE indication or, if approved, the ANCHOR indication, are not successful, our business will be materially and adversely affected. Even if we are able to 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 in developing any future product or products, 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 products we develop could constrain our ability to generate revenues and achieve profitability.

*We launched Vascepa in the MARINE indication in the United States in January 2013 with our own, newly established sales and marketing teams and distribution channels and we may not be successful. Historical results may not be consistent with or predictive of future results.*

In January 2013, we began selling and marketing Vascepa in the United States through our own, newly established sales and marketing teams and through a newly established third-party commercial distribution infrastructure. We hired key personnel in these areas over the last several years and hired and trained a professional sales force in early January 2013. In October 2013, following an FDA advisory committee recommendation against approval for the ANCHOR indication, we implemented a plan to reduce our workforce and our team of sales professionals in half. The commercial launch of a new pharmaceutical product is a complex undertaking for a company to manage, and we have very limited experience as a company operating in this area.

## Table of Contents

Factors related to building and managing our own sales and marketing organization that can inhibit our efforts to successfully commercialize Vascepa on our own 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 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 effect of our recent reduction in force and regulatory events on our ability to contact potential purchasers of Vascepa in an efficient manner;

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; and

unforeseen costs and expenses associated with operating a new independent sales and marketing organization.

In addition, we believe that investors should view with caution both the results for the twelve months ended December 31, 2013, as data for this limited period may not be representative of a trend consistent with the results presented or otherwise predictive of future results, especially in light of the recent negative advisory committee vote and the approximately 50% reduction in our sales force. We commenced our commercial launch of Vascepa on January 28, 2013. Accordingly, there is a very limited amount of information available at this time to determine the actual number of total prescriptions for Vascepa. We believe investors should consider our results for the twelve months ended December 31, 2013 together with results over several future quarters, or longer, before making an assessment about potential future performance.

In addition to the factors identified above, seasonal fluctuations in pharmaceutical sales, for example, may affect future prescription trends of Vascepa. Moreover, in accordance with our revenue recognition policy and accounting principles generally accepted in the U.S., or GAAP, until we have more experience with the commercialization of Vascepa and can reasonably estimate any product returns, we plan to recognize revenue based on the resale of Vascepa for the purposes of filling prescriptions, and not based on sales from us to such distributors. Accordingly, because of our limited selling history, during the twelve months ended December 31, 2013, we only recognized revenue on product that we could substantiate being resold by retailers, such as pharmacies, for purposes of filling prescriptions. These prescription data may differ from the data reported by third parties. The value of product shipped to distributors but not resold by the distributors to retailers has been deferred until we have evidence that the product was resold by retailers or until we gain sufficient history with our customers to be able to estimate product returns. This is the case even where invoices for such shipments have been collected in full. From launch through December 31, 2013, the Company had experienced a de minimus quantity of product returns.

We have to compete with other pharmaceutical and life sciences companies to recruit, hire, train and retain sales and marketing personnel, and turnover in our sales force and marketing personnel following our recent approximately 50% worldwide reduction in force could negatively affect sales of Vascepa. If we are not successful in our efforts to market and sell Vascepa on our own, market acceptance of Vascepa may be harmed, our anticipated revenues will be materially and negatively affected, and we may need additional funding or seek a strategic licensing or co-promotion transaction as a means of raising additional funds.

***Vascepa may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community necessary for commercial success.***

We began marketing and selling Vascepa for use in the MARINE indication in January 2013. Vascepa may fail to gain sufficient market acceptance by physicians, patients, healthcare payors and others in the medical



---

## **Table of Contents**

community. If Vascepa does not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of Vascepa for the MARINE indication and any future approved indications 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 (which was affected by our recent reduction in force);

publicity concerning Vascepa or competing products;

perception that we will continue to market and sell Vascepa in the MARINE indications and any future approved indications;

sufficient third-party coverage or reimbursement; 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.

***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 potential competitors both in the United States and Europe include large, well-established pharmaceutical companies, specialty pharmaceutical sales and marketing companies, and specialized cardiovascular treatment companies. These companies include GlaxoSmithKline plc, which currently markets Lovaza, a prescription-only omega-3 fatty acid indicated for patients with severe hypertriglyceridemia, and AbbVie, Inc., which currently markets Tricor and Trilipix for the treatment of severe hypertriglyceridemia and mixed dyslipidemia and Niaspan, which is primarily used to raise HDL-C, but is also used to lower triglycerides. In March 2011, Pronova BioPharma Norge AS, now owned by BASF, which owns the patents for Lovaza, entered into an agreement with Apotex Corp. and Apotex Inc., or Apotex, to settle their patent litigation in the United States related to Lovaza. Pursuant to the terms of the settlement agreement, Pronova/BASF granted Apotex a license to enter the United States market with a generic version of Lovaza in the first quarter of 2015, or earlier depending on circumstances. In addition, Pronova/BASF recently lost an appeal in its patent infringement lawsuit against Teva Pharmaceuticals USA Inc., or Teva, and Par Pharmaceutical Inc., or Par, which would have prevented Teva and Par from launching generic versions of Lovaza. Apotex, Teva, and Par must obtain FDA approval of generic versions of Lovaza before they are permitted to sell such products in the United States. Other companies are

also seeking to introduce generic versions of Lovaza. Each of these competitors has greater resources than we do, including financial, product development, marketing, personnel and other resources.

**Table of Contents**

In addition, we are aware of other pharmaceutical companies that are developing products that, if approved and marketed, would compete with Vascepa. These include a free fatty acid form of omega-3 (comprised of 55% EPA and 20% DHA) developed by Omthera Pharmaceuticals, now owned by AstraZeneca PLC. In July 2013, an NDA was submitted to the FDA seeking approval of this drug candidate for the treatment of severe hypertriglyceridemia. AstraZeneca has announced that the scheduled goal date for FDA approval of its product is May 5, 2014. We expect AstraZeneca will utilize its substantial commercial resources to market Omthera Pharmaceuticals' product, if approved. We also understand that another company, Trygg Pharma AS, has completed a Phase 3 study of an omega-3 based drug candidate for severe hypertriglyceridemia, but we do not believe Trygg has announced results from that study. It is possible that Trygg Pharma has filed for FDA approval of its product candidate. In addition, Acasti Pharma, a subsidiary of Neptune Technologies & Bioresources Inc., announced in late 2012 that it intends to conduct a Phase 3 clinical program to assess the safety and efficacy of its omega-3 prescription drug candidate derived from krill oil for the treatment of hypertriglyceridemia. We believe Catabasis Pharmaceuticals, or Catabasis, Resolvix Pharmaceuticals, or Resolvix, and Sancilio & Company are also developing potential treatments for hypertriglyceridemia based on omega-3 fatty acids and, to our knowledge, Catabasis initiated a Phase 2 clinical trial of its product in December 2013; Resolvix's compound remains in Phase 1 clinical testing; and Sancilio is preparing to commence Phase 3 clinical testing. In addition, we are aware that Matinas BioPharma, Inc. is developing an omega-3-based therapeutic for the treatment of severe hypertriglyceridemia and mixed dyslipidemia. Matinas BioPharma, Inc. has reported that it is preparing to file an Investigational New Drug Application with the FDA and to conduct a human study in the first half of 2014. Isis Pharmaceuticals announced favorable Phase 2 results of ISIS-APOCIII<sub>Rx</sub>, a drug candidate administered through weekly subcutaneous injections, in patients with high triglycerides and type 2 diabetes and in patients with moderate to severe high triglycerides. Finally, Madrigal Pharmaceuticals has completed Phase 1 clinical testing of MGL-3196 for the treatment of high triglycerides and various lipid parameters in patients.

*We were granted three-year FDA marketing exclusivity and competitors may now seek approval of generic versions of Vascepa.*

The Hatch-Waxman Amendments permit the FDA to approve abbreviated new drug applications, or ANDAs, for generic versions of brand name drugs like Vascepa. We refer to the process of generic drug applications as the ANDA process. The timelines and conditions that govern the ANDA process differ based on whether a drug receives three-year, or new chemical entity (NCE), marketing exclusivity. 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.

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 claim Vascepa. 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 our patents are invalid, or both. After receipt of a valid notice, we would have 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, we will be entitled to receive a 30 month stay on FDA's ability to give final approval to any of the proposed products that reference Vascepa. The stay may be shortened or lengthened if either party fails to cooperate in the litigation and it may be terminated if

## **Table of Contents**

the court decides the case in less than 30 months. If the litigation is resolved in favor of the 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.

The FDA typically makes a determination on marketing exclusivity in connection with, or soon after, an NDA approval of a drug for a new indication. 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 NCE marketing exclusivity to Vascepa and granted three-year marketing exclusivity. Such three-year exclusivity extends through July 25, 2015 and can be supplemented by a 30-month stay triggered after patent infringement litigation initiated by Amarin following a valid notice to Amarin of the filing of an ANDA with the FDA seeking approval of a generic version of Vascepa.

On February 27, 2014, we filed a lawsuit against the FDA that challenges FDA's denial of our request for five-year exclusivity for Vascepa based on our reading of the relevant statute and inconsistency with FDA's past actions. Our complaint requests that the court vacate FDA's decision, declare that Vascepa is entitled to the benefits of five-year statutory exclusivity, bar the FDA from accepting any ANDA or similar application for which Vascepa is the reference-listed drug until after the statutory exclusivity period expires, and if necessary, set aside FDA's premature acceptance of any such application.

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.

Based on communications with the FDA, we believe the FDA does not accept submitted ANDAs for review until after the FDA makes a determination on the exclusivity status of the pioneer drug. In February 2014, prior to the FDA's three-year exclusivity determination for Vascepa, we received a purported paragraph IV notice from a generic drug company with respect to an ANDA to Vascepa. The FDA confirmed with us after we received the notice and before the exclusivity determination was made that the FDA had not accepted for review any ANDA to Vascepa. The FDA has repeatedly taken the position that paragraph IV notices delivered to pioneer companies such as Amarin prior to the acceptance by the FDA for review of a submitted ANDA are not effective under the Hatch-Waxman Amendments. The generic company may challenge the FDA's position on whether the notice is valid in court in connection with patent litigation. Generic companies are thought to send such premature notices to seek to avail themselves of the 180-day generic exclusivity period for an approved product under an ANDA based on the generic's view that it would then have first-to-file status and to seek an early end to related patent litigation with the branded drug company and the associated 30-month stay. Because we and the FDA do not believe the purported paragraph IV notice is an effective notice under the Hatch-Waxman Amendments we do not plan to initiate patent litigation against the generic company that submitted the ANDA until within the 45-day period after we receive a valid paragraph IV notice.

The FDA may now accept for review a submitted ANDA to Vascepa under the Hatch-Waxman Amendments. After receipt of a valid paragraph IV notice, we are likely to engage in costly litigation with the applicant to protect our patent rights. If the generic filer is ultimately successful in patent litigation against us, meets the requirements for a generic version of Vascepa to the satisfaction of the FDA under its ANDA (after any applicable regulatory exclusivity period and, typically, the litigation-related 30-month stay period expires), and is able to supply the product in significant commercial quantities, the generic company could, with the market introduction of a generic version of Vascepa, limit our U.S. sales, 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.

---

## **Table of Contents**

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

Our only current product, Vascepa, is a prescription-only omega-3 fatty acid. Mixtures of omega-3 fatty acids are naturally occurring substances contained in various foods, including fatty fish. Omega-3 fatty acids are also marketed by others as non-prescription dietary supplements. We cannot be sure physicians will view the pharmaceutical grade purity of Vascepa as having a superior therapeutic profile to naturally occurring omega-3 fatty acids and dietary supplements. To the extent the price of Vascepa 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 may recommend these commercial alternatives instead of writing prescriptions for Vascepa or patients may elect on their own to take commercially available omega-3 fatty acids. Either 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.

***If we are not successful marketing and selling Vascepa on our own, we may need to find collaborative partners to help market and sell the product.***

If we are not successful marketing and selling Vascepa on our own, we may need to find collaborative partners to help market and sell the product or otherwise outsource these functions to third parties. Until such time as we choose to, and actually do, complete a strategic transaction with a third party to market and sell Vascepa, if ever, we will continue to market and sell Vascepa on our own. We are actively exploring collaboration opportunities for the continued marketing and sale of Vascepa as we approach the potential approval of Vascepa in the ANCHOR indication, assuming its regulatory approval.

We may choose not to enter into a collaboration to help market and sell Vascepa or, if we determine such a collaborative partner is necessary we may not be successful in finding a collaborative partner, or may be delayed in doing so. We face significant competition in seeking appropriate collaborators, and these collaborations are complex and time-consuming to negotiate and document. We may not be able to negotiate collaborations on acceptable terms, or at all. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If that were to occur, depending on Vascepa revenues, we may have to curtail the continued development of Vascepa for approval for additional indications or increase our planned expenditures and undertake additional development or commercialization activities at our own expense. 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, including our Purchase and Sale Agreement with BioPharma Secured Debt Fund II Holdings Cayman, L.P., or BioPharma. 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.

***The commercial value to us of the MARINE and ANCHOR indications 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 MARINE indication or, if approved, the ANCHOR indication. 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, with regard to the MARINE indication and any other indications for which we may gain approval, 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 for our product would suffer.



---

## **Table of Contents**

### ***Our products will be 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-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. 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 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, 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. All of these activities are also potentially subject to U.S. federal and state consumer protection and unfair competition laws. 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. In addition, even if we or our potential partners 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 or our potential partners must also compete against other products in qualifying for coverage and reimbursement under applicable third party payment and insurance programs.

***The commercial value of Vascepa may be negatively affected by the advisory committee recommendation against approval of Vascepa in the ANCHOR indication, the rescission of the ANCHOR SPA agreement or any subsequent rejection of the pending FDA application with the FDA for the use of Vascepa in the ANCHOR indication.***

Though we are restricted from promoting Vascepa under applicable regulations for any indication other than the FDA-approved MARINE indication, healthcare professionals are not restricted from prescribing Vascepa for such so-called off-labeled uses. A significant amount of the sales of Vascepa may, in fact, be attributable to so-called off-labeled uses of the drug. We expect that among the off-labeled uses of Vascepa are uses that would fall into, or be closely related to, the proposed ANCHOR indication. The recent negative recommendation of the advisory committee meeting against approval of Vascepa in the ANCHOR indication, the recent rescission by the FDA of the ANCHOR SPA, and/or a subsequent decision by the FDA to not approve Vascepa in the ANCHOR

---

**Table of Contents**

indication may negatively and materially affect the perception of the utility of Vascepa for use in the ANCHOR indication or for other purposes and thus negatively and materially affect sales of Vascepa.

***The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products. If we are found to have improperly promoted off-label uses, we may become subject to significant fines and other liability.***

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. Even though we received FDA marketing approval for Vascepa for the MARINE indication, 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. If we are found to have promoted such off-label uses, we may become subject to significant government fines and other related liability. 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 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.

***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 trial, in which case our sales of Vascepa may then suffer.***

In accordance with the SPA 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 is designed to evaluate the efficacy of Vascepa in reducing major cardiovascular events in an at-risk patient population on statin therapy.

Outcomes studies of certain other lipid-modifying therapies have failed to achieve the endpoints of such studies. 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. No significant incremental treatment benefit with extended-release niacin was observed. 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. We believe the results of these studies may not be directly applicable to the use of Vascepa over time. For instance, 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

---

**Table of Contents**

niacin are believed to work differently than Vascepa in the body and do not have as favorable a side-effect profile, and nineteen of the twenty studies included in the JAMA meta-analysis involved the use of omega-3 supplements containing a mixture of EPA and DHA, and most were evaluated at relatively lower doses. In addition, in May 2013, *The New England Journal of Medicine* published the results of an outcome study of 1 gram per day of an omega-3 acid ethyl ester composition. In that study, the composition failed to show a benefit in reducing the rate of death from cardiovascular causes or hospitalization for cardiovascular causes when administered to patients with cardiovascular risk factors under different study conditions than in the REDUCE-IT study. Vascepa is comprised of highly-pure ethyl-EPA, and has been approved by the FDA for use in patients with severe hypertriglyceridemia at a dose of 4 grams per day.

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 the JELIS study. First, the patient population was exclusively Japanese, the majority of the participants were women, and at baseline patients had a much higher LDL, limiting its generalizability to the intended target population. Second, 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 targets in the United States. Third, 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 hospitalizations for unstable angina was a primary contributor of the overall positive result, and is considered a softer endpoint than fatal cardiovascular events.

Although we believe the results of the JAMA meta-analysis and other studies are not directly applicable to the potential long-term clinical experience with Vascepa, there can be no assurance that the endpoints of the REDUCE-IT cardiovascular outcomes study will be achieved 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 fails to achieve its clinical endpoints or if the results of these long-term studies are not consistent with the 12-week clinical results, it could prevent us from expanding the label of any approved product or even call into question the efficacy of any approved product.

***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, the European Union, Japan and elsewhere. In the United States, the FDA generally requires pre-clinical 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:

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;

---

**Table of Contents**

changes in regulatory requirements for clinical or preclinical studies;

the emergence of unforeseen safety issues in clinical 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; and

government or regulatory delays or clinical holds requiring suspension or termination of a trial.

Even if we obtain positive results from early stage pre-clinical 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.

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 earn revenues from the sale of such 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 product or in connection with the manufacturer of products may result in restrictions on that product or manufacturer, including withdrawal of the product from the market, which would have a negative impact on our potential revenue stream.

***Legislative or regulatory reform of the health care 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 health care services to contain or reduce health care 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 health care 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; and

A new formula that increases the rebates a manufacturer must pay under the Medicaid Drug Rebate Program.

## **Table of Contents**

We expect further federal and state proposals and health care 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.

The continuing efforts of government and other third-party payors to contain or reduce the costs of health care through various means may limit our commercial opportunity. It will be 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 health care 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. 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.

*As we 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.*

We hired and trained a professional sales force of approximately 275 sales representatives and commenced our commercial launch of Vascepa in the MARINE indication in the United States in early January 2013. The process of establishing a commercial infrastructure is difficult, expensive and time-consuming. Our October 2013 worldwide reduction in force, which included the termination of approximately 50% of the then-staffed sales force, has made this process more difficult. As our operations expand with the anticipated growth of our produce 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**

*If we do not realize the expected benefits from recent worldwide reductions in our workforce and from future cost savings initiatives that we may implement, the value of our company and our assets and the market price of our ADSs could materially decline.*

In October 2013, we implemented a plan that reduced our worldwide workforce by approximately 50%. We cannot guarantee that we will be able to realize the cost savings and other anticipated benefits from our recent worldwide reductions in force. If we experience excessive unanticipated inefficiencies or incremental costs in connection with restructuring activities, such as unanticipated inefficiencies caused by reducing headcount, we may be unable to meaningfully realize cost savings and we may incur expenses in excess of what we anticipate. Either of these outcomes could prevent us from meeting our strategic objectives and could adversely affect our results of operations and financial condition.

## **Table of Contents**

***Our supply of product for commercial supply 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 assure you 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. Additionally, we will be reliant on third parties to supply the raw materials needed to manufacture our potential products. 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 result in lost sales. If our suppliers were unable to supply us with adequate volumes of ethyl-EPA 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), which constitutes the only active pharmaceutical ingredient, or API, of Vascepa, from a single supplier, Nisshin Pharma, or Nisshin, located in Japan. Nisshin was approved by the FDA as a Vascepa API supplier as part of our FDA marketing approval for the MARINE indication in July 2012. In April 2013, we announced the approval by the FDA of Chemport, Inc. and BASF (formerly Equateq Limited) as additional Vascepa API suppliers. We have commenced purchasing and utilizing commercial supply from Chemport in addition to Nisshin. BASF is working to complete validation of its facility for the manufacture of Vascepa. Each of the API manufacturers obtains supply of the key raw material to manufacture API from other third party sources of supply.

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 of the key raw material to manufacture the API for Vascepa, Nisshin and Chemport currently supply all of our API for Vascepa. Our strategy in adding API suppliers beyond Nisshin has been to expand manufacturing capacity and to partially mitigate the risk of reliance on one supplier.

Also, in December 2012 we announced the addition of an exclusive consortium of companies led by Slanmhor Pharmaceutical, Inc., or Slanmhor, to our planned API global supply chain for Vascepa. Slanmhor was spun-out from Ocean Nutrition Canada, or ONC, prior to the May 2012 acquisition of ONC by Royal DSM N.V., a global leader in life sciences and materials sciences. Amarin now has a total of three suppliers for Vascepa API to utilize in supporting the global commercialization of Vascepa, subject to appropriate regulatory approval of Slanmhor, for which we submitted a sNDA in August 2013. Slanmhor is working to complete construction and validation of its facility for the manufacture of Vascepa.

Expanding manufacturing capacity and qualifying such capacity is difficult 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, our API supply will be limited to the API we purchase from Nisshin and Chemport. If our third party manufacturing capacity is not expanded and compliant with application regulatory requirements, we may not be able to supply sufficient quantities of Vascepa to meet anticipated

## **Table of Contents**

demand. We cannot assure you 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 rely exclusively on Patheon for the encapsulation of Vascepa. We have encapsulation agreements with two other commercial API encapsulators. These companies are working to qualify their processes and to prove that the Vascepa capsules they produce meet the same quality standards as the capsules produced by Patheon. 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 cannot assure you 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.

***We may not be able to maintain our exclusivity with our third-party Vascepa suppliers if we do not meet minimum purchase obligations due to lower than anticipated sales of Vascepa.***

Certain of our agreements with our suppliers include minimum purchase obligations and limited exclusivity provisions based on such minimum purchase obligations. If we do not meet the respective minimum purchase obligations in our supply agreements, our suppliers will be free to sell the active pharmaceutical ingredient of Vascepa to potential competitors of Vascepa. Similarly if we terminate certain of our supply agreements, such suppliers may be free to sell the active pharmaceutical ingredient of Vascepa to potential competitors of Vascepa. On December 30, 2013, we issued a notice of termination in connection with our active pharmaceutical ingredient supply agreement with BASF as a result of BASF's non-compliance with the terms of such agreement. If BASF does not cure its non-compliance within a 60-day cure period and the agreement is terminated, BASF may be free to sell Vascepa active pharmaceutical ingredient to our competitors. While we anticipate that intellectual property barriers and FDA regulatory exclusivity will be the primary means to protect the commercial potential of Vascepa, the availability of Vascepa active pharmaceutical ingredient from our suppliers to our potential competitors would make our competitors' entry into the market easier and more attractive.

***We have limited experience with the commercial sale of Vascepa, and such inexperience may cause us to 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 have limited experience with the commercial sale of Vascepa, and as such expectations regarding expected demand may be wrong. 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 and packaging of pharmaceutical products such as Vascepa are subject to FDA requirements 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 and packaging of pharmaceutical products, such as Vascepa, are regulated by the FDA and similar foreign regulatory bodies and must be conducted in accordance with the FDA's current good manufacturing practices, or cGMPs, and comparable requirements of foreign regulatory bodies. There are a limited number of manufacturers that operate under these cGMPs regulations who are both capable of manufacturing Vascepa and willing to do so. Failure by us or our third party manufacturers to comply with



## **Table of Contents**

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 recalls of product, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business. For example, Nisshin plans to expand its capacity to supply API to us by further expanding their current facility. If we are not able to manufacture Vascepa to required specifications through Nisshin, Chemport and BASF, or other 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 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. This review may be costly and time consuming and could delay or prevent the launch of a product. For example, we have filed a supplemental NDA to add Slanmhor as an additional API supplier for Vascepa. If Slanmhor cannot establish, to the satisfaction of the FDA, that it is in substantial compliance with cGMPs, and that the product manufactured at its site meets FDA requirements, we may not be able to manufacture API from that site, our supply of API for Vascepa may be delayed, and our anticipated future revenues and financial results may be materially adversely affected if such supply cannot be satisfied by our other three API suppliers.

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 proven 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 standards, or change their interpretation and enforcement of existing standards and requirements, for manufacture, packaging or testing of products at any time. If we 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 standards, 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.

## Table of Contents

### **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.

Amarin has prosecuted, and is currently prosecuting, multiple patent applications to protect the intellectual property developed during the Vascepa cardiovascular program. As of the date of this Annual Report, we had 40 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. Of such 40 allowed and issued applications, we currently have:

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,

29 U.S. patents covering the use of Vascepa in either the MARINE or anticipated ANCHOR indication that have terms that expire in 2030,

6 additional patent applications for which the United States Patent and Trademark Office, or USPTO, has issued a Notice of Allowance each of which with terms that expire in 2030 and are related to the use of Vascepa in either the MARINE or anticipated ANCHOR indication,

1 additional patent related to the use of a pharmaceutical composition comprised of free fatty acids to treat the ANCHOR patient population that expires in 2030, and

1 additional patent application for which the United States Patent and Trademark Office, or USPTO, has issued a Notice of Allowance with a term that expires in 2030 and is related to the use of a pharmaceutical composition comprised of free fatty acids to treat the MARINE patient population.

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

## Edgar Filing: AMARIN CORP PLC\UK - Form 10-K

be given that, if and when issued, our patents will prevent competitors from competing with Vascepa. 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,

## **Table of Contents**

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. 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 and our pending patents, if and when issued, may not prevent competitors from competing with Vascepa.***

We plan to vigorously defend our rights under issued patents. 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 any of our pending patent applications will be granted or, if they grant, that they will prevent competitors from competing with Vascepa.

Securing patent protection for a product is a complex process involving many legal and factual questions. The patent applications we have filed in the United States and internationally are at varying stages of examination, the timing of which is outside our control. The process to getting a patent granted can be lengthy

---

## **Table of Contents**

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.*

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**

*We and certain of our current and former executive officers have been named as defendants in four lawsuits that could result in substantial costs and divert management's attention.*

The market price of our ADSs declined significantly after the October 2013 decision by the FDA Advisory Committee to recommend against approval of Vascepa in the ANCHOR indication. We, and certain of our current and former executive officers, have been named as defendants in four purported class action lawsuits initiated earlier this year that generally allege that we and certain of our current and former officers violated Sections 10(b) and/or 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder by making allegedly false and/or misleading statements or material omissions concerning the ANCHOR sNDA and related FDA regulatory approval process in an effort to lead investors to believe that Vascepa would receive approval from the FDA in the ANCHOR indication. The complaints seek unspecified damages, interest, attorneys' fees, and other costs.

We intend to engage in a vigorous defense of the lawsuits, and we believe that we have meritorious defenses to these claims. However, we are unable to predict the outcome of these matters at this time. Moreover, any conclusion of these matters in a manner adverse to us could have a material adverse effect on our financial condition and business. For example, we could incur substantial costs not covered by our directors' and officers' liability insurance, suffer a significant adverse impact on our reputation and divert management's attention and resources from other priorities, including the execution of business plans and strategies that are important to our ability to grow our business, any of which could have a material adverse effect on our business. In addition, any of these matters could require payments that are not covered by, or exceed the limits of, our available directors' and officers' liability insurance, which could have a material adverse effect on our operating results or financial condition.

*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

## **Table of Contents**

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, 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 Yissum Research Development Company of The Hebrew University of Jerusalem.

In June 2009, in keeping with our 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. Under the terms of this amendment, Amarin was released from all research and development diligence obligations contained in the original agreement and was authorized to seek a partner for EN101. The amendment agreement also provided that any future payment obligations payable by us to the former shareholders of Ester would be made only out of income received from potential partners. In connection with this amendment agreement, in August 2009 we issued 1,315,789 ordinary shares to the former Ester shareholders. Under the terms of this amendment agreement, the former Ester shareholders have the option of reacquiring the original share capital of Ester if we are unable to successfully partner EN101.

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

We have received several communications on behalf of the former shareholders of Ester asserting that we are in breach of its amended agreement due to the fact that Yissum terminated its license and we failed to return shares of Ester, and assets relating to EN101, to the shareholders, as was required under certain circumstances under the amended agreement. We do not believe these circumstances constitute a breach of the amended agreement, 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

---

## **Table of Contents**

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. 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. Furthermore, the lessened probability that we will obtain FDA approval for the ANCHOR indication could have an adverse impact on our ability to retain and recruit qualified personnel. In addition, on October 22, 2013, we eliminated approximately fifty percent of our staff positions worldwide as part of a restructuring following the FDA advisory committee's recommendation against the potential Vascepa label expansion. Even though all employees were offered severance pay in exchange for signing a comprehensive release of claims, this restructuring could lead to claims by former employees related to their termination. The restructuring could also have an adverse impact on our ability to retain and recruit qualified personnel. The failure to recruit key scientific, technical and management personnel would be detrimental to our ability to implement our business plan.

### **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 been profitable in any of the last five fiscal years. For the fiscal years ended December 31, 2013, 2012, and 2011, we reported losses of approximately \$166.2 million, \$179.2 million, and \$69.1 million, respectively, and we had an accumulated deficit at December 31, 2013 of \$913.9 million. 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, costs related to the commercialization of Vascepa, and from non-cash losses on changes in the fair value of warrant derivative liabilities. 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.

## **Table of Contents**

*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. In January 2013, we began to generate revenue from the marketing of Vascepa for use in the MARINE indication, 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 enter into one or more strategic collaborations to effectively market and sell Vascepa.

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 soon after generating product sales, if ever. If we are unable to generate sufficient product revenues, we will not become profitable 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 recent commercial launch of Vascepa in the MARINE indication 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 seek to obtain additional regulatory approval of Vascepa in the ANCHOR indication, including the 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. Due to the recent approval by the FDA of Vascepa and the lack of historical sales data, Vascepa sales will be 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;

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;

additional developments regarding our intellectual property portfolio and regulatory exclusivity protections, if any;

the results of our sNDA application for the ANCHOR indication and the results of the REDUCE-IT study or post-approval studies for Vascepa;



outcomes of litigation and other legal proceedings, including recently initiated shareholder litigation, regulatory matters and tax matters;

## **Table of Contents**

whether we continue the REDUCE-IT study; and.

the impact of the restructuring of the company implemented on October 22, 2013.

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

We currently operate with limited resources. We believe that our cash and cash equivalents balance of \$191.5 million at December 31, 2013 will be sufficient to fund our projected operations for at least the next twelve months.

In order to fully realize the market potential of Vascepa, we may need to enter into a 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:

revenue generated from the commercial sale of Vascepa in the MARINE indication and, subject to FDA approval, the ANCHOR indication;

the costs associated with commercializing Vascepa for the MARINE indication in the United States 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, and the cost and timing of securing commercial supply of Vascepa and the timing of entering into 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, if we continue that study;

the time and costs involved in obtaining additional regulatory approvals for Vascepa;

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.

***As a result of recent worldwide reductions in our workforce, we are in the process of reallocating certain employment responsibilities and may outsource certain corporate functions. As a result, we may be more dependent on third parties to perform these corporate functions than we have been in the past.***

As a result of the recent worldwide reductions in our workforce, we have been required to outsource certain corporate functions. This has made us more dependent on third-parties for the performance of these functions. Our ongoing results of operations could be adversely affected to the extent that we are unable to effectively reallocate employee responsibilities, retain key employees, maintain effective internal control over financial reporting and effective disclosure controls and procedures, establish and maintain agreements with competent third-party contractors on terms that are acceptable to us, and effectively manage the work performed by any retained third-party contractors.

---

**Table of Contents**

***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 Purchase and Sale Agreement with BioPharma, 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.

As of December 31, 2013, there were warrants outstanding for the purchase of up to 9,789,776 ADSs each representing one of our ordinary shares, with a weighted average exercise price of \$1.44 per share. We may issue additional warrants to purchase ADSs or ordinary shares in connection with any future financing we may conduct. In addition, on January 9, 2012, we issued \$150 million in aggregate principal amount of 3.50% exchangeable senior notes due 2032, or the notes. The notes are exchangeable under certain circumstances into cash, our ADS, or a combination of cash and ADS, at our election, with a current exchange rate of 113.4752 ADS per \$1,000 principal amount of notes. Although we intend to settle these notes in cash, if we elected physical settlement, the notes would initially be exchangeable into 17,021,280 ADS.

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

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

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

diversion of managerial resources from day-to-day operations;

exposure to litigation from the counterparties to any such transaction, other third parties or our shareholders;

misjudgment with respect to the value;

higher than expected transaction costs; or

an inability to successfully consummate any such transaction or collaboration.

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



---

## **Table of Contents**

### **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 20, 2014 we had 172,906,063 common shares outstanding including 172,440,210 shares held as ADSs and 465,853 held as common shares (which are not held in the form of ADSs). In our October 2009 private placement we issued 66.4 million ADSs and warrants to purchase an additional 33.2 million 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, such as the participants in our October 2009 private placement, 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;

regulatory developments in the United States, the European Union or 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.

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

As of the date of this Quarterly Report, our ADSs are currently trading above \$1.00; however, recent market activity has resulted in a decrease in our stock price, and our stock price may fall below the \$1.00 threshold. 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.***

## Edgar Filing: AMARIN CORP PLC\UK - Form 10-K

In accordance with the guidelines specified under Rule 10b5-1 of the Securities and Exchange Act of 1934 and our policies regarding stock transactions, a number of our directors and employees, including members of

---

## **Table of Contents**

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 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. Our status as a PFIC is subject to change in 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 Purchase and Sale Agreement with BioPharma could adversely affect our financial results and liquidity.***

Pursuant to our December 2012 Purchase and Sale Agreement with BioPharma, we are obligated to make payments to BioPharma 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 BioPharma'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 BioPharma.

Upon a transaction resulting in a change of control of Amarin, as defined in the agreement, BioPharma 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 BioPharma and (iii), unless BioPharma has been paid a certain amount under the indebtedness, the licensing 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 stockholders.

---

## **Table of Contents**

To secure our obligations under the agreement, we granted BioPharma 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 BioPharma 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, which we entered into in January 2012, consists of \$150.0 million in aggregate principal amount of 3.50% exchangeable senior notes due 2032, with provisions for the notes to be called on or after January 19, 2017. 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

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 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 (such as the notes) 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





## **Table of Contents**

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.

### ***The conditional exchange feature of the notes, if triggered, may adversely affect our financial condition and operating results.***

In the event the conditional exchange feature of the notes is triggered, holders of notes will be entitled to exchange the notes at any time during specified periods at their option. If one or more holders elect to exchange their notes, unless we elect to satisfy its exchange obligation by delivering solely the ADSs (other than cash in lieu of any fractional ADS), we would be required to settle a portion or all of its exchange obligation through the payment of cash, which could adversely affect our liquidity. In addition, even if holders do not elect to exchange their notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the notes as a current rather than long-term liability, which would result in a material reduction of our net working capital.

### ***The fundamental change repurchase feature of the notes may delay or prevent an otherwise beneficial takeover attempt of us.***

The indenture governing the notes will require us to repurchase the notes for cash upon the occurrence of a fundamental change of Amarin and, in certain circumstances, to increase the exchange rate for a holder that exchanges its notes in connection with a make-whole fundamental change. A takeover of us may trigger the requirement that we purchase the notes and/or increase the exchange rate, which could make it more costly for a potential acquirer to engage in a combinatory transaction with us. Such additional costs may have the effect of delaying or preventing a takeover of us that would otherwise be beneficial to investors.

### ***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.

---

**Table of Contents**

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 depository 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 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.

**Table of Contents**

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

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

**Item 1B. Unresolved Staff Comments**

None.

**Item 2. Properties**

The following table lists the location, use and ownership interest of our principal properties as of February 20, 2014:

Location	Use	Ownership	Size (sq. ft.)
Dublin, Ireland	Offices	Leased	320
Bedminster, New Jersey, USA	Offices	Leased	23,231
Groton, Connecticut, USA	Offices	Leased	4,327
Ely, Cambridgeshire, UK (Gemini House)			
Ground Floor	Offices	Leased and sublet	7,135
First Floor	Offices	Assigned	2,975

Effective July 1, 2011, we leased 9,747 square feet of office space in Bedminster, NJ. The lease, as amended, terminates on March 31, 2018, 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, the December 6, 2011 lease was terminated.

Effective November 1, 2011, we leased 320 square feet of office space in Dublin, Ireland. The lease terminates on October 31, 2014 and may be renewed annually.

Commencing on November 28, 2011, we leased 4,327 square feet of office space in Groton, CT. The lease terminates on January 31, 2015 and may be extended for one three year term.

Our lease for office space in Ely, Cambridgeshire expires in November 2014. The ground floor space has been sublet through the end of the lease term. On August 27, 2002 the lease for the first floor space was assigned to a third party. Amarin however, remains ultimately responsible for the lease through the end of the lease term.

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 November 1, 2013, a purported investor of Amarin filed a putative class action lawsuit captioned *Steven Sklar v. Amarin Corporation plc et al.*, No. 13-cv-6954 (D.N.J. Nov. 1, 2013) in the U.S. District Court for the



---

**Table of Contents**

District of New Jersey. Substantially similar lawsuits, captioned *Bove v. Amarin Corporation plc*, Civ. No. 13-07882 (AT) (S.D.N.Y. Nov. 5, 2013), *Bentley v. Amarin Corporation plc*, Civ. No. 13-08283 (AT) (S.D.N.Y. Nov. 20, 2013) and *Siegel v. Amarin Corporation plc*, No. 3:13-cv-07210 (D.N.J. Nov. 27, 2013), were subsequently filed in the U.S. District Court for the District of New Jersey and U.S. District Court for the Southern District of New York. On December 9, 2013 the cases filed in the Southern District of New York were transferred to the District of New Jersey, where the four cases are now proceeding in front of the same judge pending a formal order consolidating the actions.

Each of the complaints asserts claims under the Securities Exchange Act of 1934. The complaints allege that Amarin 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 the potential relevance of data from the ongoing REDUCE-IT trial to that approval. The putative class periods alleged in the complaints vary from the July 9, 2009-October 15, 2013 period alleged in the *Sklar* and *Siegel* complaints, the July 9, 2009-October 16, 2013 period alleged in the *Bentley* complaint, and August 8, 2012-October 16, 2013 period alleged in the *Bove* complaint. The lawsuits seek unspecified monetary damages and attorneys' fees and costs.

On January 3, 2014, ten plaintiffs and their respective counsel moved for appointment as lead plaintiff and lead counsel for the putative class. The plaintiffs also moved for consolidation of the pending actions. The motion for appointment of lead plaintiff was set for February 3, 2014, but has not yet been decided. After the Court appoints a lead plaintiff, and consolidates the actions, we expect that the lead plaintiff will file a consolidated amended complaint that will become the operative complaint for the action.

We believe that we have valid defenses and we will vigorously defend against the claims. We are unable to reasonably estimate the loss exposure, if any, associated with these claims. We have insurance coverage that is anticipated to cover any significant loss exposure that may arise from this action after payment by us of the associated deductible obligation under such insurance coverage.

On February 27, 2014, we filed a lawsuit against the FDA that challenges FDA's denial of our request for five-year exclusivity for Vascepa based on our reading of the relevant statute and inconsistency with FDA's past actions. Our complaint requests that the court vacate FDA's decision, declare that Vascepa is entitled to the benefits of five-year statutory exclusivity, bar the FDA from accepting any ANDA or similar application for which Vascepa is the reference-listed drug until after the statutory exclusivity period expires, and if necessary, set aside FDA's premature acceptance of any such application.

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. While the outcome of these proceedings and claims cannot be predicted with certainty, as of December 31, 2013, we were not party to any legal or arbitration proceedings that may have, or have had in the recent past, significant effects on our financial position or profitability. No governmental proceedings are pending or, to our knowledge, contemplated against us. We are not a party to any material proceedings in which any director, member of senior management or affiliate of ours is either a party adverse to us or our subsidiaries or has a material interest adverse to us or our subsidiaries.

**Item 4. Mine Safety Disclosures**

Not applicable.

**Table of Contents****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 2013		Fiscal 2012	
	High	Low	High	Low
First Quarter	\$ 9.24	\$ 6.77	\$ 12.45	\$ 6.13
Second Quarter	\$ 7.98	\$ 5.36	\$ 15.40	\$ 9.30
Third Quarter	\$ 7.40	\$ 5.12	\$ 15.96	\$ 10.86
Fourth Quarter	\$ 7.39	\$ 1.36	\$ 12.96	\$ 7.56

**Shareholders**

As of January 31, 2014, there were approximately 388 holders of record of our ordinary shares. Because many ordinary shares are held by brokers nominees, we are unable to estimate the total number of shareholders represented by these record holders. Our depository, 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 Biopharma, 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.

**Table of Contents****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.*

We believe the indices below are the most appropriate indices against which the total shareholder return of Amarin should be measured. The NASDAQ Bio Index has been selected because it is an index of U.S. quoted biotechnology and pharmaceutical companies.

Company/Market/Peer Company	12/31/2011	12/31/2012	12/31/2013
Amarin Corporation PLC	\$ 91.34	\$ 98.66	\$ 24.02
NASDAQ Composite Index	\$ 99.21	\$ 116.82	\$ 163.74
NASDAQ Biotechnology Index	\$ 112.07	\$ 148.27	\$ 246.15

Source: NASDAQ Whole Market index and Bio index. The NASDAQ Market index has been used to compare the shareholder return for all companies listed on the NASDAQ Stock Market. The NASDAQ Bio index has been used to give a comparison of the shareholder returns from biotechnology and pharmaceutical companies listed on the NASDAQ Stock Market.



**Table of Contents****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. An investment of \$100 (with reinvestment of all dividends) is assumed to have been made in our ADSs and in each of the indexes on December 31, 2008 and its relative performance is tracked through December 31, 2013.

Company/Market/Peer Company	12/31/2009	12/31/2010	12/31/2011	12/31/2012	12/31/2013
Amarin Corporation PLC	\$ 201.41	\$ 1,154.93	\$ 1,054.93	\$ 1,139.44	\$ 277.46
NASDAQ Composite Index	\$ 145.36	\$ 171.74	\$ 170.38	\$ 200.62	\$ 281.22
NASDAQ Biotechnology Index	\$ 115.96	\$ 133.61	\$ 149.75	\$ 198.10	\$ 328.88

**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.

**UNITED KINGDOM TAXATION****Capital Gains**

If you are not resident or ordinarily 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 or ordinarily 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 or ordinarily resident in the UK at the time of the disposal.

## **Table of Contents**

### **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.

#### *Issue and Transfer of Common Shares*

The issue of common shares by Amarin will not give rise to a charge to UK stamp duty or stamp duty reserve tax.

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.

**Table of Contents****Item 6. Selected Financial Data**

The selected financial data set forth below as of and for the years ended December 31, 2013, 2012, 2011, 2010, and 2009 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.

	2013	Years Ended December 31,			2009
		2012	2011	2010	
		(In thousands, except per share amounts)			
<b>Consolidated Statements of Operations Data:</b>					
Revenues	\$ 26,351	\$	\$	\$	\$
<b>Operating Expenses:</b>					
Cost of goods sold	11,912				
Research and development	72,750	58,956	21,602	28,014	20,892
Selling, general and administrative (1)	123,795	57,794	22,559	17,087	13,152
Total operating expenses	208,457	116,750	44,161	45,101	34,044
Operating loss	(182,106)	(116,750)	(44,161)	(45,101)	(34,044)
Gain (loss) on change in fair value of derivative liabilities (2)	47,710	(35,344)	(22,669)	(205,153)	5,137
Interest expense	(34,179)	(18,091)	(1)	(19)	(2,832)
Interest income	343	544	231	53	199
Other (expense) income, net	(1,189)	(427)	(10)	130	33
Loss from operations before taxes	(169,421)	(170,068)	(66,610)	(250,090)	(31,507)
Benefit from (provision for) income taxes	3,194	(9,116)	(2,516)	501	901
Net loss	(166,227)	\$(179,184)	\$(69,126)	\$(249,589)	\$(30,606)
<b>Loss per share:</b>					
Basic	\$ (1.03)	\$ (1.24)	\$ (0.53)	\$ (2.49)	\$ (0.72)
Diluted	\$ (1.28)	\$ (1.24)	\$ (0.53)	\$ (2.49)	\$ (0.72)
<b>Weighted average shares outstanding:</b>					
Basic	161,022	144,017	130,247	100,239	42,424
Diluted	167,070	144,017	130,247	100,239	42,424

	2013	2012	As of December 31,		2009
			2011	2010	
			(In thousands)		
<b>Consolidated Balance Sheet Data:</b>					
Cash and cash equivalents	\$ 191,514	\$ 260,242	\$ 116,602	\$ 31,442	\$ 52,258
Total assets	252,476	310,855	126,379	35,367	55,444
Long-term obligations	248,792	289,650	123,889	230,157	42,090
Stockholders' (deficit) equity	(33,856)	(3,997)	(5,962)	(202,367)	6,597

(1) Includes non-cash warrant-related compensation expense 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)

Edgar Filing: AMARIN CORP PLC\UK - Form 10-K

Includes non-cash charges resulting from changes in the fair value of derivative liabilities. See further discussion in Notes 2 and 7 of the Notes to the Consolidated Financial Statements.

**Table of Contents****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 our ability to successfully commercialize Vascepa in the United States for use in the MARINE indication, the progress and timing of our clinical programs, the potential for, and timing of, regulatory approval of additional indications for Vascepa and the next steps we may take thereto; the safety and efficacy of our product candidates; the goals of our development activities; the scope of our intellectual property 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 sales and marketing 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.*

**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  $\geq$ 500mg/dL) hypertriglyceridemia. We refer to this approved indication for Vascepa as the MARINE indication. We began marketing and selling Vascepa in the United States in January 2013. Vascepa is available in the United States by prescription only. We market Vascepa through our sales force of approximately 150 sales professionals, including sales representatives and their managers.

Triglycerides are fats in the blood. Hypertriglyceridemia refers to a condition in which patients have high levels of triglycerides in the bloodstream. It is estimated that over 40 million adults in the United States have elevated triglyceride levels (TG  $\geq$ 200mg/dL) and approximately 4.0 million people in the United States have severely high triglyceride levels (TG  $\geq$ 500mg/dL), commonly known as very high triglyceride levels. According to *The American Heart Association Scientific Statement on Triglycerides and Cardiovascular Disease* (2011), triglycerides also 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.

The potential efficacy and safety of Vascepa (known in its development stage as AMR 101) was studied in two Phase 3 clinical trials, the MARINE trial and the ANCHOR trial. At a daily dose of 4 grams of Vascepa, the dose at which Vascepa is FDA approved, these trials showed favorable clinical results in their respective patient populations 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

---

**Table of Contents**

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).

We are also developing Vascepa 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 which we refer to as mixed dyslipidemia. We refer to this second proposed indication for Vascepa as the ANCHOR indication. The FDA has stated that it views the proposed ANCHOR indication as ostensibly and impliedly an indication to reduce cardiovascular risk. In addition, in December 2011, we announced commencement of patient dosing in our cardiovascular outcomes study of Vascepa, titled REDUCE-IT (Reduction of Cardiovascular Events with EPA Intervention Trial). The REDUCE-IT study is designed to evaluate the efficacy of Vascepa in reducing major cardiovascular events in a high risk patient population on statin therapy.

We have a pending supplemental new drug application, or sNDA, with the FDA that seeks marketing approval of Vascepa for use in the ANCHOR indication. On October 16, 2013, the FDA convened an advisory committee to review our sNDA. This advisory committee was not asked by the FDA to evaluate whether Vascepa is effective in lowering triglycerides in the studied population, the ANCHOR indication as specified in the sNDA. Rather, the advisory panel was asked whether Vascepa has been demonstrated to improve cardiovascular outcomes or whether approval of the ANCHOR indication should wait for successful completion of the REDUCE-IT study, the first prospective study of cardiovascular outcomes in patients who have high triglyceride levels despite statin therapy. The advisory committee voted 9 to 2 against recommending approval of the ANCHOR indication based on information presented at the meeting. The FDA considers the recommendation of advisory committees, but final decisions on the approval of new drug applications are made by the FDA.

The ANCHOR trial clinical study was conducted under a special protocol assessment, or SPA, agreement with the FDA. The law governing SPA agreements requires that if the results of the trial conducted under the SPA substantiate the hypothesis of the protocol covered by the SPA, the FDA must use the data from the protocol as part of the primary basis for approval of the product. A SPA agreement is not a guarantee of FDA approval of the related new drug application. 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 of the drug after the study begins that rises to the level of a public health concern, or if the study sponsor fails to follow the protocol that was agreed upon with the FDA. On October 29, 2013, the FDA 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. As a basis for this determination, the FDA communicated that it determined that the cumulative results from outcome studies of other triglyceride-lowering drugs failed to support the hypothesis that a triglyceride-lowering drug significantly reduces the risk for cardiovascular events among the population studied in the ANCHOR trial. Thus, the FDA stated that while information we submitted supports testing the hypothesis that Vascepa 4 grams/day versus placebo reduces major adverse cardiovascular events in statin-treated subjects with residually high triglyceride levels, as is being studied in the Vascepa REDUCE-IT cardiovascular outcomes study, the FDA no longer considers a change in serum triglyceride levels as sufficient to establish the effectiveness of a drug intended to reduce cardiovascular risk in subjects with serum triglyceride levels below 500 mg/dL. In November 2013, we submitted to the FDA a request for reconsideration of its decision to rescind the ANCHOR SPA agreement. On January 17, 2014, we were notified by the FDA that it does not intend to reinstate the ANCHOR SPA agreement. Our plan is to continue appealing the rescission decision to successively higher administrative levels within the FDA in accordance with FDA dispute resolution guidance.

The FDA did not take action on the ANCHOR sNDA by the Prescription Drug User Fee Act, or PDUFA, goal date for completion of FDA's review, December 20, 2013. Instead, the FDA notified us on December 19, 2013 that it would first consider our appeal of the ANCHOR SPA agreement rescission. No new PDUFA goal date for the ANCHOR sNDA was established. Based on information available to us, we do not expect a

---

**Table of Contents**

determination on the ANCHOR sNDA while our appeal of the January 17, 2014 FDA decision to uphold the ANCHOR SPA rescission is in process. We are also continuing our efforts toward a positive determination on the pending ANCHOR sNDA. There also can be no assurance that the FDA will not communicate the results of its review of the ANCHOR sNDA prior to the timing expected.

Based on our communications with the FDA, we currently expect that final positive results from the REDUCE-IT outcomes study will be required for FDA approval of Vascepa for the ANCHOR indication. There can be no assurance that we will be successful in our effort to reinstate the ANCHOR SPA agreement or obtain a label expansion reflecting the ANCHOR clinical trial. Such label expansion could include FDA approval of the addition of an ANCHOR indication statement and/or the addition of the ANCHOR clinical trial data to our currently approved labeling.

On October 22, 2013, in an effort to reduce operating expenses following the recommendation of the advisory committee to the FDA against approval of the ANCHOR indication, we implemented a worldwide reduction in force of approximately 50% of our staff positions. The majority of affected staff members were sales professionals who supported the initial commercial launch of Vascepa. We incurred approximately \$2.8 million in charges related to the reduction in force, all of which includes cash expenditures for one-time termination benefits and associated costs. The charges were recorded in the fourth quarter of 2013 and the related payments will be made by the first half of 2014. As part of the reduction in force, we retained approximately 130 sales representatives, excluding sales management, in the United States in sales territories that we believe have demonstrated the greatest potential for Vascepa sales growth. We plan to have this team cover the target base of physicians responsible for the majority of Vascepa prescription volume and growth since its launch in early 2013. With these changes and resulting target base coverage, we anticipate continued Vascepa revenue growth over time. We also anticipate that such sales growth may be inconsistent from period to period.

We have over 6,500 patients enrolled in the REDUCE-IT study. We currently estimate that we will complete patient enrollment in this study in the first half of 2015. However, if we do not receive an expansion of Vascepa labeling for the ANCHOR indication, we plan to re-evaluate continuation of the REDUCE-IT study in its present form and re-evaluate whether it is advisable to continue the study. If continued, the REDUCE-IT study will be completed after reaching an aggregate number of cardiovascular events. Based on event rates in other outcomes studies, we estimate completing the REDUCE-IT study in or about 2017 with results expected to be available in 2018. 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 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 resolution of the ANCHOR sNDA with the FDA. If we do not receive FDA approval for the ANCHOR indication, we may discontinue development of AMR102.

*Commercialization Strategy*

Vascepa became commercially available in the United States by prescription in January 2013 when we commenced sales and shipments to our network of U.S.-based wholesalers. On January 28, 2013, we commenced our full commercial launch of Vascepa in the United States. In preparation for our commercial launch, we hired and trained a direct sales force of approximately 275 sales representatives. In October 2013, we reduced our number of sales representatives to approximately 130, excluding sales management, in the United States to focus on the sales territories that we believe have demonstrated the greatest potential for Vascepa sales growth. We now market Vascepa in the United States through our sales force of approximately 150 sales professionals and their managers. We also employ various marketing and medical affairs personnel to support our commercialization of Vascepa. Our

---

## **Table of Contents**

clinical and commercial supply is provided to us under agreements with various third-party suppliers. As of February 1, 2014, over 16,000 clinicians had written prescriptions for Vascepa.

In December 2013, we completed our eleventh full calendar month of marketing and selling Vascepa. Based on monthly compilations of data provided by a third party, Symphony Health Solutions, the estimated number of normalized total Vascepa prescriptions for the year ended December 31, 2013 was approximately 225,000. According to data from another third party, IMS Health, the estimated number of normalized total Vascepa prescriptions was approximately 195,000 for that same period. Normalized total prescriptions represent the estimated total number of Vascepa prescriptions shipped to patients, calculated on a normalized basis (i.e., total capsules shipped divided by 120 capsules, or one month's supply). The data reported above is based on information made available to us from a third party resource and may be subject to adjustment and may overstate or understate actual prescriptions.

Although we believe these data are prepared on a period-to-period basis in a manner that is generally consistent and that such results are generally indicative of current prescription trends, these data are based on estimates and should not be relied upon as definitive. In addition, because of our limited selling history, during the year ended December 31, 2013, we only recognized revenue on product that was resold for purposes of filling prescriptions. Those prescription data may differ from data reported by other third parties.

Prior to commencing our U.S. commercial launch of Vascepa in January 2013, we had no revenue from Vascepa. Because of our limited selling history, change in the size of our sales force and uncertainty regarding resolution of the ANCHOR sNDA with the FDA, we do not believe that we can provide a reasonably accurate forecast of Vascepa prescriptions or revenues. While we expect to be able to grow Vascepa revenues, we provide no quantified guidance regarding anticipated levels of Vascepa prescriptions or revenues and no such guidance should be inferred from the operating metrics described above. 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 and other factors. We believe investors should consider our results over several quarters, or longer, before making an assessment about potential future performance.

We secured managed care coverage for over 200 million lives, including as of February 1, 2014 over 100 million lives covered on Tier 2. This level of Tier 2 coverage exceeds 66% of the maximum level of Tier 2 coverage which has been achieved over multiple years by comparable therapies.

The commercial launch of a new pharmaceutical product is a complex undertaking, and our ability to effectively and profitably launch 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*.

### *Commercial Supply Update*

During the year ended December 31, 2013, we acquired approximately \$25.7 million of Vascepa active pharmaceutical ingredient, or API, of which \$22.0 million was capitalized to inventory as of December 31, 2013. The balance of such Vascepa API purchase costs was included as a component of research and development expense because it was received from suppliers that had not yet been qualified by the FDA.

In April 2013, the FDA approved our sNDAs covering Chemport, Inc. and BASF (formerly Equateq Limited) as additional Vascepa API suppliers. We are working with Slanmhor Pharmaceuticals, Inc. to pursue FDA approval for Slanmhor to manufacture Vascepa API and submitted an sNDA in August 2013. Until an API supplier is approved, all Vascepa API purchased from such supplier is included as a component of research and development expense.



## **Table of Contents**

The amount of supply purchases in 2014 and beyond will depend on the level of growth of Vascepa revenues, which will be significantly impacted by the outcome of the FDA's decision on approval of the ANCHOR indication, and, with certain suppliers, will depend on the timing of their qualification to consistently produce Vascepa to our specification and to minimum purchase commitments. We anticipate that our gross margin from Vascepa sales will be lower in 2013 than in subsequent years due to multiple factors, including API supply pricing with our earliest approved supplier, Nisshin. This is the case particularly as it relates to our earliest volume of purchases from Nisshin being higher than supply pricing later agreed with other suppliers, tiered supply pricing at certain suppliers such that cost per kilogram of supply purchases are scheduled to decline as volume of purchases increase, recent improvement in currency exchange rates, geographic location of our suppliers, special initial stocking discounts provided to wholesalers and pharmacies to encourage them to stock Vascepa in advance of Vascepa's January 2013 commercial launch, and rebate cards offered to consumers filling prescriptions for Vascepa to reduce the size of the consumer's co-payment requirements while we work with payors to migrate Vascepa coverage from tier-3 to tier-2 in these payors' drug pricing systems. We anticipate rebate amounts that we will agree to provide payors for tier-2 insurance coverage on sales of Vascepa will ultimately cost us less than our current rebate card program.

### *Financial Position*

We believe that our cash and cash equivalents balance of \$191.5 million at December 31, 2013 is sufficient to fund our projected operations for at least the next twelve months, including the continued commercialization of Vascepa for the MARINE indication, preparations for commercialization of Vascepa for the ANCHOR indication, if approved, and the advancement of the REDUCE-IT cardiovascular outcomes study.

### **Financial Operations Overview**

*Revenue.* All of our revenue is derived from product sales 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, who resell the product to retail pharmacies for purposes of their reselling the product to fill patient prescriptions. In accordance with GAAP, until we have the ability to reliably estimate returns of Vascepa from our Distributors, revenue will be recognized based on the resale of Vascepa for the purposes of filling patient prescriptions, and not based on sales from us to such Distributors. Consistent with industry practice, once we achieve sufficient history such that we can reliably estimate returns based on sales to our Distributors, we anticipate that our revenues will be recognized based on sales to our Distributors. We currently defer Vascepa revenue recognition until the earlier of the product being resold for purposes of filling patient prescriptions; and the expiration of the right of return (twelve months after the expiration date of the product). We also defer the related cost of product sales and record such amounts as finished goods inventory held by others until revenue related to such product sales is recognized. Through December 31, 2013, product returns were de minimus.

*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, insurance and quality assurance. 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, the majority of which through December 31, 2013 was from Nisshin, our first approved API supplier.

*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

---

## **Table of Contents**

cost to support current development efforts, including patent costs and milestone payments. We expense research and development costs as incurred. 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 Expense.* Selling, general and administrative expense consists primarily of salaries and other related costs for personnel, including stock-based compensation expense, in our sales, marketing, executive, business development, finance and information technology functions. Other costs primarily include facility costs and professional fees for accounting, consulting and legal services.

*Interest and Other (Expense) Income, Net.* Interest expense consists of interest incurred under lease obligations, interest incurred under our 3.5% exchangeable debt and interest incurred under our December 2012 financing arrangement with BioPharma Secured Debt Fund II Holdings Cayman LP, or BioPharma. Interest expense under our 3.5% exchangeable debt includes the amortization of the conversion option related to our exchangeable debt, the amortization of the related debt discount and debt obligation coupon interest. Interest income consists of interest earned on our cash and cash equivalents. Other (expense) income, net, consists primarily of foreign exchange losses and gains.

### **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 other 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. 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. We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our consolidated financial statements.

*Revenue Recognition* 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 health care 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. In accordance with GAAP, until we have the ability to reliably estimate returns of Vascepa from our Distributors, revenue will be recognized based on the resale of Vascepa for the purposes of filling patient prescriptions, and not based on sales from us to such Distributors. Consistent with industry practice, once we achieve sufficient history such that we can reliably estimate returns based on sales to our Distributors, we anticipate that our revenues will be recognized based on sales to our Distributors. We currently defer Vascepa revenue recognition until the earlier of the product being resold for purposes of filling patient prescriptions; and the expiration of the right of return (twelve months after the expiration date of the product). We also defer the related cost of product sales and record such amounts as finished goods inventory held by others until revenue related to such product sales is recognized. As of December 31, 2013, we had experienced de minimus product returns.

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

**Table of Contents**

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.

*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 valuation techniques; typically we use the Black-Scholes option pricing model. 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. Fluctuations in the assumptions used in the valuation model would result in adjustments to the fair value of the warrant derivative liability 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 recorded a financial derivative related to the change in control provision associated with our December 2012 debt financing. During 2013, we recorded a derivative liability related to our forward foreign exchange contracts, which was extinguished prior to December 31, 2013. The fair value of these derivatives could fluctuate based on changes in the assumptions used in the valuation models.

*Inventory* Prior to July 26, 2012, when we received approval from the FDA to market and sell Vascepa in the United States for the MARINE indication, Vascepa was considered a product candidate under development. All supply of Vascepa purchased prior to July 26, 2012 was not capitalized and instead charged as a component of research and development expense in the period received. After Vascepa was approved, we began to capitalize inventory purchased from Nisshin, the API supplier approved in the NDA. Prior to April 2013, only Nisshin was an FDA-approved supplier of API for Vascepa. In April 2013, the FDA approved our sNDAs covering Chemport and BASF as additional Vascepa API suppliers. All supply from Chemport and BASF prior to FDA approval of these API suppliers was not capitalized and instead charged as a component of research and development expense in the period received. Subsequent to the approval of these suppliers, we capitalize API purchases from them. We are working with Slanmhor to pursue FDA approval for Slanmhor to manufacture Vascepa API and submitted an sNDA in August 2013. Until an API supplier is approved, all Vascepa API purchased from such supplier is included as a component of research and development expense. Upon sNDA approval of each additional supplier, we capitalize subsequent Vascepa API purchases from such supplier as inventory. Purchases of Vascepa API received and expensed before such regulatory approvals are not subsequently capitalized, and all such purchases are quarantined and not used for commercial supply until such time as the sNDA for the supplier that produced the API is approved. 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

---

## **Table of Contents**

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.

We assess the realizability of 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. The Company has been historically profitable in the U.S. When making its assessment about the realization of its U.S. deferred tax assets at December 31, 2013, the Company considered all available evidence, placing particular weight on evidence that could be objectively verified. The evidence considered included the (i) historical profitability of the Company's U.S. operations, (ii) sources of future taxable income, giving weight to sources according to the extent to which they can be objectively verified, and (iii) the risks to our business related to the commercialization and development of Vascepa. Based on its assessment, the Company concluded that the U.S. deferred tax assets are more likely than not realizable as of December 31, 2013. Changes in historical earnings performance and future earnings projections, among other factors, may cause us to adjust our valuation allowance on deferred tax assets, which would impact our income tax expense in the period in which we determine that these factors have changed. In the event sufficient taxable income is not generated in future periods, additional valuation allowances of up to approximately \$12 million could be required relating to these U.S. deferred tax assets.

### **Recent Accounting Pronouncements**

In July 2013, the Financial Accounting Standards Board issued an update that clarified existing guidance on the presentation of unrecognized tax benefits when various qualifying tax benefit carryforwards exist, including when the unrecognized tax benefit should be presented as a reduction to deferred tax assets or as a liability. This update is required to be adopted for all annual periods and interim reporting periods beginning after December 15, 2013, with early adoption permitted. The adoption of this pronouncement is not expected to have a material impact on our financial statements.

From time to time, new accounting pronouncements are issued by FASB and are adopted by us as of the specified effective date. Unless otherwise discussed, we believe that the impact of recently issued accounting pronouncements will not have a material impact on consolidated financial position, results of operations, and cash flows, or do not apply to our operations.

### **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, 2013 versus December 31, 2012***

*Revenue.* We recorded revenue of \$26.4 million during the year ended December 31, 2013. We commenced our full commercial launch of Vascepa in the United States for use in the MARINE indication in January 2013. We recorded no revenue in 2012. All of our revenue in the year ended December 31, 2013 was derived from product sales of Vascepa, net of allowances, discounts, incentives, rebates, chargebacks and returns.

We sell Vascepa to Distributors. In accordance with our revenue recognition policy, until we have more experience with the sale of Vascepa and can better estimate product returns, we currently recognize revenue only for product which has been used for of the purpose of filling prescriptions. The excess of the amount billed and the amount recognized as revenue for the year ended December 31, 2013, net of applicable discounts and rebates, has been recorded as deferred revenue.

During the year ended December 31, 2013, our net product revenues included an adjustment for co-pay mitigation rebates provided by us to commercially insured patients. Such rebates are intended to offset the

---

**Table of Contents**

differential for patients of Vascepa not covered by commercial insurers at the time of launch on tier 2, resulting in higher co-pay amounts for such patients. Our cost for these co-payment mitigation rebates is up to \$75 per prescription filled during 2013. Commencing in March and April 2013, certain third-party payors added Vascepa to their tier 2 coverage, which results in lower co-payments for patients covered by these third-party payors. As of February 1, 2014, approximately 100 million lives covered by medical insurance were under insurance plans that have added Vascepa to their tier 2 coverage. In connection with the start of 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. As of February 1, 2014, over 16,000 clinicians had written prescriptions for Vascepa. As of February 1, 2014, we are not aware of any clinician who is responsible for 10% or more of the aggregate prescriptions written for Vascepa.

On October 22, 2013, in an effort to reduce operating expenses following the recommendation of the advisory committee to the FDA, we implemented a worldwide reduction in force including a reduction of approximately fifty percent of our sales representatives. Following the reduction in force, we retained approximately 130 sales representatives in the United States in sales territories which have demonstrated what we believe is the greatest potential for Vascepa sales growth. This team will cover the target base of physicians responsible for the majority of Vascepa prescription volume and growth since its launch in early 2013. With these changes and resulting target base coverage, we anticipate continued Vascepa revenue growth over time. We further anticipate that such revenue growth may be inconsistent from period to period.

*Cost of Goods Sold.* Cost of goods sold during the year ended December 31, 2013 was \$11.9 million, and 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, as well as a portion of API carried at zero cost for material which was purchased prior to FDA approval of Vascepa on July 26, 2012 or was purchased prior to the sNDA approval of our suppliers.

The majority of API included in the calculation of the average cost of goods sold during the year ended December 31, 2013 was sourced from one API supplier. The contracted cost of supply from this API supplier for initial purchase volumes is higher than the contracted cost from our other API suppliers. Contracted purchase costs from this initial API supplier reflect that they were working with Amarin prior to commencement of the MARINE and ANCHOR clinical trials and are anticipated to decline as additional API volume is purchased. In the future, we anticipate making continued purchases from this initial supplier at substantially lower unit pricing than the pricing of the initial purchases from this supplier and to make additional lower unit cost purchases of Vascepa API from other API suppliers. We began purchasing lower unit cost API from Chemport, which was approved by the FDA in April 2013 to produce Vascepa, in the three months ended June 30, 2013. During the year ended December 31, 2013, the cost basis of product sold that had a carrying value of zero was approximately \$4.0 million. Had such inventories been valued at acquisition cost, it would have resulted in an increase in cost of goods sold and a decrease in gross margin during such periods. We expect current inventories with a carrying value of zero to be utilized in 2014. We may have additional zero cost inventories in the future to the extent that we receive approval of the sNDA for our fourth commercial supplier. As of December 31, 2013, we maintained inventory with a carrying value of zero and an acquisition cost of approximately \$0.6 million, which has an estimated net realizable value of \$2.6 million based on our average net selling price for the year ended December 31, 2013.

Our gross margin improved during each quarter for the year ended December 31, 2013. This improvement was primarily driven by lower unit cost API purchases made during 2013. The gross margin for the year ended December 31, 2013 was 55%. In addition to expected continued lower average unit cost purchases of API, we

**Table of Contents**

also expect that API costs will be lower in the future due to recent improvements in foreign currency exchange rates and potential advantages derived from the geographical mix of our suppliers. We recorded no cost of goods sold in 2012.

*Research and Development Expense.* Research and development expense for the year ended December 31, 2013 was \$72.8 million, versus \$59.0 million in the prior year period, an increase of \$13.8 million, or 23.4%. Research and development expenses for the years ended December 31, 2013 and 2012 are summarized in the table below (in thousands):

	Year Ended December 31,	
	2013	2012
REDUCE-IT study (1)	\$ 46,994	\$ 25,563
Other clinical trial programs (2)	1,518	606
Pre-approval commercial supply (3)	5,819	16,141
Regulatory filing fees and expenses (4)	3,819	(256)
Internal staffing, overhead and other (5)	11,763	13,202
Research and development expense, excluding non-cash expense	69,913	55,256
Non-cash stock-based compensation (6)	2,837	3,700
Total research and development expense	\$ 72,750	\$ 58,956

The increase in research and development expenses for the year ended December 31, 2013, as compared to the prior year period, is primarily due to an increase in costs associated with the REDUCE-IT study as further described below.

- (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 in reducing major cardiovascular events in a high risk patient population on statin therapy. The study duration is dependent on the rate of clinical events in the study, which rate may be affected by the number of patients enrolled in the study and the epidemiology of the patients enrolled in the study. 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. We currently have over 6,500 patients enrolled in REDUCE-IT. We estimate that we will complete patient enrollment in this study in the first half of 2015. The REDUCE-IT study will be completed after reaching an aggregate number of cardiovascular events. Based on event rates in other outcomes studies, we estimate completing the REDUCE-IT study in or about 2017 with results expected to be available in 2018. For 2013, we incurred expenses through our CRO in connection with this trial of approximately \$38.4 million. Inclusive of CTM costs, the combined CRO and CTM costs in 2013 for REDUCE-IT were approximately \$47.0 million. We expense costs for CTM upon receipt. The aggregate cost of this outcomes study will depend on the rate of clinical events in the study. We currently estimate that costs incurred for this study in 2014 will continue at approximately the same levels as we have incurred in 2013. Based on our current assumptions of CRO and CTM costs, we estimate that aggregate remaining costs to complete the REDUCE-IT study and evaluate its results to likely exceed \$100 million. We anticipate that our costs for this outcomes study will continue to represent the most significant component of our research and development expenditures. However, if we do not receive FDA approval of the ANCHOR indication, we plan to re-evaluate the REDUCE-IT study, including the likelihood of REDUCE-IT providing clinically and commercially useful results, the likelihood of FDA approval for an expanded indication for Vascepa based on these results and whether it is advisable to continue or discontinue the study. We anticipate that in any such re-evaluation we will seek further feedback from the FDA.
- (2) In 2012 and 2013, other clinical trial programs consisted of fixed-dose combination studies. In December 2012, we completed dosing and pharmacokinetic sampling in a study to test a fixed-dose combination of

**Table of Contents**

- Vascepa capsules and a leading statin which we refer to as AMR102. In August 2013, we completed dosing in a randomized, open-label, single-dose, 4-way cross-over study to continue testing of the relative bioavailability of AMR102 capsules, Vascepa capsules with a 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 resolution of the ANCHOR sNDA with the FDA.
- (3) Until an API supplier is approved by the FDA to manufacture commercial supply of Vascepa, all Vascepa purchased from such supplier is included as a component of research and development expense. Upon approval of the supplier, we capitalize subsequent Vascepa API purchases from such supplier as inventory. Purchases of Vascepa API received and expensed before such regulatory approvals are not subsequently capitalized, and all such purchases are quarantined and not used for commercial supply until such time as the supplier that produced the API is approved. The commercial supply expense for the periods shown above represents inventory received from Nisshin prior to NDA approval of Vascepa on July 26, 2012 or received from our other suppliers prior to their sNDA approvals. In April 2013, sNDAs were approved for two of our additional suppliers, BASF and Chemport. A sNDA was submitted in August 2013 for Novasep as part of the Slanmhor consortium. The amount of commercial supply that we receive from Novasep prior to sNDA approval depends upon production schedules at Novasep and the timing of regulatory approval, and we are unable to estimate these amounts at this time. We will continue to expense inventory received from the unapproved supplier until such time as FDA approval is obtained. Additionally, during the year ended December 31, 2013, we wrote off \$1.8 million related to product that is not recoverable. This product is from a supplier from which no supply has yet been released for commercial use.
- (4) The regulatory filing fees primarily represent costs incurred in connection with regulatory filings associated with requests for regulatory approvals, such as the sNDA for the ANCHOR indication and annual FDA fees for maintaining manufacturing sites. In the year ended December 31, 2013, such fees also include costs associated with preparing for the October 16, 2013 FDA advisory committee meeting. In the year ended December 31, 2012, the regulatory filing fees balance included a credit representing the reimbursement of \$1.5 million in fees by the FDA related to the NDA filing for Vascepa.
- (5) Internal staffing, overhead and other research and development expenses primarily relate to the costs of our personnel employed to managed research, development and regulatory affairs activities and related overhead costs including consulting and other professional fees that are not allocated to specific projects. Such costs also include costs related to qualifying suppliers and legal costs. We anticipate a reduction in such costs in 2014 compared to 2013 levels as a result of a company-wide reduction in force announced in October 2013. As a result of the reduction in force, we incurred approximately \$0.2 million in severance expenses in 2013.
- (6) 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.

*Selling, General and Administrative Expense.* Selling, general and administrative expense for the year ended December 31, 2013 was \$123.8 million, versus \$57.8 million in the prior year, an increase of \$66.0 million, or 114.2%. Selling, general and administrative expenses for the years ended December 31, 2013 and 2012 are summarized in the table below (in thousands):

	2013	2012
Selling, general and administrative expenses (1)	\$ 113,100	\$ 43,172
Non-cash warrant related compensation (income) expense (2)	(3,703)	247
Non-cash stock based compensation expense (3)	11,848	14,375
Severance (4)	2,550	
	\$ 123,795	\$ 57,794

- (1) Selling, general and administrative expense, excluding non-cash charges for stock and warrant compensation, for the year ended December 31, 2013 was \$113.1 million, versus \$43.2 million in the prior year, an increase of \$69.9 million, or 161.8%. The increase was primarily due to cost increases in 2013 for

**Table of Contents**

sales force staffing, an increase in marketing program spending and increased general and administrative costs incurred in connection with the initial commercialization of Vascepa.

- (2) Non-cash warrant related compensation (income) expense for the year ended December 31, 2013 was \$3.7 million of income, versus \$0.2 million of expense in the prior year. Warrant related compensation income (expense) reflects the non-cash change in fair value of the warrant derivative liability associated with warrants issued in October 2009 to three former officers of Amarin, net of warrants exercised. The change in fair value in 2013 and 2012 was due primarily to the change in our stock price during each period. The value of this warrant derivative liability may increase or decrease from period to period based upon changes in the price of our common stock. Such non-cash changes in valuation could be significant as the history of our stock price has been volatile. The gain or loss resulting from such non-cash changes in valuation could have a material impact on our reported net income or loss from period to period. In particular, if the price of our stock increases, the change in valuation of this warrant derivative liability will add to our history of operating losses.
- (3) Non-cash stock based compensation expense for the year ended December 31, 2013 was \$11.8 million, versus \$14.4 million in the prior year period, a decrease of \$2.6 million, due primarily to a decrease in the number of awards outstanding as a result of the company-wide reduction in force announced in October 2013.
- (4) Severance costs in 2013 relate to cash expenditures for one-time termination benefits and associated costs incurred in conjunction with a company-wide reduction in force announced in October 2013.

Selling, general and administrative costs in 2013 have increased over 2012 levels as we continue to support the commercialization of Vascepa, including costs for market research, sales force staffing and support costs and investments in infrastructure. We anticipate a reduction in the level of such costs in 2014 as a result of the reduction in force announced in October 2013 and expected reductions in certain marketing program spend and other overhead costs.

*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, 2013 was a gain of \$47.7 million versus a loss of \$35.3 million in the prior year period. Gain (loss) on change in fair value of derivative liabilities is comprised of the change in fair value of the warrant derivative liability and the change in fair value of the derivative liability related to the change in control provision associated with the December 2012 BioPharma financing.

The warrant derivative liability is 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 and recorded a \$48.3 million warrant derivative liability, representing the fair value of the warrants issued. As these warrants have been classified as a derivative liability, they are revalued at each reporting period, with changes in fair value recognized in the statement of operations. The fair value of the warrant derivative liability at December 31, 2013 was \$6.9 million and we recognized a \$44.2 million gain on change in fair value of derivative liability for the year ended December 31, 2013 for these warrants. The fair value of the warrant derivative liability at December 31, 2012 was \$54.9 million and we recognized a \$35.4 million loss on change in fair value of derivative liability for the year ended December 31, 2012. The change in fair value of the warrant derivative liability is due primarily to the change in the price of our common stock on the date of valuation.

Our December 2012 financing agreement with BioPharma contains a redemption feature whereby, upon a change of control, we would be required to pay \$140 million, less any previously repaid amount, if the change of control occurs on or before December 31, 2013, or required to repay \$150 million, less any previously repaid amount, if the change of control event occurs after December 31, 2013. 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. At December 31, 2013, the fair value of the derivative was determined to be \$11.1 million, and at December 31, 2012, the fair value of the derivative was determined to be \$14.6 million. We recognized a gain on change in fair value of derivative liability of \$3.5 million and \$0.02 million for the years ended December 31, 2013 and 2012, respectively.



**Table of Contents**

*Interest Expense, net.* Net interest expense for the year ended December 31, 2013 was \$33.8 million, versus \$17.5 million in the prior year period, an increase of \$16.3 million, or 93.1%. Net interest expense for the years ended December 31, 2013 and 2012 is summarized in the table below (in thousands):

	Year Ended December 31,	
	2013	2012
<b>Exchangeable senior notes:</b>		
Amortization of debt discount created upon allocation of proceeds to the conversion option	\$ 12,546	\$ 10,686
Contractual coupon interest	5,250	5,119
Amortization of the discount from the underwriter's discounts and offering costs	2,521	2,147
<b>Total Exchangeable senior notes interest expense</b>	<b>20,317</b>	<b>17,952</b>
<b>Long-term debt BioPharma financing (1):</b>		
Cash interest - current	1,843	114
Cash interest - deferred	9,451	
Non-cash interest	2,565	23
<b>Total long-term debt interest expense</b>	<b>13,859</b>	<b>137</b>
Other interest expense	3	2
<b>Total interest expense</b>	<b>34,179</b>	<b>18,091</b>
Interest income (2)	(343)	(544)
<b>Total interest expense, net</b>	<b>\$ 33,836</b>	<b>\$ 17,547</b>

- (1) Cash and non-cash interest expenses related to the BioPharma financing for the year ended December 31, 2013 were \$11.3 million and \$2.6 million, respectively. These amounts reflect the assumption that our Vascepa revenue levels will not be high enough to support repayment to BioPharma in accordance with the repayment schedule without the optional reduction which is allowed to be elected by us if the threshold revenue levels are not achieved. For the three months ended September 30, 2013 and December 31, 2013, our revenues were below the contractual threshold amount such that we made a cash payment of \$0.8 million in November 2013 based on \$8.4 million in revenue recognized in the third quarter of 2013 and we will make a cash payment of \$1.0 million in February 2014 based on \$10.1 million in revenue recognized in the fourth quarter of 2013, reflecting the calculated optional reduction amount as opposed to the contractual threshold payments of \$2.5 million for each quarterly period.
- (2) Interest income for the year ended December 31, 2013 was \$0.3 million, versus \$0.5 million in the prior year period, a decrease of \$0.2 million, or 40.0%. Interest income represents income earned on cash balances.

*Other (Expense) Income, net.* Other (expense) income, net for the year ended December 31, 2013 was a \$1.2 million expense versus a \$0.4 million expense in the prior year. Other (expense) income, net primarily consists of losses and gains on foreign exchange transactions, including realized gains and losses on foreign exchange forward contracts. We use foreign exchange forward contracts to hedge against changes in exchange rates for inventory purchases denominated in foreign currency. The unrealized gains and losses on such contracts are recorded within gain (loss) on change in fair value of derivative liability. As of December 31, 2013, all such contracts had been settled. For the year ended December 31, 2013, we recognized a realized loss of \$1.1 million related to the settlement of the foreign exchange forward contracts, which was included as a component of other (expense) income, net. There were no forward exchange forward contracts outstanding in 2012. Other (expense) income for the year ended December 31, 2012 was a net expense of \$0.4 million.

*Benefit from (Provision for) Income Taxes.* Benefit from (provision for) income taxes for the year ended December 31, 2013 was a \$3.2 million benefit versus a \$9.1 million provision in the prior year. The current

**Table of Contents**

benefit (provision) relates entirely to our United States subsidiary operations. We are profitable in the United States as a result of intercompany transactions between our United States subsidiary and our other companies. The 2013 benefit primarily relates to tax credits for research and development activities. The 2012 provision for income taxes primarily relates to the exercise of stock options of which the excess benefits related to the option exercises are recorded to additional-paid-in capital.

**Comparison of Fiscal Years Ended December 31, 2012 versus December 31, 2011**

*Revenue.* We recorded no revenue in 2012 or 2011.

*Research and Development Expense.* Research and development expense for the year ended December 31, 2012 was \$59.0 million, versus \$21.6 million in the prior year period, an increase of \$37.4 million, or 173%. Research and development expenses for the years ended December 31, 2012 and 2011 are summarized in the table below:

	2012	2011
Research and development expenses (1)	\$ 55,256	\$ 20,138
Non-cash stock based compensation expense (2)	3,700	1,464
	\$ 58,956	\$ 21,602

- (1) Research and development expense, excluding non-cash charges for stock compensation, for the year ended December 31, 2012 was \$55.3 million, versus \$20.1 million in the prior year period, an increase of \$35.2 million, or 175%. The increase in research and development expense was due to increased costs in 2012 for our Vascepa cardiovascular program, primarily increased clinical costs for the REDUCE-IT cardiovascular outcomes study, costs of supply purchases prior to NDA approval and costs associated with study of AMR102. Prior to FDA approval of Vascepa on July 26, 2012, all supply purchases of Vascepa were expensed to research and development. After FDA approval, supply purchases of Vascepa were capitalized, with the exception of clinical trial material which continues to be expensed to research and development. During the year ended December 31, 2012, non-capitalized supply purchases and vendor qualification costs were approximately \$16.1 million. During the year ended December 31, 2012, expenses incurred through our CRO for the REDUCE-IT study were approximately \$23.3 million.
- (2) Non-cash stock based compensation expense included within research and development was \$3.7 million and \$1.5 million for the years ended December 31, 2012 and 2011, respectively.

*Selling, General and Administrative Expense.* Selling, general and administrative expense for the year ended December 31, 2012 was \$57.8 million, versus \$22.6 million in the prior year, an increase of \$35.2 million, or 155.8%. Selling, general and administrative expenses for the years ended December 31, 2012 and 2011 are summarized in the table below:

	2012	2011
Selling, general and administrative expenses (1)	\$ 43,172	\$ 14,825
Non-cash warrant related compensation (income) expense (2)	247	(96)
Non-cash stock based compensation expense (3)	14,375	7,830
	\$ 57,794	\$ 22,559

- (1) Selling, general and administrative expense, excluding non-cash charges for stock and warrant compensation, for the year ended December 31, 2012 was \$43.2 million, versus \$14.8 million in the prior year, an increase of \$28.4 million, or 192%. The increase was primarily due to cost increases in 2012 for marketing research activities, medical education (approximately \$16.1 million) and higher staffing levels and related travel (approximately \$5.2 million) plus increased facility costs and other general and administrative costs incurred in order to prepare for the commercialization of Vascepa.



**Table of Contents**

- (2) Non-cash warrant related compensation expense (income) for the year ended December 31, 2012 was \$0.3 million of expense, versus \$0.1 million of income in the prior year. Warrant related compensation expense for the period ended December 31, 2012 reflects non-cash income for the change in fair value of the warrant derivative liability associated with warrants issued in October 2009 to three former officers of Amarin, net of warrants exercised. The expense in 2012 was due primarily to the increase in the fair value of these warrants, the increase in the fair value of the warrants is due primarily to an increase in our stock price between December 31, 2011 and December 31, 2012. The value of this warrant derivative liability may increase or decrease from period to period based upon changes in the price of our common stock. Such non-cash changes in valuation could be significant as the history of our stock price has been volatile. The gain or loss resulting from such non-cash changes in valuation could have a material impact on our reported net income or loss from period to period. In particular, if the price of our stock increases, the change in valuation of this warrant derivative liability will add to our history of operating losses.
- (3) Non-cash stock based compensation expense for the year ended December 31, 2012 was \$14.4 million, versus \$7.8 million in the prior year period, an increase of \$6.6 million due primarily reflects an increase in the number of awards outstanding during the 2012 year versus the prior period, and also in the fair value of new option awards granted to attract and retain qualified employees.

*Gain (Loss) on Change in Fair Value of Derivative Liabilities.* (Gain) loss on change in fair value of derivative liability for the year ended December 31, 2012 was a loss of \$35.3 million versus a loss of \$22.7 million in the prior year period. The loss on change in fair value of derivative liability is primarily 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 and recorded a \$48.3 million warrant derivative liability, representing the fair value of the warrants issued. As these warrants have been classified as a derivative liability, they are revalued at each reporting period, with changes in fair value recognized in the statement of operations. The fair value of the warrant derivative liability at December 31, 2011 was \$123.1 million and we recognized a \$22.7 million loss on change in fair value of derivative liability for the period ended December 31, 2011 for these warrants. The fair value of the warrant derivative liability at December 31, 2012 was \$54.9 million and we recognized a \$35.4 million loss on change in fair value of derivative liability for the period ended December 31, 2012. The decrease in the warrant derivative liability value was due primarily to the exercises of warrants. Upon exercise, the fair value of warrants exercised is remeasured and reclassified from warrant liability to additional paid-in-capital. The fair value of the long term debt redemption feature at December 31, 2012 was \$14.6 million. The Company recognized a \$0.02 million gain on change in fair value of derivative liability at December 31, 2012. See further discussion of the warrant derivative liability in Note 2 and Note 7 of the Notes to the Consolidated Financial Statements.

*Interest Expense, net.* Interest income includes interest earned on cash balances. Interest expense includes the amortization of the exchange option related to our exchangeable debt, the amortization of debt discounts and debt obligation coupon interest. During the twelve months ended December 31, 2012, we recognized interest expense of \$18.1 million, of which \$10.7 million represents amortization of the debt discount, \$5.2 million represents contractual coupon interest and \$2.2 million represents the amortization of the discount from underwriter discounts and offering costs. Interest expense in 2011 was de minimis.

*Other (Expense) Income, net.* Other (expense) income, net in 2012 primarily represents a loss due to the fluctuation in the exchange rate of a milestone payment to Laxdale in the amount of \$0.5 million. Also included are gains and losses on other foreign exchange transactions. Other (expense) income in 2011 was de minimis.

*Benefit from (Provision for) Income Taxes.* Benefit from (provision for) income taxes for the year ended December 31, 2012 was a \$9.1 million provision versus a \$2.5 million provision in the prior year. The current provision relates entirely to the United States subsidiary operations. We are profitable in the United States as a result of intercompany transactions between our United States subsidiary and our other companies. The increase in the 2012 provision for income taxes primarily relates to the exercise of stock options of which the excess benefits related to the option exercises are recorded to additional-paid-in capital.

**Table of Contents****Liquidity and Capital Resources**

Our sources of liquidity as of December 31, 2013 include cash and cash equivalents of \$191.5 million. Our projected uses of cash include commercialization of Vascepa for the MARINE indication, preparations for commercialization of Vascepa for the ANCHOR indication, if approved, the continued funding of the REDUCE-IT cardiovascular outcomes study, working capital and other general corporate activities. 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):

	Years Ended December 31,		
	2013	2012	2011
Cash (used in) provided by:			
Operating activities	\$ (190.3)	\$ (122.3)	\$ (39.4)
Investing activities	(0.0)	(14.3)	(2.0)
Financing activities	121.6	280.2	126.6
(Decrease) increase in cash and cash equivalents	\$ (68.7)	\$ 143.6	\$ 85.2

In July 2013, we sold 21.7 million shares of our common shares, par value £0.50 per share, at a price of \$5.60 per share, resulting in net proceeds of approximately \$121.2 million after deducting underwriting commissions and expenses payable by us associated with this transaction.

On December 6, 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 million received at the closing of the agreement which closing occurred in December 2012. We have agreed to repay BioPharma up to \$150 million of future revenue and receivables. The first repayment under the agreement was a repayment of \$0.8 million of interest in November 2013, reflective of the option reduction described below. Additional quarterly repayments are due thereafter in accordance with the following schedule: \$2.5 million of interest in the first quarter of 2014; \$8.0 million per quarter in each of the next four quarters, \$10.0 million per quarter in each of the next four quarters, \$15.0 million per quarter in each of the next four quarters and a final payment of \$13.0 million due in May 2017. The quarterly repayments through the third quarter of September 2014 represent interest only. Quarterly payments do not begin to reduce the principal balance until the fourth quarter of 2014. For the three months ended September 30, 2013 and December 31, 2013, revenues were below the contractual threshold amount such that a cash payment of \$0.8 million is was made in November 2013 and a cash payment of \$1.0 million is due in February 2014, reflecting the calculated optional reduction amount as opposed to the contractual threshold payment of \$2.5 million for each quarterly period. In accordance with the agreement with BioPharma, quarterly differences between the calculated optional reduction amounts and the repayment schedule amounts are rescheduled for payment beginning in the second quarter of 2017. 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 revenues. Except upon a change of control in Amarin, the agreement does not expire until \$150 million has been repaid. Under the agreement, upon a change of control, we would be required to pay \$140 million, less any previously repaid amount, if the change of control occurs on or before December 31, 2013, or required to repay \$150 million, less any previously repaid amount, if the change of control event occurs after December 31, 2013. We can prepay after October 1, 2013, an amount equal to \$150 million less any previously repaid amount. We currently estimate that Vascepa revenue levels will not be high enough in each quarter to support repayment to BioPharma in accordance with threshold amounts in the repayment schedule.

On January 9, 2012, Amarin, through our wholly-owned subsidiary Corsicanto Limited, or Corsicanto, a private limited 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 proceeds we received from the January 2012 debt offering were approximately \$144.3 million, net of fees and transaction costs. These notes

**Table of Contents**

were issued pursuant to an indenture dated as of January 9, 2012, by and among Corsicanto, us as guarantor, and Wells Fargo Bank, National Association, as trustee. The notes are the senior unsecured obligations of Corsicanto and are guaranteed by us. The notes bear interest at a rate of 3.5% per annum, payable semi-annually in arrears on January 15 and July 15 of each year, beginning on July 15, 2012. The notes mature on January 15, 2032, unless earlier repurchased, redeemed or exchanged. On or after January 19, 2017, we may elect to redeem for cash all or a portion of the notes for the principal amount of the notes plus accrued and unpaid interest. On each of January 19, 2017, January 19, 2022 and January 19, 2027, the holders of the notes may require that we repurchase in cash the principal amount of the notes plus accrued and unpaid interest. At any time prior to January 15, 2032, upon certain circumstances, which circumstances include our issuing a notice of redemption to the note holders, the price of our shares trading above 130% of the exchange price, or certain other events defined in the note agreement, the holders of the notes may elect to convert the notes. The exchange rate for conversion is 113.4752 ADSs per \$1,000 principal amount of the notes (equivalent to an initial exchange price of approximately \$8.8125 per ADS), subject to adjustment in certain circumstances, including adjustment if we pay cash dividends. Upon exchange, the notes may be settled, at our election, subject to certain conditions, in cash, ADSs or a combination of cash and ADSs.

As of December 31, 2013, we had cash and cash equivalents of \$191.5 million, a decrease of \$68.7 million from December 31, 2012. The decrease is primarily due to net cash used in operating activities in support of the commercial launch of Vascepa, net of proceeds from financing activities. We have incurred annual operating losses since our inception and, as a result, we had an accumulated deficit of \$913.9 million as of December 31, 2013. We believe that our cash and cash equivalents balance of \$191.5 million at December 31, 2013 will be sufficient to fund our projected operations for at least the next twelve months. We anticipate that net cash outflows in 2014 will be significantly lower than net cash outflows in 2013 as a result of a reduction in expenses associated with the commercialization of Vascepa, lower headcount and lower supply purchases.

**Contractual Obligations**

The following table summarizes our contractual obligations at December 31, 2013 and the effects such obligations are expected to have on our liquidity and cash flows in future periods (in millions):

**Payments Due by Period**

	Total	2014	2015 to 2016	2017 to 2018	After 2018
<b>Contractual Obligations:</b>					
Purchase obligations (1)	\$ 106.9	\$ 18.7	\$ 60.6	\$ 23.8	\$ 3.8
Operating lease obligations (2)	3.0	0.8	1.3	0.9	
Interest payment obligations exchangeable debt (3)	26.3	5.3	10.5	10.5	
Principal & Interest payment obligations Biopharma (4)	149.2	25.0	93.0	31.2	
<b>Total contractual cash obligations</b>	<b>\$ 285.4</b>	<b>\$ 49.8</b>	<b>\$ 165.4</b>	<b>\$ 66.4</b>	<b>\$ 3.8</b>

- (1) We have agreements with API suppliers which include minimum purchase levels to enable us to maintain exclusivity with each respective supplier, and to prevent potential termination of the agreements based on our estimated minimum purchase requirements. The amounts in the table above reflect amounts potentially payable to our suppliers based on our minimum purchase obligations. These amounts reflect the assumption that the sNDA for Slanmhor is approved and that Slanmhor completes construction and validation of its manufacturing facility and that BASF is able to successfully complete the validation of its manufacturing process.
- (2) Represents operating lease costs, primarily consisting of leases for facilities in Dublin, Ireland, Bedminster, NJ and Groton, CT.
- (3) Represents interest payments due under the terms of our 3.5% exchangeable senior notes ( notes ) due 2032, assuming they remain outstanding for the next five years and have not been exchanged for ADRs. The

**Table of Contents**

- above table does not reflect the repayment of the \$150.0 million notes as they may be exchanged for ADRs.
- (4) Represents principal and interest payments which we anticipate paying under the terms of the agreement entered into with Biopharma Secured Debt Fund II Holdings Cayman LP (Biopharma) reflecting full payment based on the quarterly repayment schedule under that agreement, without regard to our potential to elect quarterly reductions in such payment amounts in the event that Vascepa revenue levels result in calculation under the agreement of lower quarterly repayment amounts. Under this agreement, the Company granted to Biopharma a security interest in future receivables and all rights to Vascepa, in exchange for \$100 million received at the closing of the agreement which closing occurred in December 2012. The Company has agreed to repay Biopharma up to \$150 million of future revenue and receivables. The first repayment under the agreement of \$0.8 million was made to Biopharma in November 2013 and a second quarterly payment of \$1.0 million is due in the first quarter of 2014. Additional quarterly repayments are due thereafter in accordance with the following schedule: \$8.0 million per quarter in each of the next four quarters, \$10.0 million per quarter in each of the next four quarters, \$15.0 million per quarter in each of the next four quarters and a final payment of \$13.0 million due in May 2017. All such payments reduce the remainder of the \$150 million in aggregate payments to Biopharma. For accounting purposes, the quarterly repayments through the third quarter of September 2014 represent interest only. Quarterly payments do not begin to reduce the principal balance until the fourth quarter of 2014. These quarterly payments are subject to a quarterly threshold amount whereby, if a calculated threshold, based on quarterly Vascepa revenues, is not achieved, the quarterly payment payable in that quarter can at our election be reduced and with the reduction carried forward without interest for payment in a future period. The table above reflects payment in full of the scheduled quarterly amounts without regard to such potential elected reductions.
- We do not enter into financial instruments for trading or speculative purposes.

In April 2013, we announced the approval by the FDA of the sNDAs covering two of our API suppliers, Chemport, Inc. and BASF (formerly Equateq Limited). 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. BASF is entitled to a 60-day cure period and the table above includes minimum purchase commitments to BASF assuming that BASF cures within this period and successfully completes the validation of its manufacturing process for the manufacture of Vascepa API. These commercial supply agreements provide access to additional API supply that is incremental to supply from Nisshin, our other existing FDA-approved API supplier. Each of these additional API agreements contemplates a phased capacity expansion plan aimed at creating sufficient capacity to meet anticipated demand for API material for Vascepa following commercial launch. These API suppliers are self-funding these expansion plans with contributions from us. These agreements include requirements for the suppliers to qualify their materials and facilities. We anticipate incurring certain costs associated with the qualification of product manufactured by these suppliers. These agreements include annual purchase levels enabling us to maintain supply exclusivity with each respective supplier, and to prevent potential termination of the agreements. The Chemport agreement includes a provision that any shortfall in the minimum purchase commitments is payable in cash, and the maximum amounts payable pursuant to this provision are reflected in the table above. The sNDA for the consortium led by Slanmhor, our intended fourth API supplier, is not yet approved and the construction and validation of their facility has not been completed for the manufacture of Vascepa API, however, the minimum purchase commitments that could result in a future cash obligation have been included in the above table.

The two supply agreements entered into in 2011 with BASF and Chemport also include (i) development fees up to a maximum of \$0.5 million, (ii) material commitments of up to \$5.0 million for initial raw materials, which will be credited against future API purchases, and is refundable to us if a supplier does not successfully develop and qualify the API by a certain date, and (iii) a raw material purchase commitment of \$1.1 million. We have paid \$3.1 million related to these commitments through December 31, 2013. Under all of our supply agreements, during the year ended December 31, 2013 we purchased approximately \$25.7 million of Vascepa API. The agreement with the fourth API supplier, when all contingencies are eliminated by the supplier, provides for development fees of up to \$2.3 million and a commitment of up to \$15.0 million, which will be credited against future API material purchases. We have paid \$6.2 million related to these commitments through

---

## **Table of Contents**

December 31, 2013. The \$15.0 million commitment fee is contingent upon the mutually agreed upon expansion of Slanmhor's API manufacturing capacity beyond the facility which has already been constructed and is in the process of being qualified by Slanmhor. As of the date of this Annual Report, the parties have not agreed upon such additional expansion. Under this agreement, during 2013 and 2012, we made payments of \$6.1 million and \$1.6 million to Slanmhor related to stability and technical batches and advances on future API purchases.

Concurrent with our supply agreements with Chemport entered into in 2011 for the supply of API materials for Vascepa, we agreed to make a non-controlling minority share equity investment in the supplier of up to \$3.3 million. We invested \$1.7 million under this agreement in July 2011 and the remaining \$1.6 million during 2012. In September 2013, we entered into an equity sale and purchase agreement between this supplier and a third party in which we agreed to sell approximately \$1.3 million of our investment in the supplier to the third party at cost. This transaction closed in the first quarter of 2014. The carrying amount of \$3.3 million as of December 31, 2013 and 2012 is included in other long term assets and is accounted for under the cost method.

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 and \$0.3 million during the years ended December 31, 2013 and 2012, respectively. 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 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 \$12.4 million at December 31, 2013). Additionally, upon receipt of a marketing approval in the U.S. or Europe for a further indication of Vascepa (or further indication of any other product using Amarin Neuroscience intellectual property), we must make an aggregate stock or cash payment (at the sole option of each of the sellers) of £5 million (approximately \$8.2 million at December 31, 2013) for each of the two potential market approvals (i.e. £10 million maximum, or approximately \$16.5 million at December 31, 2013).

In addition to the obligations in the table above, we have recorded a liability of \$0.6 million for uncertain tax positions that have been recorded in long-term liabilities at December 31, 2013. We are not able to reasonably estimate in which future periods these amounts will ultimately be settled.

### **Off-Balance Sheet Arrangements**

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

### **Shelf Registration Statement**

On March 29, 2011, we filed with the SEC a universal shelf registration statement on Form S-3 (Registration No. 333-173132), which provides for the offer, from time to time, of an indeterminate and unlimited amount 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. In addition, if we identify any security holder(s) in a prospectus supplement, they may also offer identified securities under this registration statement although we will not receive any of the proceeds from the sale of securities by any of these selling security holders. This universal shelf registration statement was automatically effective upon its filing. 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.



**Table of Contents****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 prior to 2013 we entered into no foreign exchange contracts. Our investments meet high credit quality and diversification standards, as specified in our investment policy. At December 31, 2013, we recorded as a liability the fair value of warrants to purchase 8.1 million shares of our common stock issued to investors. The fair value of this warrant derivative liability is determined using the Black-Scholes option valuation model and is therefore sensitive to changes in the market price and volatility of our common stock among other factors. In the event of a hypothetical 10% increase in the market price of our common shares (\$2.17 based on the \$1.97 market price of our stock at December 31, 2013) on which the December 31, 2013 valuation was based, the value of the derivative liability would have increased by \$1.3 million. Such increase would have been reflected as a loss on change in fair value of derivative liability and increase in warrant compensation expense in our statement of operations.

*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 supply from Nisshin in Japanese Yen. As our level of supply purchases from Nisshin increased in 2013, we entered into short-term forward currency pricing contracts to lock-in the exchange rate on a portion of our anticipated purchases denominated in Japanese Yen. All such contracts were settled as of December 31, 2013 and there are no outstanding forward currency contracts.

*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, 2013, the fair value of our cash and cash equivalents maturing in one year or less was \$191.5 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, 2013 (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

---

## **Table of Contents**

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, 2013. 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*.

Based upon this evaluation and those criteria, management believes that, as of December 31, 2013, our internal controls over financial reporting were effective.

Deloitte and Touche 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, 2013. 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 2013 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

---

**Table of Contents**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders of

Amarin Corporation plc

Dublin, Ireland

We have audited the internal control over financial reporting of Amarin Corporation plc and its subsidiaries (the Company) as of December 31, 2013, based on criteria established in *Internal Control Integrated Framework (1992)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. 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 conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). 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.

A company's internal control over financial reporting is a process designed by, or under the supervision of, the company's principal executive and principal financial officers, or persons performing similar functions, and effected by the company's 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. 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 the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of the internal control over financial reporting to future periods are subject to the risk that the controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2013, based on the criteria established in *Internal Control Integrated Framework (1992)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements as of and for the year ended December 31, 2013 of the Company and our report dated February 27, 2014 expressed an unqualified opinion on those financial statements.

/s/ DELOITTE & TOUCHE LLP

Parsippany, New Jersey

February 27, 2014

**Table of Contents**

**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 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.

**Table of Contents**

**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 2014 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 2014 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 2014 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 2014 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 2014 Annual General Meeting of Shareholders. Such information is incorporated herein by reference.

**Table of Contents****PART IV****Item 15. Exhibits and Financial Statement Schedules**

<b>Exhibit</b>		<b>Incorporated by Reference Herein</b>	
<b>Number</b>	<b>Description</b>	<b>Form</b>	<b>Date</b>
3.1	Articles of Association of the Company	Quarterly Report on Form 10-Q, File No. 0-21392, as Exhibit 3.1	August 8, 2013
4.1	Form of Amended and Restated Deposit Agreement, dated as of November 4, 2011, among the Company, Citibank, N.A., as Depositary, and all holders from time to time of American Depositary Receipts issued thereunder	Annual Report on Form 10-K for the year ended December 31, 2011, File No. 0-21392, as Exhibit 4.1	February 29, 2012
4.2	Indenture, dated as of January 9, 2012, by and among Corsicanto Limited, the Company and Wells Fargo Bank, National Association, as trustee	Current Report on Form 8-K dated January 9, 2012, File No. 0-21392, as Exhibit 4.1	January 10, 2012
4.3	Form of Ordinary Share certificate	Annual Report on Form 20-F for the year ended December 31, 2002, File No. 0-21392, as Exhibit 2.4	April 24, 2003
4.4	Form of American Depositary Receipt evidencing ADSs	Annual Report on Form 10-K for the year ended December 31, 2011, File No. 0-21392, as Exhibit 4.4	February 29, 2012
10.1	The Company 2002 Stock Option Plan*	Annual Report on Form 20-F for the year ended December 31, 2006, File No. 0-21392, as Exhibit 4.17	March 5, 2007
10.2	The Company 2011 Stock Option Plan*	Quarterly Report on Form 10-Q for the period ended June 30, 2011, File No. 0-21392, as Exhibit 10.4	August 9, 2011
10.3	Amendment No. 1 to 2011 Stock Option Incentive Plan*	Quarterly Report on Form 10-Q for quarterly period ended June 30, 2012, File No. 0-21392, as Exhibit 10.1	August 8, 2008
10.4	Amendment No. 2 to 2011 Stock Option Incentive Plan*	Quarterly Report on Form 10-Q for quarterly period ended June 30, 2012, File No. 0-21392, as Exhibit 10.2	August 8, 2008
10.5	Amendment No. 3 to 2011 Stock Option and Incentive Plan*	Annual Report on Form 10-K for the year ended December 31, 2012, File No. 0-21392, as Exhibit 10.5	February 28, 2012
10.6	Amarin Corporation plc Management Incentive Compensation Plan*	Annual Report on Form 10-K for the year ended December 31, 2010, File No. 0-21392, as Exhibit 10.44	March 16, 2011
10.7	Form of Incentive Stock Option Award Agreement	Annual Report on Form 10-K for the year ended December 31, 2011, File No. 0-21392, as Exhibit 10.3	February 29, 2012



**Table of Contents**

Exhibit	Incorporated by Reference Herein		
	Number	Description	Date
10.8	Form of Non-Qualified Stock Option Award Agreement	Annual Report on Form 10-K for the year ended December 31, 2011, File No. 0-21392, as Exhibit 10.4	February 29, 2012
10.9	Form of Restricted Stock Unit Award Agreement	Annual Report on Form 10-K for the year ended December 31, 2011, File No. 0-21392, as Exhibit 10.5	February 29, 2012
10.10	Letter Agreement dated August 1, 2008 with Paresh Soni*	Annual Report on Form 10-K for the year ended December 31, 2010, File No. 0-21392, as Exhibit 10.20	March 16, 2011
10.11	Letter Agreement dated October 12, 2009 with Dr. Declan Doogan*	Registration Statement on Form F-1, File No. 333-163704, as Exhibit 4.101	December 14, 2009
10.12	Letter Agreement dated October 12, 2009 with Joseph S. Zakrzewski*	Registration Statement on Form F-1, File No. 333-163704, as Exhibit 4.102	December 14, 2009
10.13	Letter Agreement dated October 16, 2009 with Thomas G. Lynch*	Registration Statement on Form F-1, File No. 333-163704, as Exhibit 4.103	December 14, 2009
10.14	Letter Agreement, dated December 2, 2009, among the Company, Sunninghill Limited, Michael Walsh and Simon Kukes	Annual Report on Form 10-K for the year ended December 31, 2010, File No. 0-21392, as Exhibit 10.35	March 16, 2011
10.15	Letter Agreement dated December 9, 2009 with Thomas G. Lynch, Alan Cooke and Tom Maher*	Registration Statement on Form F-1, File No. 333-163704, as Exhibit 4.106	December 14, 2009
10.16	Letter Agreement, dated August 16, 2010, between the Company and Colin Stewart*	Annual Report on Form 10-K for the year ended December 31, 2010, File No. 0-21392, as Exhibit 10.39	March 16, 2011
10.17	Letter Agreement, dated November 15, 2010, between the Company and John F. Thero*	Annual Report on Form 10-K for the year ended December 31, 2010, File No. 0-21392, as Exhibit 10.42	March 16, 2011
10.18	Letter Agreement dated March 1, 2010 with Frederick W. Ahlholm*	Annual Report on Form 10-K for the year ended December 31, 2010, File No. 0-21392, as Exhibit 10.46	March 16, 2011
10.19	Letter Agreement dated January 28, 2011 with Paul Huff*	Quarterly Report on Form 10-Q for the period ended March 31, 2011, File No. 0-21392, as Exhibit 10.1	May 10, 2011
10.20	Letter Agreement with Joseph Kennedy, dated December 13, 2011*	Current Report on Form 8-K dated December 23, 2011, File No. 0-21392, as Exhibit 10.5	December 23, 2011
10.21	Letter Agreement with Stuart Sedlack, dated December 23, 2011*	Current Report on Form 8-K dated December 23, 2011, File No. 0-21392, as Exhibit 10.3	December 23, 2011



**Table of Contents**

<b>Exhibit</b>		<b>Incorporated by Reference Herein</b>	
<b>Number</b>	<b>Description</b>	<b>Form</b>	<b>Date</b>
10.22	Letter Agreement with John Thero, dated December 23, 2011*	Current Report on Form 8-K dated December 23, 2011, File No. 0-21392, as Exhibit 10.1	December 23, 2011
10.23	Letter Agreement with Paul Huff, dated December 23, 2011*	Current Report on Form 8-K dated December 23, 2011, File No. 0-21392, as Exhibit 10.2	December 23, 2011
10.24	Letter Agreement with Paresh Soni, dated December 23, 2011*	Current Report on Form 8-K dated December 23, 2011, File No. 0-21392, as Exhibit 10.4	December 23, 2011
10.25	Letter Agreement with Steve Ketchum, dated February 8, 2012*	Current Report on Form 8-K dated February 16, 2012, File No. 0-21392, as Exhibit 10.1	February 16, 2012
10.26	2011 Long Term Incentive Award with Joseph Kennedy dated December 16, 2011*	Form S-8, File No. 333-180180, as Exhibit 4.1	March 16, 2012
10.27	2012 Long Term Incentive Award with Steven Ketchum dated March 1, 2012*	Form S-8, File No. 333-180180, as Exhibit 4.2	March 16, 2012
10.28	Compromise Agreement, dated October 16, 2009, between the Company and Alan Cooke	Annual Report on Form 20-F for the year ended December 31, 2008, File No. 0-21392, as Exhibit 4.95	October 22, 2009
10.29	Warrant Agreement, dated October 16, 2009, between the Company and Thomas G. Lynch*	Annual Report on Form 20-F for the year ended December 31, 2008, File No. 0-21392, as Exhibit 4.96	October 22, 2009
10.30	Employment Agreement dated November 5, 2009 with John F. Thero*	Registration Statement on Form F-1, File No. 333-163704, as Exhibit 4.104	December 14, 2009
10.31	Compromise Agreement dated December 10, 2009 with Tom Maher*	Report of Foreign Private Issuer filed on Form 6-K, File No. 0-21392, as Exhibit 99.3	December 14, 2009
10.32	Transitional Employment Agreement, dated August 16, 2010, between the Company and Declan Doogan*	Annual Report on Form 10-K for the year ended December 31, 2010, File No. 0-21392, as Exhibit 10.38	March 16, 2011
10.33	Resignation and Release Agreement, dated November 9, 2010, between the Company and Colin Stewart*	Annual Report on Form 10-K for the year ended December 31, 2010, File No. 0-21392, as Exhibit 10.41	March 16, 2011
10.34	Employment Agreement, effective December 31, 2010, between the Company and Joseph S. Zakrzewski*	Annual Report on Form 10-K for the year ended December 31, 2010, File No. 0-21392, as Exhibit 10.43	March 16, 2011
10.35	Consulting Agreement, dated November 10, 2010, between the Company and Joseph S. Zakrzewski*	Annual Report on Form 10-K for the year ended December 31, 2010, File No. 0-21392, as Exhibit 10.45	March 16, 2011

**Table of Contents**

Exhibit Number	Description	Incorporated by Reference Herein	
		Form	Date
10.36	Amended and Restated Employment Agreement with Joe Zakrzewski, dated October 20, 2011*	Current Report on Form 8-K dated October 20, 2011, File No. 0-21392, as Exhibit 10.1	October 20, 2011
10.37	Stuart Sedlack offer letter, dated August 1, 2007*	Quarterly Report on Form 10-Q for the period ended September 30, 2011, File No. 0-21392, as Exhibit 10.1	November 8, 2011
10.38	Sale and Purchase Agreement, dated March 14, 2003, between F. Hoffmann-La Roche Limited, Hoffmann-La Roche Inc., and the Company	Annual Report on Form 20-F for the year ended December 31, 2002, File No. 0-21392, as Exhibit 4.22	April 24, 2003
10.39	Share Purchase Agreement, dated October 8, 2004 between the Company, Vida Capital Partners Limited and the Vendors named therein	Registration Statement on Form F-3, File No. 333-121431, as Exhibit 4.24	December 20, 2004
10.40	Agreement, dated January 18, 2007, between Neurostat Pharmaceuticals Inc., Amarin Pharmaceuticals Ireland Limited, the Company and Mr. Tim Lynch	Annual Report on Form 20-F for the year ended December 31, 2007, File No. 0-21392, as Exhibit 4.62	May 19, 2008
10.41	Development and License Agreement dated March 6, 2007 between Amarin Pharmaceuticals Ireland Limited and Elan Pharma International Limited	Annual Report on Form 20-F for the year ended December 31, 2007, File No. 0-21392, as Exhibit 4.67	May 19, 2008
10.42	Termination and Assignment Agreement, dated July 21, 2009 between Elan Pharma International Limited and Amarin Pharmaceuticals Ireland Limited	Annual Report on Form 20-F for the year ended December 31, 2008, File No. 0-21392, as Exhibit 4.90	October 22, 2009
10.43	Form of Purchase Agreement, dated June 1, 2007, between the Company and the Purchasers named therein	Annual Report on Form 20-F for the year ended December 31, 2007, File No. 0-21392, as Exhibit 4.69	May 19, 2008
10.44	Form of Equity Securities Purchase Agreement for U.S. Purchasers, dated December 4, 2007, between the Company and the Purchasers named therein	Report of Foreign Private Issuer filed on Form 6-K, File No. 0-21392, as Exhibit 99.5	December 17, 2007
10.45	Form of Equity Securities Purchase Agreement for Non-U.S. Purchasers, dated December 4, 2007, between the Company and the Purchasers named therein	Report of Foreign Private Issuer filed on Form 6-K, File No. 0-21392, as Exhibit 99.6	December 17, 2007

**Table of Contents**

Exhibit	Incorporated by Reference Herein		
	Number	Description	Date
10.46	Form of Debt Securities Purchase Agreement, dated December 4, 2007, between the Company and the Purchasers named therein	Report of Foreign Private Issuer filed on Form 6-K, File No. 0-21392, as Exhibit 99.7	December 17, 2007
10.47	Stock Purchase Agreement, dated December 5, 2007, between the Company, the selling shareholders of Ester Neurosciences Limited, Ester Neurosciences Limited and Medica II Management L.P.	Report of Foreign Private Issuer filed on Form 6-K, File No. 0-21392, as Exhibit 99.1	January 28, 2008
10.48	Letter Agreement, dated December 6, 2007, between the Company and the Sellers Representative of the selling shareholders of Ester Neurosciences Limited	Report of Foreign Private Issuer filed on Form 6-K, File No. 0-21392, as Exhibit 99.1	February 1, 2008
10.49	Amendment No. 1 to Stock Purchase Agreement, dated April 7, 2008, between the Company and Medica II Management L.P.	Annual Report on Form 20-F for the year ended December 31, 2007, File No. 0-21392, as Exhibit 4.79	May 19, 2008
10.50	Securities Purchase Agreement, dated May 12, 2008, among the Company and the Purchasers named therein	Annual Report on Form 20-F for the year ended December 31, 2008, File No. 0-21392, as Exhibit 4.80	October 22, 2009
10.51	Form of Securities Purchase Agreement, dated May 13, 2008, between the Company and the Purchasers named therein	Annual Report on Form 20-F for the year ended December 31, 2007, File No. 0-21392, as Exhibit 4.81	May 19, 2008
10.52	Amendment and Waiver Agreement, dated May 25, 2009, between Ester Neurosciences Limited, Medica II Management L.P. and the Company	Annual Report on Form 20-F/A for the year ended December 31, 2008, File No. 0-21392, as Exhibit 4.88	December 4, 2009
10.53	Bridge Loan Agreement, dated July 31, 2009 between the Company and the Lenders identified therein	Annual Report on Form 20-F for the year ended December 31, 2008, File No. 0-21392, as Exhibit 4.93	October 22, 2009
10.54	Amendment No. 1 to Bridge Loan Agreement, dated September 30, 2009, between the Company and the Lenders identified therein	Annual Report on Form 10-K for the year ended December 31, 2010, File No. 0-21392, as Exhibit 10.21	March 16, 2011
10.55	Form of Securities Purchase Agreement dated October 12, 2009 between the Company and the Purchasers named therein	Annual Report on Form 20-F for the year ended December 31, 2008, File No. 0-21392, as Exhibit 4.94	October 22, 2009

**Table of Contents**

Exhibit Number	Description	Incorporated by Reference Herein	
		Form	Date
10.56	Amendment No. 1, dated December 2, 2009, to Securities Purchase Agreement dated October 12, 2009 between the Company and the Purchasers named therein	Registration Statement on Form F-1, File No. 333-163704, as Exhibit 4.105	December 14, 2009
10.57	Master Services Agreement, dated September 29, 2009, between Medpace Inc. and Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Limited	Annual Report on Form 20-F for the year ended December 31, 2008, File No. 0-21392, as Exhibit 4.92	October 22, 2009
10.58	Amendment Agreement dated October 12, 2009, to the Form of Equity Securities Purchase Agreement dated May 13, 2008 between the Company and the Purchasers named therein	Annual Report on Form 20-F for the year ended December 31, 2008, File No. 0-21392, as Exhibit 4.97	October 22, 2009
10.59	Management Rights Deed of Agreement dated October 16, 2009 by and among the Company and Purchasers named therein	Annual Report on Form 20-F for the year ended December 31, 2009, File No. 0-21392, as Exhibit 4.100	June 25, 2010
10.60	Supply Agreement, dated November 1, 2010, between Nisshin Pharma Inc. and Amarin Pharmaceuticals Ireland Limited	Annual Report on Form 10-K for the year ended December 31, 2010, File No. 0-21392, as Exhibit 10.40	March 16, 2011
10.61	API Commercial Supply Agreement, dated May 25, 2011, between Amarin Pharmaceuticals Ireland Ltd. and Chemport Inc.	Quarterly Report on Form 10-Q for the period ended June 30, 2011, File No. 0-21392, as Exhibit 10.2	August 9, 2011
10.62	Amendment to API Commercial Supply Agreement by and between Amarin Pharmaceuticals Ireland Ltd and Chemport Inc., dated April 4, 2012	Quarterly Report on Form 10-Q for quarterly period ended June 30, 2012, File No. 0-21392, as Exhibit 10.6	August 8, 2008
10.63	Second Amendment to API Commercial Supply Agreement by and between Amarin Pharmaceuticals Ireland Ltd. and Chemport Inc., dated July 19, 2012	Quarterly Report on Form 10-Q for quarterly period ended September 30, 2012, File No. 0-21392, as Exhibit 10.1	November 8, 2012
10.64	API Commercial Supply Agreement, dated May 25, 2011, between Amarin Pharmaceuticals Ireland Ltd. and Equateq Limited	Quarterly Report on Form 10-Q for the period ended June 30, 2011, File No. 0-21392, as Exhibit 10.1	August 9, 2011

**Table of Contents**

Exhibit Number	Description	Incorporated by Reference Herein	
		Form	Date
10.65	Amendment to API Commercial Supply Agreement, dated October 19, 2011, between Amarin Pharmaceuticals Ireland Ltd. and Equateq Limited	Annual Report on Form 10-K for the year ended December 31, 2011, File No. 0-21392, as Exhibit 10.51	February 29, 2012
10.66	Second Amendment to API Supply Agreement by and between Amarin Pharmaceuticals Ireland Ltd. and Equateq Limited dated January 9, 2012	Quarterly Report on Form 10-Q for quarterly period ended March 31, 2012, File No. 0-21392, as Exhibit 10.1	May 5, 2012
10.67	Third Amendment to API Supply Agreement by and between Amarin Pharmaceuticals Ireland Ltd. and Equateq Limited dated May 7, 2012	Quarterly Report on Form 10-Q for quarterly period ended March 31, 2012, File No. 0-21392, as Exhibit 10.2	May 5, 2012
10.68	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	Quarterly Report on Form 10-Q for the period ended June 30, 2011, File No. 0-21392, as Exhibit 10.3	August 9, 2011
10.69	Second Amendment to Irrevocable License Agreement, by and between Bedminster 2 Funding, LLC and Amarin Pharmaceuticals Ireland Ltd., dated April 25, 2012	Quarterly Report on Form 10-Q for quarterly period ended June 30, 2012, File No. 0-21392, as Exhibit 10.4	August 8, 2008
10.70	Third Amendment to Irrevocable License Agreement by and between Bedminster 2 Funding, LLC and Amarin Pharmaceuticals Ireland Ltd., dated July 17, 2012	Quarterly Report on Form 10-Q for quarterly period ended June 30, 2012, File No. 0-21392, as Exhibit 10.5	August 8, 2008
10.71	Fourth Amendment to Irrevocable License Agreement by and between Bedminster 2 Funding, LLC and Amarin Pharmaceuticals Ireland Ltd., dated December 15, 2012	Annual Report on Form 10-K for the year ended December 31, 2012, File No. 0-21392, as Exhibit 10.71	February 28, 2012
10.72	Online Office Agreement dated as of September 30, 2011 by Amarin Corporation plc and Regus CME Ireland Ltd.	Quarterly Report on Form 10-Q for the period ended September 30, 2011, File No. 0-21392, as Exhibit 10.2	November 8, 2011
10.73	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	Annual Report on Form 20-F for the year ended December 31, 2006, File No. 0-21392, as Exhibit 4.71	March 5, 2007

**Table of Contents**

Exhibit	Incorporated by Reference Herein		
	Number	Description	Date
10.74	Lease Agreement dated May 8, 2013, by and between Amarin Pharma, Inc. and Bedminster 2 Funding, LLC.	Quarterly Report on Form 10-Q for the period ended March 31, 2013, File No. 0-21392, as Exhibit 10.1	May 9, 2013
10.75	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	Annual Report on Form 10-K for the year ended December 31, 2011, File No. 0-21392, as Exhibit 10.61	February 29, 2012
10.76	Sublease Agreement by and among Advance Realty Management, Inc., Bedminster 2 Funding, LLC and Amarin Pharma Inc., dated April 25, 2012	Quarterly Report on Form 10-Q for quarterly period ended June 30, 2012, File No. 0-21392, as Exhibit 10.3	August 8, 2008
10.77	Purchase and Sale Agreement, dated December 6, 2012, by and between Amarin Corporation plc, Amarin Pharmaceuticals Ireland Limited and Biopharma Secured Debt Fund II Holdings Cayman LP	Annual Report on Form 10-K for the year ended December 31, 2012, File No. 0-21392, as Exhibit 10.76	February 28, 2012
14.1	Code of Ethics	Registration Statement on Form F-3, File No. 333-170505, as Exhibit 99.1	November 10, 2010
21.1	List of Subsidiaries	Filed herewith	
23.1	Consent of Independent Registered Public Accounting Firm	Filed herewith	
31.1	Certification of President and Chief Executive Officer (Principal Executive Officer) pursuant to Section 302 of Sarbanes-Oxley Act of 2002	Filed herewith	
31.2	Certification of Controller (Principal Financial Officer) pursuant to Section 302 of Sarbanes-Oxley Act of 2002	Filed herewith	
32.1	Certification of President and Chief Executive Officer (Principal Executive Officer) and Controller (Principal Financial Officer) pursuant to Section 906 of Sarbanes-Oxley Act of 2002	Filed herewith	
101	INS XBRL Instance Document		
101	SCH XBRL Taxonomy Extension Schema Document		

**Table of Contents**

<b>Exhibit</b>		<b>Incorporated by Reference Herein</b>	
		<b>Form</b>	<b>Date</b>
<b>Number</b>	<b>Description</b>		
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 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.

**Table of Contents****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*

Date: February 27, 2014

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.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ John F. Thero John F. Thero	President and Chief Executive Officer ( Principal Executive Officer)	February 27, 2014
/s/ Michael J. Farrell Michael J. Farrell	Controller (Principal Financial and Accounting Officer)	February 27, 2014
/s/ Lars Ekman Lars Ekman	Director	February 27, 2014
/s/ James Healy, M.D., Ph.D. James Healy, M.D., Ph.D.	Director	February 27, 2014
/s/ Patrick O Sullivan Patrick O Sullivan	Director	February 27, 2014
/s/ Kristine Peterson Kristine Peterson	Director	February 27, 2014
/s/ David Stack David Stack	Director	February 27, 2014
/s/ Jan van Heek	Director	February 27, 2014



Edgar Filing: AMARIN CORP PLC\UK - Form 10-K

Jan van Heek

/s/ Joseph Zakrzewski

Director

February 27, 2014

Joseph Zakrzewski

**Table of Contents**

AMARIN CORPORATION PLC

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

	<b>Page</b>
<u>Report of Independent Registered Public Accounting Firm</u>	F-2
Financial Statements:	
<u>Consolidated Balance Sheets</u>	F-3
<u>Consolidated Statements of Operations</u>	F-4
<u>Consolidated Statements of Stockholders' Deficit</u>	F-5
<u>Consolidated Statements of Cash Flows</u>	F-6
<u>Notes to Consolidated Financial Statements</u>	F-7
<u>Financial Statement Schedules:</u>	
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.	

**Table of Contents**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders of

Amarin Corporation plc

Dublin, Ireland

We have audited the accompanying consolidated balance sheets of Amarin Corporation plc and subsidiaries (the Company) as of December 31, 2013 and 2012, and the related consolidated statements of operations, stockholders' deficit, and cash flows for each of the three years in the period ended December 31, 2013. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of Amarin Corporation plc and subsidiaries as of December 31, 2013 and 2012, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2013, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of December 31, 2013, based on the criteria established in *Internal Control - Integrated Framework (1992)* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 27, 2014 expressed an unqualified opinion on the Company's internal control over financial reporting.

/s/ DELOITTE & TOUCHE LLP

Parsippany, New Jersey

February 27, 2014

**Table of Contents**

## AMARIN CORPORATION PLC

## CONSOLIDATED BALANCE SHEETS

	As of December 31,	
	2013	2012
	(in thousands, except share amounts)	
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 191,514	\$ 260,242
Restricted cash	1,000	
Accounts receivable	3,645	
Inventory, current	21,209	21,262
Deferred tax assets	471	937
Other current assets	1,563	3,253
<b>Total current assets</b>	<b>219,402</b>	<b>285,694</b>
Property, plant and equipment, net	579	811
Inventory, long term	5,482	
Deferred tax assets	11,944	8,044
Other non-current assets	4,360	4,951
Intangible asset, net	10,709	11,355
<b>TOTAL ASSETS</b>	<b>\$ 252,476</b>	<b>\$ 310,855</b>
<b>LIABILITIES AND STOCKHOLDERS DEFICIT</b>		
Current Liabilities:		
Accounts payable	\$ 6,375	\$ 17,458
Accrued interest payable	12,974	2,520
Warrant derivative liability, current	6,894	
Deferred revenue	1,703	
Accrued expenses and other current liabilities	9,594	5,224
<b>Total current liabilities</b>	<b>37,540</b>	<b>25,202</b>
Long-Term Liabilities:		
Warrant derivative liability, long-term		54,854
Exchangeable senior notes	149,317	134,250
Long-term debt	87,717	85,153
Long-term debt redemption feature	11,100	14,577
Other long-term liabilities	658	816
<b>Total liabilities</b>	<b>286,332</b>	<b>314,852</b>
Commitments and contingencies (Note 9)		
Stockholders Deficit:		
Common stock, £0.50 par value, unlimited authorized; 172,691,063 issued, 172,670,984 outstanding at December 31, 2013; 150,360,933 issued, 150,340,854 outstanding at December 31, 2012	141,477	124,597
Additional paid-in capital	738,754	619,266
Treasury stock; 20,079 shares at December 31, 2013 and 2012	(217)	(217)

Edgar Filing: AMARIN CORP PLC\UK - Form 10-K

Accumulated deficit	(913,870)	(747,643)
Total stockholders' deficit	(33,856)	(3,997)
<b>TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT</b>	<b>\$ 252,476</b>	<b>\$ 310,855</b>

See the notes to the consolidated financial statements.

F-3

**Table of Contents**

## AMARIN CORPORATION PLC

## CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended December 31,		
	2013	2012	2011
	(In thousands, except per share amounts)		
Revenues	\$ 26,351	\$	\$
Operating Expenses:			
Cost of goods sold	11,912		
Research and development	72,750	58,956	21,602
Selling, general and administrative	123,795	57,794	22,559
Total operating expenses	208,457	116,750	44,161
Operating loss	(182,106)	(116,750)	(44,161)
Gain (loss) on change in fair value of derivative liabilities	47,710	(35,344)	(22,669)
Interest expense	(34,179)	(18,091)	(1)
Interest income	343	544	231
Other (expense) income, net	(1,189)	(427)	(10)
Loss from operations before taxes	(169,421)	(170,068)	(66,610)
Benefit from (provision for) income taxes	3,194	(9,116)	(2,516)
Net loss	\$ (166,227)	\$ (179,184)	\$ (69,126)
Loss per share:			
Basic	\$ (1.03)	\$ (1.24)	\$ (0.53)
Diluted	\$ (1.28)	\$ (1.24)	\$ (0.53)
Weighted average shares outstanding:			
Basic	161,022	144,017	130,247
Diluted	167,070	144,017	130,247

See the notes to the consolidated financial statements.

**Table of Contents**

## AMARIN CORPORATION PLC

**CONSOLIDATED STATEMENTS OF STOCKHOLDERS DEFICIT****YEARS ENDED DECEMBER 31, 2013, 2012 and 2011****(in thousands, except share data)**

	Common Shares	Common Stock	Additional Paid-in Capital	Treasury Stock	Accumulated Deficit	Total Stockholders Deficit
<b>At January 1, 2011</b>	<b>106,856,731</b>	<b>\$ 90,465</b>	<b>\$ 206,718</b>	<b>\$ (217)</b>	<b>\$ (499,333)</b>	<b>\$ (202,367)</b>
Exercise of warrants	12,888,369	10,289	8,413			18,702
Exercise of stock options	2,273,221	1,833	3,261			5,094
Stock issued in January financing	13,800,000	10,723	87,931			98,654
Tax benefits realized from stock-based compensation			4,199			4,199
Transfer of fair value of warrants exercised from liabilities to equity			129,517			129,517
Share issuances for services	14,221	11	60			71
Stock-based compensation			9,294			9,294
Net loss					(69,126)	(69,126)
<b>At December 31, 2011</b>	<b>135,832,542</b>	<b>\$ 113,321</b>	<b>\$ 449,393</b>	<b>\$ (217)</b>	<b>\$ (568,459)</b>	<b>\$ (5,962)</b>
Exercise of warrants	11,047,579	8,540	8,180			16,720
Exercise of stock options	3,380,413	2,659	5,546			8,205
Vesting of restricted stock units	97,398	76	(76)			
Conversion option contained in exchangeable notes			22,898			22,898
Tax benefits realized from stock-based compensation			11,334			11,334
Transfer of fair value of warrants exercised from liabilities to equity			103,885			103,885
Share issuances for services	3,001	1	31			32
Stock-based compensation			18,075			18,075
Net loss					(179,184)	(179,184)
<b>At December 31, 2012</b>	<b>150,360,933</b>	<b>\$ 124,597</b>	<b>\$ 619,266</b>	<b>\$ (217)</b>	<b>\$ (747,643)</b>	<b>\$ (3,997)</b>
Exercise of warrants	147,050	113	47			160
Exercise of stock options	386,000	292	335			627
Stock issued in July financing	21,700,000	16,401	104,805			121,206
Vesting of restricted stock units	93,048	71	(71)			
Tax provision on stock-based compensation			(361)			(361)
Transfer of fair value of warrants exercised from liabilities to equity			24			24
Share issuances for services	4,032	3	24			27
Stock-based compensation			14,685			14,685
Net loss					(166,227)	(166,227)
<b>At December 31, 2013</b>	<b>172,691,063</b>	<b>\$ 141,477</b>	<b>\$ 738,754</b>	<b>\$ (217)</b>	<b>\$ (913,870)</b>	<b>\$ (33,856)</b>

See the notes to the consolidated financial statements.





**Table of Contents**

## AMARIN CORPORATION PLC

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

	Years Ended December 31,		
	2013	2012	2011
	(in thousands)		
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net loss	\$ (166,227)	\$ (179,184)	\$ (69,126)
Adjustments to reconcile loss to net cash used in operating activities:			
Depreciation and amortization	246	180	76
Stock-based compensation	14,685	18,075	9,294
Stock-based compensation warrants	(3,703)	247	(96)
Excess tax provision (benefit) from stock-based awards	361	(11,334)	(4,199)
Accrued interest payable	10,454	2,520	
Amortization of debt discount and debt issuance costs	17,631	12,856	
Amortization of intangible asset	646	269	
Foreign exchange loss on intangible asset		519	
(Gain) loss on changes in fair value of derivative liabilities	(47,710)	35,344	22,669
Deferred income taxes	(3,434)	(3,714)	(2,493)
Change in lease liability	6	(50)	(21)
Shares issued for services	27	32	71
Changes in assets and liabilities:			
Restricted cash	(1,000)		
Accounts receivable	(3,645)		
Other current assets	1,690	(1,416)	(774)
Inventory	(5,429)	(21,262)	
Other non-current assets	591	(1,060)	(591)
Deferred revenue	1,703		
Accounts payable, accrued expenses and other current liabilities	(7,228)	25,675	5,751
Net cash used in operating activities	(190,336)	(122,303)	(39,439)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Purchases of equipment	(14)	(549)	(398)
Purchase of long-term investment		(1,650)	(1,650)
Purchase of intangible asset		(12,143)	
Net cash used in investing activities	(14)	(14,342)	(2,048)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Proceeds from issuance of common stock, net of transaction costs	121,206		98,654
Proceeds from exercise of stock options, net of transaction costs	627	8,205	5,094
Proceeds from exercise of warrants, net of transaction costs	160	16,720	18,702
Proceeds on issuance of exchangeable senior notes, net of transaction costs		144,316	
Proceeds from long term debt, net of transaction costs		99,730	
Excess tax (provision) benefit from stock-based awards	(361)	11,334	4,199
Repayment of capital leases	(10)	(20)	(2)
Net cash provided by financing activities	121,622	280,285	126,647
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(68,728)	143,640	85,160
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	260,242	116,602	31,442
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 191,514	\$ 260,242	\$ 116,602

Edgar Filing: AMARIN CORP PLC\UK - Form 10-K

Supplemental disclosure of cash flow information:

Cash paid during the year for:

Interest	\$ 6,090	\$ 2,713	\$
Income taxes	\$ 1,395	\$ 1,118	\$ 761

Supplemental disclosure of non-cash items:

Reclass of warrant liability to additional paid-in capital	\$ 24	\$ 103,885	\$ 129,517
--	-------	------------	------------

See the notes to the consolidated financial statements.

F-6

**Table of Contents**

## 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.

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  $\geq$ 500mg/dL) hypertriglyceridemia. The Company refers to this approved indication for Vascepa as the MARINE indication. The Company began marketing and selling Vascepa in the United States in January 2013. Vascepa is available in the United States by prescription only. The Company markets Vascepa through its sales force of approximately 150 sales professionals, including sales representatives and their managers.

Triglycerides are fats in the blood. Hypertriglyceridemia refers to a condition in which patients have high levels of triglycerides in the bloodstream. It is estimated that over 40 million adults in the United States have elevated triglyceride levels (TG  $\geq$ 200mg/dL) and approximately 4.0 million people in the United States have severely high triglyceride levels (TG  $\geq$ 500mg/dL), commonly known as very high triglyceride levels. According to *The American Heart Association Scientific Statement on Triglycerides and Cardiovascular Disease* (2011), triglycerides also 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.

The potential efficacy and safety of Vascepa (known in its development stage as AMR 101) was studied in two Phase 3 clinical trials, the MARINE trial and the ANCHOR trial. At a daily dose of 4 grams of Vascepa, the dose at which Vascepa is FDA approved, these trials showed favorable clinical results in their respective patient populations 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).

The Company is also developing Vascepa 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 which the Company refers to as mixed dyslipidemia. The Company refers to this second proposed indication for Vascepa as the ANCHOR indication. The FDA has stated that it views the proposed ANCHOR indication as ostensibly and impliedly an indication to reduce cardiovascular risk. In addition, in December 2011, Amarin announced commencement of patient dosing in a cardiovascular outcomes study of Vascepa, titled REDUCE-IT (Reduction of Cardiovascular Events with EPA Intervention Trial). The REDUCE-IT study is designed to evaluate the efficacy of Vascepa in reducing major cardiovascular events in a high risk patient population on statin therapy.

The Company has a pending supplemental new drug application, or sNDA, with the FDA that seeks marketing approval of Vascepa for use in the ANCHOR indication. On October 16, 2013, the FDA convened an advisory

---

**Table of Contents**

committee to review the sNDA. This advisory committee was not asked by the FDA to evaluate whether Vascepa is effective in lowering triglycerides in the studied population, the ANCHOR indication as specified in the sNDA. Rather, the advisory committee was asked whether Vascepa has been demonstrated to improve cardiovascular outcomes or whether approval of the ANCHOR indication should wait for successful completion of the REDUCE-IT study, the first prospective study of cardiovascular outcomes in patients who have high triglyceride levels despite statin therapy. The advisory committee voted 9 to 2 against recommending approval of the ANCHOR indication based on information presented at the meeting. The FDA considers the recommendation of advisory committee, but final decisions on the approval of new drug applications are made by the FDA. On October 22, 2013, in an effort to reduce operating expenses following the recommendation of the advisory committee, the Company implemented a worldwide reduction in force of approximately 50% of its staff positions (See Note 15 Restructuring).

The ANCHOR trial clinical study was conducted under a special protocol assessment, or SPA, agreement with the FDA. The law governing SPA agreements requires that if the results of the trial conducted under the SPA substantiate the hypothesis of the protocol covered by the SPA, the FDA must use the data from the protocol as part of the primary basis for approval of the product. A SPA agreement is not a guarantee of FDA approval of the related new drug application. 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 of the drug after the study begins that rises to the level of a public health concern, or if the study sponsor fails to follow the protocol that was agreed upon with the FDA. On October 29, 2013, the FDA 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. As a basis for this determination, the FDA communicated that it determined that the cumulative results from outcome studies of other triglyceride-lowering drugs failed to support the hypothesis that a triglyceride-lowering drug significantly reduces the risk for cardiovascular events among the population studied in the ANCHOR trial. Thus, the FDA stated that while information the Company submitted supports testing the hypothesis that Vascepa 4 grams/day versus placebo reduces major adverse cardiovascular events in statin-treated subjects with residually high triglyceride levels, as is being studied in the Vascepa REDUCE-IT cardiovascular outcomes study, the FDA no longer considers a change in serum triglyceride levels as sufficient to establish the effectiveness of a drug intended to reduce cardiovascular risk in subjects with serum triglyceride levels below 500 mg/dL. In November 2013, the Company submitted to the FDA a request for reconsideration of its decision to rescind the ANCHOR SPA agreement. On January 17, 2014, the Company was notified by the FDA that it does not intend to reinstate the ANCHOR SPA agreement. The Company plans to continue appealing the rescission decision to successively higher administrative levels within the FDA in accordance with FDA dispute resolution guidance.

The FDA did not take action on the ANCHOR sNDA by the Prescription Drug User Fee Act, or PDUFA, goal date for completion of FDA's review, December 20, 2013. Instead, the FDA notified the Company on December 19, 2013 that it would first consider our appeal of the ANCHOR SPA agreement rescission. No new PDUFA goal date for the ANCHOR sNDA was established. Based on information available, the Company does not expect a determination on the ANCHOR sNDA while the Company's appeal of the January 17, 2014 FDA decision to uphold the ANCHOR SPA rescission is pending. The Company is also continuing its efforts toward a positive determination on the pending ANCHOR sNDA. There also can be no assurance that the FDA will not communicate the results of its review of the ANCHOR sNDA prior to the timing expected.

Based on the Company's communications with the FDA, the Company currently expects that final positive results from the REDUCE-IT outcomes study will be required for FDA approval of Vascepa for the ANCHOR indication. There can be no assurance that the Company will be successful in its efforts to reinstate the ANCHOR SPA agreement or obtain a label expansion reflecting the ANCHOR clinical trial. Such label expansion could include FDA approval of the addition of an ANCHOR indication statement and/or the addition of the ANCHOR clinical trial data to the currently approved labeling. If the FDA does not approve the ANCHOR indication, it could have a material impact on the Company's future results of operations and financial condition.

---

## **Table of Contents**

The Company has evaluated subsequent events from December 31, 2013 through the date of the issuance of these consolidated financial statements. See Note 17 Subsequent Events.

### **Basis of Presentation**

The accompanying consolidated financial statements of the Company and subsidiaries are prepared in conformity with accounting principles generally accepted in the U.S. (GAAP) and 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. Prior to 2004, the Company was in the business of selling a previous biopharmaceutical compound, which has since been discontinued. The Company's current focus is on the commercialization and development of Vascepa, which received approval from the FDA in 2012 and for which the Company commenced marketing and sales in 2013.

At December 31, 2013, the Company had cash and cash equivalents of \$191.5 million. The Company's consolidated balance sheet also includes a derivative liability (see Note 7 Warrants and Warrant Derivative Liability) as well as Long term debt and Exchangeable Senior Notes (see Note 8 Debt). The derivative liability reflects the fair value of outstanding warrants to purchase shares of the Company's common stock. The long term debt is not callable except upon a change in control. The Exchangeable Senior Notes may be redeemed on or after January 19, 2017 at the option of the holders. The Notes are exchangeable under certain circumstances into cash, American Depository Shares (ADSs), or a combination of cash and ADSs, at the Company's election. Accordingly, the warrant derivative liability, long term debt and Exchangeable Senior Notes do not present a short term claim on the liquid assets of the Company.

The Company believes its cash and cash equivalents will be sufficient to fund its operations for at least the next twelve months.

## **(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**

The preparation of the Company's consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Accounting estimates are based on historical experience and other factors that are considered reasonable under the circumstances. Actual results could differ from those 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, that in turn resell Vascepa to retail pharmacies for subsequent resale to patients and health care 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 commenced its commercial launch in the United States in January 2013. Prior to 2013, the Company recognized no revenue from Vascepa sales. In accordance with GAAP, until the Company has the ability to reliably estimate returns of Vascepa from its Distributors, revenue will be recognized based on the

---

**Table of Contents**

resale of Vascepa for the purposes of filling patient prescriptions, and not based on sales from the Company to such Distributors. Consistent with industry practice, once the Company achieves sufficient history such that it can reliably estimate returns, the Company will recognize revenue based on sales to its Distributors. The Company currently defers Vascepa revenue recognition until the earlier of the product being resold for purposes of filling patient prescriptions; or the expiration of the right of return (twelve months after the expiration date of the product). The Company also defers the related cost of product sales and records such amounts as finished goods inventory held by others until revenue related to such product sales is recognized.

The Company has contracts with its primary Distributors and delivery 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 or when the product is utilized. 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 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 payment within 30 days. Based on the Company's 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 unexpired 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. As of December 31, 2013, the Company had experienced a de minimus quantity of product returns. During the year ended December 31, 2013, the period in which the Company began selling Vascepa, the Company was not able to reasonably estimate product returns for all product sold to Distributors but the Company was able to reasonably estimate product returns for certain sales of Vascepa based on product used to fill patient prescriptions as determined by inventory estimated to be in the distribution channel and third party reports of prescriptions filled. In making this assessment, the Company used (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

**Table of Contents**

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 its estimates regarding the portion of issued rebates that it estimates will not be redeemed. In addition, as is customary prior to the launch of new drugs, the Company provided certain of its Distributors with financial incentives to begin stocking Vascepa prior to the Company's commercial launch of Vascepa in order to ensure that Vascepa was readily available to fill patient prescriptions upon launch. Such incentives were only offered on purchases of initial launch quantities of Vascepa stocked by Distributors in January 2013. The amount of these financial incentives was recorded by the Company as a reduction to revenues on a pro-rata basis for each of the bottles subject to such financial incentives. The Company estimates that all of these initial launch quantities stocked by its primary Distributors in January 2013 were resold by such Distributors prior to December 31, 2013.

The following table summarizes activity in each of the product revenue allowance and reserve categories described above for the year ended December 31, 2013 (in thousands):

	Trade Allowances	Rebates, Chargebacks and Discounts	Product Returns	Other Incentives	Total
<b>Balance at January 1, 2013</b>	\$	\$	\$	\$	\$
Provision related to current period and deferred sales	4,178	4,282	72	3,114	11,646
Credits/payments made for current period and deferred sales	(3,107)	(3,145)	\$	(2,925)	(9,177)
<b>Balance at December 31, 2013</b>	1,071	1,137	72	189	2,469

The following table summarizes product revenue recognized and deferred during the year ended December 31, 2013 (in thousands):

	December 31, 2013	December 31, 2012
Product revenue recognized	\$ 26,351	\$
Deferred product revenue	1,703	
	\$ 28,054	\$

In conjunction with the Company's recognition and deferral of product revenues, the Company expensed and capitalized the associated cost of goods, as follows, during the year ended December 31, 2013 (in thousands):

	December 31, 2013	December 31, 2012
Cost of goods sold expensed	\$ 11,912	\$
Finished goods inventory held by others	627	
	\$ 12,539	\$





**Table of Contents****Cash and Cash Equivalents**

Cash and cash equivalents consist of cash, deposits with banks and short term highly liquid 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.

**Inventory**

The Company states 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 market value due to obsolescence, damage or quantities in excess of expected demand, the Company will reduce the carrying value of such inventory to market value. The Company received FDA approval for Vascepa on July 26, 2012 and after that date began capitalizing inventory purchases of saleable product from approved suppliers. Until an API supplier is approved, all Vascepa API purchased from such supplier is included as a component of research and development expense. Upon sNDA approval of each additional supplier, the Company capitalizes subsequent Vascepa API purchases from such supplier as inventory. Purchases of Vascepa API received and expensed before such regulatory approvals is not subsequently capitalized, and all such purchases are quarantined and not used for commercial supply until such time as the sNDA for the supplier that produced the API is approved.

**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 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 assets consist 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. The Company concluded that use of the straight-line method was appropriate as the majority of cash flows are expected to be generated ratably over the estimated useful life and no degradation of the cash flows over time is currently anticipated. See Note 9 Commitments and Contingencies for further information regarding other obligations related to the acquisition of Laxdale Limited.

## **Table of Contents**

### **Deferred Revenue**

Deferred revenue represents product shipments to Distributors for which the Company has invoiced the Distributors but not recognized as revenue because the product was not reported to the Company as having been resold for the purpose of filling prescriptions on or before December 31, 2013.

### **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 costs of salaries, programs and infrastructure necessary for the general conduct of the Company's business, including the 2013 commercial launch of Vascepa in the United States for the MARINE indication. Included as part of selling, general and administrative costs is warrant related expense from non-cash changes in fair value of the derivative liability associated with warrants issued in October 2009 to former officers of Amarin which is recorded as compensation income (expense).

### **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.

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 the realizability of deferred tax assets. Changes in historical earnings performance and future earnings projections, 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.

### **Derivative Instruments**

Derivative financial liabilities are recorded at fair value, with gains and losses arising for changes in fair value recognized in the 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. The warrants are valued using a Black-Scholes option pricing model due to the nature of instrument. The long term debt redemption feature is valued 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.

If the terms of warrants that initially require the warrant to be classified as a derivative financial liability lapse, the derivative financial liability is reclassified out of financial liabilities into equity at its fair value on that date. At settlement date, if the instruments are settled in shares, the carrying value of the warrants are derecognized and transferred to equity at their fair value at that date. The cash proceeds received from exercises of warrants are recorded in common stock and additional paid-in capital.

**Table of Contents****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 earnings per share purposes, the impact of such gains is reversed and the treasury stock method is used to determine diluted earnings per share.

The calculation of net loss and the number of shares used to compute basic and diluted earnings per share for the years ended December 31, 2013, 2012 and 2011 are as follows:

<b>In thousands</b>	<b>2013</b>	<b>2012</b>	<b>2011</b>
Net loss basic	\$ (166,227)	\$ (179,184)	\$ (69,126)
Gain on warrant derivative liability	(47,936)		
Net loss diluted	(214,163)	(179,184)	(69,126)
Net loss per share basic	\$ (1.03)	\$ (1.24)	\$ (0.53)
Weighted average shares outstanding basic	161,022	144,017	130,247
Warrant exercises	6,048		
Weighted average shares outstanding diluted	167,070	144,017	130,247
Net income loss per share diluted	\$ (1.28)	\$ (1.24)	\$ (0.53)

For the years ended December 31, 2013, 2012 and 2011, the following potentially dilutive securities were not included in the computation of net loss per share because the effect would be anti-dilutive:

<b>In thousands</b>			
Stock options		9,330	10,892
Restricted stock and restricted stock units		196	465
Warrants		1,702	9,937
		21,106	

**Debt Instruments**

Debt instruments are initially recorded at fair value, with coupon interest and amortization of debt issuance discounts recognized in the statement of operations as interest expense each period such instruments are outstanding. 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 Company's exchangeable notes contain a conversion option which is classified as equity. The fair value of the liability component of the debt instrument was deducted from the initial proceeds to determine the proceeds to be allocated to the conversion option. The embedded conversion option is indexed to the Company's stock and treated as equity on the balance sheet. The conversion option is evaluated on a quarterly basis to determine if it still meets the criteria to be equity classified. The excess principal amount of the debt over the carrying value of the liability is amortized to interest expense over the term of the debt.

The Company's December 2012 debt financing agreement contains a redemption feature triggered upon a change of control, which has been classified as an embedded derivative. The fair value of the derivative was recorded as a reduction to the fair value of the note payable. The fair value of this derivative liability is remeasured at each reporting period, with changes in fair value recognized in the statement of operations. The discount recorded to the note payable is being amortized to interest expense over the term of the note payable.



## **Table of Contents**

### **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 cost over the requisite service period. Equity awards granted to non-employees or for which the fair value is not determinable are marked to fair value each reporting period over the requisite service period.

### **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. The Company's top three customers accounted for 96% of gross product sales for the year ended December 31, 2013 and 95% of the gross accounts receivable balance as of December 31, 2013. The Company's largest customer accounted for 38% of gross product sales for the year ended December 31, 2013 and 41% of the gross accounts receivable balance as of December 31, 2013.

### **Foreign Currency**

All subsidiaries use the United States dollar as the functional currency. Monetary assets and liabilities denominated in a foreign currency are remeasured into United States dollars at period-end exchange rates. Non-monetary assets and liabilities carried in a foreign currency are remeasured into United States dollars using rates of exchange prevailing when such assets or liabilities were obtained or incurred, and expenses are generally remeasured using rates of exchange prevailing when such expenses are incurred. Gains and losses from the remeasurement are included in other (expense) income, net in the consolidated statements of operations. For transactions settled during the applicable period, gains and losses are included in other (expense) income, net in the consolidated statements of operations. The Company periodically uses foreign exchange forward contracts to hedge against changes in exchange rates for inventory purchases denominated in foreign currency. As of December 31, 2013, there were no outstanding foreign exchange contracts.

### **Debt Issuance Costs**

Debt issuance costs are initially capitalized as a deferred cost and amortized to interest expense using the effective interest method over the expected term of the related debt. Unamortized debt issuance costs related to 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.

### **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.

**Table of Contents**

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 table presents information about the Company's assets and liabilities as of December 31, 2013 and 2012 that are measured at fair value on a recurring basis and indicates the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value:

<i>In millions</i>	<b>Total</b>	<b>December 31, 2013</b>		
		<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>
<b>Asset:</b>				
Cash equivalents money markets	\$ 113.5	\$ 113.5	\$	\$
<b>Liabilities:</b>				
Warrant derivative liability	\$ 6.9	\$	\$	\$ 6.9
Long term debt redemption feature	\$ 11.1	\$	\$	\$ 11.1

<i>In millions</i>	<b>Total</b>	<b>December 31, 2012</b>		
		<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>
<b>Asset:</b>				
Cash equivalents money markets	\$ 64.1	\$ 64.1	\$	\$
<b>Liabilities:</b>				
Warrant derivative liability	\$ 54.9	\$	\$	\$ 54.9
Long term debt redemption feature	\$ 14.6	\$	\$	\$ 14.6

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

**Warrant Derivative Liability**

The Company's warrant derivative liability 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 initial fair value of the warrant derivative liability at the date of issuance in October 2009 was determined to be \$48.3 million using the Black-Scholes option valuation model applying the following assumptions: (i) risk-free rate of 2.37%, (ii) remaining term of 5 years, (iii) no dividend yield, (iv) volatility of 119%, and (v) the stock price on the date of measurement.

At December 31, 2012, the fair value of the warrant derivative liability was determined to be \$54.9 million using the Black-Scholes option valuation model applying the following assumptions: (i) risk-free rate of 0.25%, (ii) remaining term of 1.8 years, (iii) no dividend yield (iv) volatility of 95%, and (v) the stock price on the date of measurement. For the year ended December 31, 2012, the \$35.6 million increase in the fair value of the warrants, net of exercises, was recognized as a \$35.4 million loss on change in fair value of derivative liability and \$0.2 million in compensation expense for change in fair value of warrants issued to former employees within the consolidated statement of operations. As of December 31, 2013, the fair value of the warrant derivative liability was determined to be \$6.9 million using the Black-Scholes option valuation applying the following assumptions: (i) risk-free rate of 0.12%, (ii) remaining term of 0.8 years, (iii) no dividend yield (iv) volatility of 99%, and (v) the stock price on the date of measurement. A \$47.9 million decrease in the fair value of the

**Table of Contents**

warrants during the year, net of exercises was recognized as a \$44.2 million gain on change in fair value of derivative liability and \$3.7 million in compensation income for the change in fair value of warrants issued to former employees within the consolidated statement of operations for the year ended December 31, 2013.

The fair value of this warrant liability is therefore sensitive to changes in the market price and volatility of our common stock among other factors. In the event of a hypothetical 10% increase in the market price of the Company's common shares (\$2.17 based on the \$1.97 market price of the Company's stock at December 31, 2013) on which the December 31, 2013 valuation was based, the value of the derivative liability would have increased by \$1.3 million. Such increase would have been reflected as a loss on change in fair value of derivatives and as an increase in warrant compensation expense in our statement of operations. Significant increases (decreases) in this input in isolation would result in a significantly higher (lower) fair value measurement.

**Long Term Debt Redemption Feature**

The Company's December 2012 financing agreement contains a redemption feature whereby, upon a change of control, the Company would be required to pay \$140 million, less any previously repaid amount, if the change of control occurs on or before December 31, 2013, or required to repay \$150 million, less any previously repaid amount, if the change of control event occurs after December 31, 2013. 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 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, 2012, the debt was valued by comparing debt issues of similar companies with (i) terms of between 4.8 and 8.0 years, (ii) coupon rates of between 3.0% and 11.5% and (iii) market yields of between 10.7% and 27.7%. The initial fair value of the derivative liability at the date of issuance in December 2012 was determined to be \$14.6 million and the Company recognized a \$0.02 million gain on change in fair value of derivative liability at December 31, 2012. As of December 31, 2013, the debt was valued by comparing debt issues of similar companies with (i) terms of between 3.3 and 6.6 years, (ii) coupon rates of between 9.9% and 12.5% and (iii) market yields of between 9.0% and 29.4%. The fair value of the derivative liability at December 31, 2013 was determined to be \$11.1 million and the Company recognized a \$3.5 million gain on change in fair value of derivative liability during the year ended December 31, 2013.

The change in the fair value of financial instruments is as follows (in thousands):

	October 2009 Warrants	Debt Redemption Feature	Totals
<b>Balance at December 31, 2011</b>	<b>\$ 123,125</b>	<b>\$</b>	<b>\$ 123,125</b>
Initial measurement December 2012 financing		14,600	14,600
Loss (gain) on change in fair value of derivative liability	35,367	(23)	35,344
Compensation expense for change in fair value of warrants issued to former employees	247		247
Transfers to equity	(103,885)		(103,885)
<b>Balance at December 31, 2012</b>	<b>\$ 54,854</b>	<b>\$ 14,577</b>	<b>\$ 69,431</b>
Gain on change in fair value of derivative liabilities	(44,233)	(3,477)	(47,710)
Compensation income for change in fair value of warrants issued to former employees	(3,703)		(3,703)
Transfers to equity	(24)		(24)
<b>Balance at December 31, 2013</b>	<b>\$ 6,894</b>	<b>\$ 11,100</b>	<b>\$ 17,994</b>

**Table of Contents****Segment and Geographical Information**

For the years ended December 31, 2013, 2012 and 2011, the Company has reported its business as a single reporting segment. The Company's chief decision maker, who is the President and Chief Executive Officer, regularly evaluates the Company on a consolidated basis.

**Recent Accounting Pronouncements**

In July 2013, the Financial Accounting Standards Board issued an update that clarified existing guidance on the presentation of unrecognized tax benefits when various qualifying tax benefit carryforwards exist, including when the unrecognized tax benefit should be presented as a reduction to deferred tax assets or as a liability. This update is required to be adopted for all annual periods and interim reporting periods beginning after December 15, 2013, with early adoption permitted. The adoption of this pronouncement is not expected to have a material impact on the Company's financial statements.

From time to time, new accounting pronouncements are issued and are adopted by the Company as of the specified effective date. The Company believes that the impact of other recently issued but not yet adopted accounting pronouncements will not have a material impact on its consolidated financial position, results of operations, and cash flows, or do not apply to the Company's operations.

**(3) Intangible Assets**

Intangible assets as of December 31, 2013 are as follows:

	Gross	Accumulated Amortization	Net	Weighted Average Remaining Useful Life (years)
Technology rights	\$ 11,624	\$ (915)	\$ 10,709	16.6

Amortization expense for the years ended December 31, 2013 and 2012 was \$0.6 million and \$0.3 million, respectively, and is included in research and development expense. Estimated future amortization expense, based upon the Company's intangible assets as of December 31, 2013 is as follows:

Year Ending December 31,	Amount
2014	\$ 646
2015	646
2016	646
2017	646
2018	646
Thereafter	7,479
<b>Total</b>	<b>\$ 10,709</b>



**Table of Contents****(4) Inventory**

After approval of Vascepa on July 26, 2012 by the FDA, the Company began capitalizing its purchases of saleable inventory of Vascepa from suppliers that have been qualified by the FDA. Inventories consist of the following (in thousands):

	December 31, 2013	December 31, 2012
Raw materials, current	\$ 4,246	\$ 5,465
Work in process	11,310	15,471
Finished goods	5,026	326
Finished goods inventory held by others	627	
<b>Total inventory, current</b>	<b>21,209</b>	<b>21,262</b>
Raw materials, long-term	5,482	
<b>Total inventory</b>	<b>\$ 26,691</b>	<b>\$ 21,262</b>

During the year ended December 31, 2013, the Company wrote off \$1.8 million of inventories deemed to be unrecoverable. The charge was recorded within research and development expense in the statement of operations as this supplier has yet to produce material qualified for commercial sale. In addition, \$5.5 million of raw material inventory was reclassified to long-term inventory, as it is not anticipated to be sold within the next twelve months based on current estimates.

**(5) Property, Plant and Equipment**

Property, plant and equipment consist of the following:

	December 31, 2013	December 31, 2012
	(in thousands)	
Leasehold improvements	\$ 107	\$ 129
Computer equipment	63	221
Furniture and fixtures	240	243
Software	559	502
	969	1,095
Accumulated depreciation and amortization	(390)	(356)
Construction in progress		72
	\$ 579	\$ 811

Depreciation expense for the years ended December 31, 2013, 2012, and 2011 was \$0.2 million, \$0.2 million and \$0.1 million, respectively.

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

Accrued expenses and other current liabilities consist of the following at December 31, 2013 and 2012:

2013      2012  
(in thousands)

Edgar Filing: AMARIN CORP PLC\UK - Form 10-K

Payroll and payroll-related expenses	\$ 2,112	\$ 2,065
Sales and marketing accruals	4,138	
All other	3,344	3,159
	\$ 9,594	\$ 5,224

F-19

**Table of Contents****(7) Warrants and Warrant Derivative Liability**

The Company had 9,789,776 warrants to purchase common shares outstanding at December 31, 2013 at a weighted-average exercise price of \$1.44, as summarized in the following table:

Issue Date	Amount	Exercise Price	Expiration Date
4/27/07	17,500	17.90	1/17/14
7/31/09	1,684,888	1.00	7/30/14
10/16/09	7,487,388	1.50	10/15/14
10/16/09	600,000	1.50	10/15/14
	<b>9,789,776</b>	<b>\$ 1.44</b>	

*October 2009 Warrants 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 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 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 of which 7.5 million are outstanding at December 31, 2013.

In conjunction with the October 2009 financing, the Company issued an additional 0.9 million warrants to three former officers of which 0.6 million are outstanding as of December 31, 2013. 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 are not considered to be indexed to the Company's common stock. Accordingly, the warrants do not qualify for the exception to classify the warrants within equity and are classified as a derivative liability.

The fair value of this warrant derivative liability is remeasured at each reporting period, with changes in fair value recognized in the statement of operations. Upon exercise, the fair value of the warrants exercised is remeasured and reclassified from warrant liability to additional paid-in-capital. Although the warrants contain a pricing variability feature, the number of warrants issuable remains fixed. Therefore, the maximum number of common shares issuable as a result of the October 2009 private placement is 36.1 million. The change in fair value of the warrant derivative liability is discussed in Note 2.

*July 2009 and April 2007 Warrants*

The Company issued several warrants in July 2009 and April 2007. As of December 31, 2013 and 2012 these warrants have been classified as equity instruments and have been included in the Company's consolidated balance sheet within additional paid-in-capital.

**(8) Debt***Long term debt December 2012 Financing*

On December 6, 2012 the Company entered into an agreement with Biopharma Secured Debt Fund II Holdings Cayman LP ( Biopharma ). Under this agreement, the Company granted to Biopharma a security interest in

---

**Table of Contents**

future receivables associated with the Vascepa patent rights, in exchange for \$100 million received at the closing of the agreement which occurred in December 2012. The Company has agreed to repay Biopharma up to \$150 million of future revenue and receivables. The first repayment under the agreement of \$0.8 million was paid to Biopharma in November 2013 for the fiscal quarter ended September 30, 2013. This payment was calculated based on the threshold limitation, as described below, to the otherwise scheduled quarterly repayments. Additional quarterly repayments, subject to the threshold limitation described below, are scheduled to be paid thereafter in accordance with the following schedule: \$2.5 million of interest in the first quarter of 2014; \$8.0 million per quarter in each of the next four quarters, \$10.0 million per quarter in each of the next four quarters, \$15.0 million per quarter in each of the next four quarters and a final payment of \$13.0 million scheduled for payment in May 2017. All such payments reduce the remainder of the \$150 million in aggregate payments to Biopharma. The quarterly repayments through the third quarter of September 2014 represent interest only. Quarterly payments do not begin to reduce the principal balance until the fourth quarter of 2014. These quarterly payments are subject to a quarterly threshold amount whereby, if a calculated threshold, based on quarterly Vascepa revenues, is not achieved, the quarterly payment payable in that quarter can at the Company's election be reduced and 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 revenue levels. Except upon a change of control in Amarin, the agreement does not expire until \$150 million has been repaid. Under the agreement, upon a change of control, the Company would be required to pay \$140 million, less any previously repaid amount, if the change of control occurs on or before December 31, 2013, or required to repay \$150 million, less any previously repaid amount, if the change of control event occurs after December 31, 2013. The Company can prepay after October 1, 2013, an amount equal to \$150 million less any previously repaid amount.

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 statement of operations. The Company recognized a gain on change in fair value of derivative liability of \$3.5 million and \$0.02 million for the years ended December 31, 2013 and 2012, respectively.

For the year ended December 31, 2013, the Company recorded \$11.3 million and \$2.6 million of cash and non-cash interest expense, respectively. For the year ended December 31, 2012, the Company recorded \$0.1 million and \$0.02 million of cash and non-cash interest expense, respectively. The Company will periodically evaluate the remaining term of the agreement and the effective interest will be reassessed each period based on the Company's most current estimate of repayment.

The Company currently estimates that its Vascepa revenue levels will not be high enough in each quarter to support repayment to Biopharma in accordance with the threshold amounts in the repayment schedule. For the quarters ended September 30 and December 31, 2013, revenues were below the contractual threshold amount such that cash payments of \$0.8 million and \$1.0 million were calculated for each period, respectively, reflecting the optional reduction amount as opposed to the contractual threshold payment of \$2.5 million for each quarterly period. The payment of \$0.8 million for the quarter ended September 30, 2013 was made in November 2013 and the payment of \$1.0 million for the quarter ended December 31, 2013 is due in February 2014. In accordance with the agreement with BioPharma, quarterly differences between the calculated optional reduction amounts and the repayment schedule amounts are 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 revenues. These estimates will be reevaluated each reporting period by the Company and adjusted if necessary.

**Table of Contents**

To secure the obligations under the agreement with BioPharma, the Company granted BioPharma 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 BioPharma may attempt to collect the maximum amount payable by the Company under this agreement (after deducting any payments we have already made).

**Exchangeable Senior Notes**

In January 2012, the Company issued \$150.0 million in principal amount of 3.5% exchangeable senior notes due 2032 (the Notes). The Notes were issued by Corsicanto Limited, an Irish limited company acquired by Amarin in January 2012. Corsicanto Limited is a wholly-owned subsidiary of Amarin. The general, unsecured, senior obligations are fully and unconditionally guaranteed by Amarin but not by any of the Company's subsidiaries. Corsicanto Limited has no assets, operations, revenues or cash flows other than those related to the issuance, administration and repayment of the Notes. There are no significant restrictions on the ability of Amarin to obtain funds from Corsicanto Limited in the form of cash dividends, loans, or advances. Net proceeds to the Company, after payment of underwriting fees and expenses, were approximately \$144.3 million.

The Notes have a stated interest rate of 3.5% per year, payable semiannually in arrears on January 15 and July 15 of each year beginning on July 15, 2012, and ending upon the Notes' maturity on January 15, 2032. The Notes are subject to repurchase by the Company at the option of the holders on each of January 19, 2017, January 19, 2022, and January 19, 2027, at a price equal to 100% of the principal amount of the Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the repurchase date. The Notes are exchangeable under certain circumstances into cash, ADSs, or a combination of cash and ADSs, at the Company's election, with an initial exchange rate of 113.4752 ADSs per \$1,000 principal amount of Notes. It is the Company's current intention to settle these obligations in cash. If the Company elected physical settlement, the Notes would initially be exchangeable into 17,021,280 ADSs. Based on the closing price of the Company's stock at December 31, 2013, the principal amount of the Notes would exceed the value of the shares if converted on that date by \$116.5 million.

Additional covenants include: (i) limitations on future indebtedness under certain circumstances, (ii) the timely filing of documents and reports pursuant to Section 13 or 15(d) of the Exchange Act with both the SEC and the Trustee, and (iii) maintaining the tradability of the Notes. The Company is required to use commercially reasonable efforts to procure and maintain the listing of the Notes on the Global Exchange Market operated under the supervision of the Irish Stock Exchange (or other recognized stock exchange as defined in the Note Indenture) prior to July 15, 2012. If the Notes are not freely tradable, as a result of restrictions pursuant to U.S. securities law or the terms of the Indenture or the Notes, the Company shall pay additional interest on the Notes at the rate of 0.50% per annum of the principal amount of Notes outstanding for each day during such period for which the Company's failure to file has occurred and is continuing or for which the Notes are not freely tradable.

The Company may not redeem the Notes prior to January 19, 2017, other than in connection with certain changes in the tax law of a relevant taxing jurisdiction that results in additional amounts becoming due with respect to payments and/or deliveries on the Notes. On or after January 19, 2017 and prior to the maturity date, the Company may redeem for cash all or part of the Notes at a redemption price equal to 100% of the principal amount of the Notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date. There is no prepayment penalty or sinking fund provided for the Notes. If the Company undergoes a fundamental change, holders may require the Company to repurchase for cash all or part of their Notes at a repurchase price equal to 100% of the principal amount of the Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date. The Notes are the Company's senior unsecured obligations.

**Table of Contents**

and rank senior in right of payment to the Company's future indebtedness that is expressly subordinated in right of payment to the Notes and equal in right of payment to the Company's future unsecured indebtedness that is not so subordinated. The Notes are effectively junior in right of payment to future secured indebtedness to the extent of the value of the assets securing such indebtedness.

The Notes are exchangeable under certain circumstances. The Company calculated the fair value of the liability component of the 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. The discount created from allocating proceeds to the conversion option is being amortized to interest expense using the effective interest method over the Notes' estimated remaining life, which was calculated to be a period of twenty-four months. The effective interest rate of the Notes is 14.5%. As of December 31, 2013, the unamortized discount created from the allocation of the proceeds to the conversion option was \$0.6 million. The conversion option will not be subsequently remeasured as long as it continues to meet the criteria for equity classification.

The Company also recorded a debt discount to reflect the value of the underwriter's discounts and offering costs. A portion of the debt discount from underwriter's discounts and offering costs was allocated to the equity and liability components of the Notes in proportion to the proceeds allocated to each component. The portion of the debt discount from underwriter's discounts and offering costs allocated to the liability component is being amortized as interest expense over the estimated remaining life of the Notes of twenty-four months. As of December 31, 2013, the unamortized debt discount was \$0.1 million and the carrying value of the Notes, net of the unamortized discount, was \$149.3 million. During the year ended December 31, 2013, the Company recognized interest expense of \$20.3 million related to the Notes, of which \$12.5 million represents amortization of the debt discount created upon allocation of proceeds to the conversion option, \$5.3 million represents contractual coupon interest, and \$2.5 million represents the amortization of the discount from the underwriter's discounts and offering costs. As of December 31, 2012, the unamortized debt discount was \$2.6 million and the carrying value of the Notes, net of the unamortized discount, was \$134.3 million. During the year ended December 31, 2012, the Company recognized interest expense of \$18.0 million related to the Notes, of which \$10.7 million represents amortization of the debt discount created upon allocation of proceeds to the conversion option, \$5.1 million represents contractual coupon interest, and \$2.2 million represents the amortization of the discount from the underwriter's discounts and offering costs. At December 31, 2013 and 2012, the Company had accrued interest of \$2.4 million, which is included in other current liabilities.

The Company made the contractual interest payments due on the Notes in 2013 and 2012 of \$5.3 million and \$2.7 million, respectively.

**(9) Commitments and Contingencies****Litigation**

On November 1, 2013, a purported investor of Amarin filed a putative class action lawsuit captioned *Steven Sklar v. Amarin Corporation plc et al.*, No. 13-cv-6954 (D.N.J. Nov. 1, 2013) in the U.S. District Court for the District of New Jersey. Substantially similar lawsuits, captioned *Bove v. Amarin Corporation plc*, Civ. No. 13-07882 (AT) (S.D.N.Y. Nov. 5, 2013), *Bentley v. Amarin Corporation plc*, Civ. No. 13-08283 (AT) (S.D.N.Y. Nov. 20, 2013) and *Siegel v. Amarin Corporation plc*, No. 3:13-cv-07210 (D.N.J. Nov. 27, 2013), were subsequently filed in the U.S. District Court for the District of New Jersey and U.S. District Court for the Southern District of New York. On December 9, 2013 the cases filed in the Southern District of New York were transferred to the District of New Jersey, where the four cases are now proceeding in front of the same judge pending a formal order consolidating the actions.

Each of the complaints asserts claims under the Securities Exchange Act of 1934. The complaints allege that Amarin 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 the potential relevance of data from the

**Table of Contents**

ongoing REDUCE-IT trial to that approval. The putative class periods alleged in the complaints vary from the July 9, 2009-October 15, 2013 period alleged in the *Sklar* and *Siegel* complaints, the July 9, 2009-October 16, 2013 period alleged in the *Bentley* complaint, and August 8, 2012-October 16, 2013 period alleged in the *Bove* complaint. The lawsuits seek unspecified monetary damages and attorneys' fees and costs.

On January 3, 2014, ten plaintiffs and their respective counsel moved for appointment as lead plaintiff and lead counsel for the putative class. The plaintiffs also moved for consolidation of the pending actions. The motion for appointment of lead plaintiff was set for February 3, 2014, but has not yet been decided. After the Court appoints a lead plaintiff, and consolidates the actions, the Company expects that the lead plaintiff will file a consolidated amended complaint that will become the operative complaint for the action.

The Company believes that it has valid defenses and will vigorously defend against the claims. The Company is unable to reasonably estimate the loss exposure, if any, associated with these claims.

In addition to the above, in the ordinary course of business, the Company is from time to time involved in lawsuits, claims, investigations, proceedings, and threats of litigation relating to intellectual property, commercial arrangements and other matters. While the outcome of these proceedings and claims cannot be predicted with certainty, as of December 31, 2013, the Company was not party to any legal or arbitration proceedings that may have, or have had in the recent past, significant effects on the Company's financial position or profitability. No governmental proceedings are pending or, to our knowledge, contemplated against the Company. The Company is not a party to any material proceedings in which any director, member of senior management or affiliate of ours is either a party adverse to the Company or its subsidiaries or has a material interest adverse to the Company or its subsidiaries.

**Leases**

The Company leases office space and office equipment under operating and capital leases. Future minimum lease payments under these leases as of December 31, 2013 are as follows (in thousands):

<b>Year Ending December 31,</b>	<b>Operating</b>	<b>Capital</b>
2014	\$ 828	\$ 6
2015	662	4
2016	675	
2017	687	
2018	172	
<b>Total</b>	<b>\$ 3,024</b>	<b>10</b>
<b>Less: interest</b>		
<b>Total principal obligations</b>		<b>10</b>
<b>Less: current portion</b>		<b>6</b>
<b>Long-term capital lease</b>		<b>\$ 4</b>

On November 28, 2011, the Company entered into a lease agreement for 4,327 net useable square feet of office space in Groton, Connecticut. The Lease terminates on January 31, 2015, but may be extended by Amarin for a period of three years. Under the Lease, Amarin pays monthly rent of approximately \$8,500.

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 agreement began November 1, 2011 and terminates on October 31, 2014 and can be extended automatically for successive one year periods. Monthly rent is approximately 2,700 (approximately \$3,500). The agreement can be terminated by either party with three months prior written notice.





---

## **Table of Contents**

On July 1, 2011, the Company leased 9,747 square feet of office space in Bedminster, New Jersey. The lease, as amended, terminates on March 31, 2018, 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. Effective December 31, 2013, the December 6, 2011 lease was terminated.

Total rent expense during the years ended 2013, 2012 and 2011 was approximately \$1.0 million, \$0.6 million, and \$0.5 million, respectively.

### **Lease Liability**

In December 2005 the Company ceased using office space in Ely, Cambridgeshire. Amarin is obligated to pay rent, service charges and rates to the end of the lease, which expires in November 2014. The premises have been sublet through November 2014. In December 2013, the Company ceased using the office space in Groton, Connecticut. The Company is obligated to pay rent through the end of the lease in January 2015. Liabilities for exited lease facilities at December 31, 2013 and 2012 were \$0.1 million and \$17 thousand, respectively, and are included within the consolidated balance sheets under accrued expenses and other long-term liabilities.

### **Royalty and Milestone Obligations**

The Company is party to certain milestone and royalty obligations under several product development agreements, as follows:

The Company's active pharmaceutical ingredient, or API, supply agreement with Nisshin Pharma, Inc. ( Nisshin ), provided for minimum supply purchase obligations on behalf of the Company to enable Amarin to maintain exclusivity with this supplier, and to prevent potential termination of the agreement based on estimated minimum purchase requirements. As of December 31, 2013, the API aggregate minimum purchase obligations under this supply agreement had been achieved and as a result, the Company has no future minimum purchase obligation from Nisshin.

In 2011, the Company entered into agreements with two additional suppliers, Chemport, Inc. ( Chemport ) and BASF (formerly Equateq Limited) for the supply of API materials for Vascepa. In 2012, the Company agreed to terms with a fourth API supplier, Slanmhor Pharmaceutical, Inc., or Slanmhor. These agreements include requirements for the suppliers to qualify their materials and facilities with applicable regulatory authorities including the FDA. The Company will incur certain costs associated with the qualification of product produced by these suppliers as described below. In each case, following qualification of the supplier for the manufacture of API for commercial sale, these agreements include annual purchase levels to enable Amarin to maintain exclusivity with each respective supplier, and to prevent potential termination of the agreements. Chemport and BASF were approved by the FDA to manufacture API for commercial sale in April 2013. 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. BASF is entitled to a 60-day cure period. If the agreement is not terminated and BASF successfully completes validation of their manufacturing process for the production of Vascepa API, the Company will be subject to minimum purchase obligations. The Company has begun to purchase commercial supply from Chemport. The agreement with Chemport contains a provision requiring the Company to pay Chemport in cash for any shortfall in the minimum purchase obligations. The minimum purchase commitment was achieved in 2013. The agreement with Slanmhor contains a provision requiring the Company to pay Slanmhor in cash for any shortfall in the minimum purchase obligations, which will become effective upon the approval for manufacture by the FDA of supply from Slanmhor. The 2011 supply agreements include commitments for the Company to fund (i) development fees up to a maximum of \$0.5 million (ii) material purchases of up to \$5.0 million for initial raw materials, which amount will be credited against future API purchases and (iii) a raw material purchase commitment of \$1.1 million. We have paid \$3.1 million related to these

**Table of Contents**

commitments through December 31, 2013. Under these agreements, during the year ended December 31, 2013, the Company made payments of \$6.9 million and \$0.1 million to Chemport and BASF, respectively. The agreement with Slanmhor provides for development fees of up to \$2.3 million and a commitment of up to \$15.0 million, which will be credited against future API material purchases. We have paid \$6.2 million related to these commitments through December 31, 2013. The \$15.0 million commitment fee is contingent upon the mutually agreed upon expansion of Slanmhor's API manufacturing capacity. Under this agreement, during the year ended December 31, 2013, the Company made payments of \$6.1 million to Slanmhor related to stability and technical batches and advances on future API purchases.

Concurrent with its entry into one of the two agreements entered into in 2011 for the supply of API materials for Vascepa, the Company agreed to make a non-controlling minority share equity investment in the supplier of up to \$3.3 million. The Company invested \$1.7 million under this agreement in July 2011 and the remaining \$1.6 million during 2012. In September 2013, the Company entered into an equity sale and purchase agreement between this supplier and a third party in which the Company agreed to sell approximately \$1.3 million of its investment in the supplier to the third party at cost. This transaction closed in the first quarter of 2014. The carrying amount of \$3.3 million as of December 31, 2013 and 2012 is included in other long term assets and is accounted for under the cost method.

Under the 2004 share repurchase agreement with Laxdale Limited, or Laxdale, upon receipt of marketing approval in the U.S. and/or Europe for the first indication for Vascepa (or first indication of any product containing Amarin Neuroscience 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 \$12.4 million at December 31, 2013) for each of the two potential marketing approvals. Upon approval of Vascepa by the FDA on July 26, 2012, the Company capitalized this first Laxdale milestone (\$11.6 million on July 26, 2012) as an intangible asset. This long-term asset will be amortized over the estimated useful life of the intellectual property the Company acquired from Laxdale and the Company recognized amortization expense of \$0.6 million during the year ended December 31, 2013. The Company paid \$12.1 million in cash in November 2012 in settlement of this liability and recognized a currency exchange loss of \$0.5 million.

Also under the Laxdale agreement, upon receipt of a marketing approval in the U.S. or Europe for a further indication of Vascepa (or further indication of any other product using Amarin Neuroscience 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 \$8.2 million at December 31, 2013) for each of the two potential market approvals (i.e. £10 million maximum, or approximately \$16.5 million at December 31, 2013).

The Company has no provision for any of the obligations above since the amounts are either not probable or estimable at December 31, 2013.

**(10) Equity**

On July 12, 2013, the Company completed a public offering of 21,700,000 ADSs. The underwriters purchased the ADSs from Amarin at a price of \$5.60 per ADS, resulting in net proceeds to Amarin of approximately \$121.2 million, after deducting estimated offering expenses payable by the Company. Amarin also granted the underwriters a 30-day option to purchase an additional 3,255,000 ADSs, which was not exercised. The stated use of proceeds in connection with this offering were as follows: primarily to continue the commercial launch of Vascepa capsules in the MARINE indication, prepare for and commercially launch Vascepa in the ANCHOR indication, if approved, advance the Company's REDUCE-IT cardiovascular outcomes trial, and for general corporate and working capital purposes.

During the years ended December 31, 2013 and 2012, as a result of the exercise of stock options the Company issued 386,000 and 3,380,413 shares, respectively, resulting in gross and net proceeds of \$0.6 million for the year ended December 31, 2013 and \$8.2 million for the year ended December 31, 2012.

---

**Table of Contents**

During the years ended December 31, 2013 and 2012, as a result of the exercise of warrants the Company issued 147,050 and 11,047,579 shares, respectively, resulting in gross and net proceeds of \$0.2 million for the year ended December 31, 2013 and \$16.7 million for the year ended December 31, 2012.

In August and September of 2013, the Company granted a total of 44,000 restricted stock units ( RSUs ) to several employees under the Amarin Corporation plc 2011 Stock Incentive Plan ( 2011 Plan ). These RSUs vest upon the achievement of certain operational milestones. In the year ended December 31, 2013, as a result of the operational milestones not being achieved, all of these RSU s were forfeited and no shares were issued as a result of vesting. The Company recorded no expense during the year ended December 31, 2013 related to the vesting of these RSUs.

In July 2013, the Company granted a total of 54,000 deferred stock units ( DSUs ) to members of the Company s Board of Directors under the Amarin Corporation plc 2011 Stock Incentive Plan ( 2011 Plan ). As of December 31, 2013, none of these DSU s were forfeited and no shares were issued as a result of vesting. The DSU s vest over a three year period. The DSUs will become fully vested upon a change of control of the Company. Upon termination of service to the Company, 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. The Company recorded expense during the year ended December 31, 2013 of \$31 thousand related to the vesting of these DSUs.

In January 2013, the Company granted 454,875 RSUs to several employees under the 2011 Plan. These RSUs vest upon the achievement of certain operational milestones. In the year ended December 31, 2013, as a result of the operational milestones not being achieved, all of these RSU s were forfeited and no shares were issued as a result of vesting. The Company recorded no expense during the year ended December 31, 2013 related to the vesting of these RSUs.

In February 2012, the Company granted 584,400 RSUs to several employees under the 2011 Plan. As of December 31, 2013, a total of 251,818 RSUs were forfeited. These RSUs vest upon the achievement of certain regulatory and time-based milestones. The RSUs will become fully vested upon a change of control of the Company. Upon vesting of each RSU, the participant shall be entitled to a payment equal to the fair market value of one share of Amarin common stock. The payment shall be paid to the participant in cash, or at the sole discretion of the Compensation Committee in shares or a combination of cash or shares. During the years ended December 31, 2013 and 2012, the Company issued 93,048 and 97,398 shares, respectively, as a result of the vesting of these RSUs. The fair value of the RSUs was determined on the date of grant, and compensation expense related to the RSUs is recognized once the related milestone is deemed probable. During the years ended December 31, 2013 and 2012, the Company recorded expense of \$0.3 million and \$1.4 million, respectively, related to the vesting of these RSUs.

**(11) Income Taxes**

As of December 31, 2013 and 2012, interest and penalties related to any uncertain tax positions have 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 \$1.7 million as of December 31, 2013, as compared to \$1.2 million as of December 31, 2012.

**Table of Contents**

The following is a reconciliation of the total amounts of unrecognized tax benefits for the years ended December 31, 2013, 2012 and 2011:

	2013	2012 (In thousands)	2011
Beginning uncertain tax benefits	\$ 1,243	\$ 997	\$ 558
Current year increases	687	294	439
Current year decreases	(256)	(48)	
Ending uncertain tax benefits	\$ 1,674	\$ 1,243	\$ 997

The Company files income tax returns in the U.S., Ireland and United Kingdom. The Company remains subject to tax examinations in the following jurisdictions as of December 31, 2013:

Jurisdiction	Tax Years
United States (Federal and State)	2010-2013
Ireland	2008-2013
United Kingdom	2012-2013

The Company expects gross liabilities of \$254,000 to expire in 2014 based on statutory lapses.

The components of loss from operations before taxes were as follows at December 31:

	2013	2012 (In thousands)	2011
United States	\$ (9,234)	\$ 1,874	\$ 1,019
Ireland and United Kingdom	(160,187)	(171,942)	(67,629)
	\$ (169,421)	\$ (170,068)	\$ (66,610)

The (benefit) expense from income taxes shown in the accompanying consolidated statements of operations consists of the following for fiscal 2013, 2012 and 2011:

	2013	2012 (In thousands)	2011
<b>Current:</b>			
Federal-U.S.	\$ 122	\$ 10,265	\$ 3,908
State-U.S.	118	2,565	1,101
Total Current	\$ 240	\$ 12,830	\$ 5,009
<b>Deferred:</b>			
Federal-U.S.	(4,065)	(2,803)	(1,936)
State-U.S.	631	(911)	(557)
Ireland and United Kingdom	(33,106)	(22,515)	(5,566)
Change in valuation allowance	33,106	22,515	5,566
Total Deferred	\$ (3,434)	\$ (3,714)	\$ (2,493)

\$ (3,194)	\$ 9,116	\$ 2,516
------------	----------	----------

F-28

**Table of Contents**

The (benefit) expense 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 2013, 2012 and 2011:

	2013	2012 (In thousands)	2011
Benefits from taxes at statutory rate	\$ (42,355)	\$ (42,517)	\$ (16,652)
Rate differential	18,494	13,249	3,952
Change in valuation reserves	33,106	22,515	7,120
Permanent & other	(985)	6,809	2,209
Warrant derivative liabilities	(11,984)	8,904	5,643
Other	530	156	244
	\$ (3,194)	\$ 9,116	\$ 2,516

The Company is subject to corporate tax rate in Ireland of 25% for non-trading activities and 12.5% for trading activities. For the years ended December 31, 2013, 2012 and 2011, 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.

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

	2013 (In thousands)	2012
Deferred tax assets:		
Net operating losses	\$ 85,724	\$ 55,086
Stock based compensation	11,660	9,155
Depreciation	(126)	(189)
Tax credits	1,256	5
Other reserves and accrued liabilities	2,900	818
Gross deferred tax asset	101,414	64,875
Less: valuation allowance	(88,999)	(55,894)
	\$ 12,415	\$ 8,981

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 deferred tax assets would not be realized in future periods and a full valuation allowance has been provided for all periods.

The Company has combined Irish, UK, and Israeli net operating loss carryforwards of \$528.2 million, which do not expire. In addition, the Company has available U.S. Federal tax credit carryforwards of \$4.1 million and state tax credit carryforwards of \$1.8 million. These carryforwards, which will expire starting between 2029 and 2032 may be used to offset future taxable income, if any.

The Company recognized a tax benefit related to the extension of 2012 research and development credits into 2013 and recorded a discrete benefit of approximately \$1.9 million.

**(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



**Table of Contents**

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 ADSs, as to be issued under the 2011 Plan shall not exceed the sum of (i) 3.5 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 our Board of Directors and expires on July 12, 2021.

In addition to the grants under the 2011 Plan, the Company grants nonqualified 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 10 year term and are granted at an exercise price equal to the closing price of the Company's American Depository Shares on the grant date. The following table summarizes all stock option activity for the year ended December 31, 2013:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
(in thousands, except for per share amounts)				
Outstanding January 1, 2013	10,892	\$ 7.29		
Granted	1,217	7.49		
Cancelled/Expired	(2,393)	10.83		
Exercised	(386)	1.61		
Outstanding, December 31, 2013	9,330	6.64	7.4 years	\$ 1,063
Exercisable, December 31, 2013	7,077	5.87	7.1 years	\$ 1,062
Vested and Expected to Vest, December 31, 2013	9,062	6.57	7.4 years	\$ 1,063
Available for future grant at December 31, 2013	9,212			

The weighted average fair value of the stock options granted during the years ended December 31, 2013, 2012 and 2011 was \$6.18, \$8.79 and \$8.61, respectively.

During the years ended December 31, 2013 and 2012, the Company received cash of \$0.6 million and \$8.3 million from the exercise of options. The intrinsic value of options exercised during 2013 was \$2.4 million and \$34.1 million during 2012. As of December 31, 2013 and 2012, there was \$15.7 million and \$41.8 million of unrecognized stock-based compensation expense related to unvested stock option share-based compensation arrangements granted under the Company's stock award plans. This expense is expected to be recognized over a weighted-average period of approximately 2.2 years. There was \$(0.4) million and \$11.3 million for the years ended December 31, 2013 and 2012, respectively, reflected as a (provision) benefit within the consolidated statement of cash flows related to excess tax (provision) benefits on the U.S. federal level that have been realized as an (increase) reduction in taxes payable. 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 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 based on the short-cut method based on



**Table of Contents**

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 granted prior to June 30, 2009 generally vested over a three-year service period. Employee stock options granted after June 30, 2009 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 Company recorded compensation expense in relation to stock options of \$14.3 million, \$16.7 million and \$9.2 million for the years ended December 31, 2013, 2012 and 2011, respectively.

For 2013, 2012 and 2011, the Company used the following assumptions to estimate the fair value of share-based payment awards:

	2013	2012	2011
Risk free interest rate	0.91% - 2.07%	0.81% - 1.39%	2.03% - 2.56%
Expected dividend yield	0.00%	0.00%	0.00%
Expected option life (years)	6.25	6.25	6.25
Expected volatility	91% - 110%	109% - 111%	105% - 112%

**Restricted Stock Units**

The 2011 Plan also allows for granting of restricted stock unit awards under the terms of the Plan. The majority of the restricted stock units vest upon the achievement of various performance conditions such as FDA approval. Additionally, there is a service condition tied to each performance condition achieved. The Company estimated the fair value of the restricted stock units using the market price of its common stock on the date of grant. The fair value of restricted stock units is amortized on a straight-line basis over the vesting period. The following table presents the restricted stock unit activity for the years ended December 31, 2013 and 2012.

	Shares (in thousands)	Weighted Average Grant Date Fair Value
Outstanding as of January 1, 2013	465	8.86
Granted	553	7.75
Vested	(93)	8.86
Forfeited	(729)	8.21
Outstanding as of December 31, 2013	196	6.96

The Company recorded compensation expense in relation to restricted stock units of \$0.4 million, \$1.4 million and zero for the years ended December 31, 2013, 2012 and 2011 respectively.

The following table presents the stock-based compensation expense related to stock based awards for the period ended December 31:

	2013	2012	2011
	(in thousands)		
Research and development	\$ 2,837	\$ 3,700	\$ 1,464
Selling, general and administrative	11,848	14,375	7,830
Stock-based compensation expense	\$ 14,685	\$ 18,075	\$ 9,294



**Table of Contents****(13) Defined Contribution Plan**

The Company makes available a 401(k) plan for its U.S. employees to which it made contributions in prior years. The Company did not make any contributions in 2013, 2012 or 2011.

**(14) Related Party Transaction****October 2009 Private Placement**

Several of Amarin's current and 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., where Dr. James I. Healy, a 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 of an ADS. Of the \$6.9 million warrant derivative liability at December 31, 2013, the fair value of the warrants held by the current and former directors of the Company and their related investment funds amounted to \$4.5 million.

**(15) Restructuring**

As part of a program to reduce costs and increase operational efficiencies, in October 2013, the Company announced a plan to streamline operations to better align its cost structure with current market conditions by reducing its global workforce by approximately 50%. In connection with this program, the Company recorded \$2.8 million in charges for severance and related benefits to reduce the Company's workforce during the quarter ended December 31, 2013, of which \$0.2 million is recorded in research and development expense and \$2.6 million is recorded in selling, general and administrative expense in the accompanying consolidated statement of operations. The Company does not expect to incur any additional charges related to this program subsequent to December 31, 2013 and expects to make all remaining payments in the first half of 2014.

The restructuring charges, which are included in accrued expenses and other current liabilities in the accompanying consolidated balance sheet as of December 31, 2013, are summarized as follows:

	<b>Employee Severance and Benefits</b>
Balance as of January 1, 2013	\$
Restructuring charges	2,781
Cash payments	(2,646)
Balance as of December 31, 2013	\$ 135

**(16) Quarterly Summarized Financial Information (Unaudited)****Immaterial Restatement**

The Company's operating results reflected net losses for each fiscal quarter during the years ended December 31, 2013 and 2012. During certain of these quarters, net loss included gains recorded on changes in the fair value of the warrant derivative liability (See Note 2). The diluted earnings per share amounts for certain quarterly periods have been restated to reflect the increase in loss per share which occurs if such gains recorded on changes in the fair value of the warrant derivative liability are excluded from the calculation of net loss. The diluted weighted

**Table of Contents**

average share amounts for such quarterly periods have also been adjusted to reflect the incremental outstanding shares utilizing the treasury stock method assuming the warrants associated with the derivative liability had been exercised. For the year ended December 31, 2012, changes in the fair value of the warrant derivative liability resulted in a net loss and as a result, there was no impact of the quarterly restatements to diluted net loss per share on our consolidated financial statements for that period.

	Fiscal year ended December 31, 2013							
	1st Quarter		2nd Quarter		3rd Quarter		4th Quarter	
	As Reported	As Restated	As Reported	As Restated	As Reported	As Restated	As Reported	As Restated
	(In thousands, except per share amounts)							
Revenue	\$ 2,342	\$ 2,342	\$ 5,500	\$ 5,500	\$ 8,403	\$ 8,403	\$ 10,106	\$ 10,106
Net loss	(62,158)	(62,158)	(39,774)	(39,774)	(48,884)	(48,884)	(15,411)	(15,411)
Net loss per share :								
Basic	\$ (0.41)	\$ (0.41)	\$ (0.26)	\$ (0.26)	\$ (0.29)	\$ (0.29)	\$ (0.09)	\$ (0.09)
Diluted	\$ (0.41)	\$ (0.43)	\$ (0.26)	\$ (0.34)	\$ (0.29)	\$ (0.29)	\$ (0.27)	\$ (0.27)

	Fiscal year ended December 31, 2012							
	1st Quarter		2nd Quarter		3rd Quarter		4th Quarter	
	As Reported	As Restated	As Reported	As Restated	As Reported	As Restated	As Reported	As Restated
	(In thousands, except per share amounts)							
Revenue	\$	\$	\$	\$	\$	\$	\$	\$
Net loss	(88,285)	(88,285)	(53,904)	(53,904)	(26,426)	(26,426)	(10,569)	(10,569)
Net loss per share :								
Basic	\$ (0.65)	\$ (0.65)	\$ (0.38)	\$ (0.38)	\$ (0.18)	\$ (0.18)	\$ (0.07)	\$ (0.07)
Diluted	\$ (0.65)	\$ (0.65)	\$ (0.38)	\$ (0.38)	\$ (0.18)	\$ (0.28)	\$ (0.07)	\$ (0.30)

**(17) Subsequent Events**

On January 8, 2014, the Company granted a total of 2,082,000 RSUs and 2,605,500 stock options to employees under the 2011 Plan. The RSU s vest annually over a three year period and the stock options vest monthly over a four year period.

On February 21, 2014, in connection with the July 26, 2012 approval of the MARINE indication, the FDA denied a grant of New Chemical Entity (NCE) marketing exclusivity to Vascepa and granted three-year marketing exclusivity. Such three-year exclusivity extends through July 25, 2015 and can be supplemented by a 30-month stay triggered after patent infringement litigation initiated by Amarin following a valid notice to Amarin of the filing of an application to the FDA seeking approval of a generic version of Vascepa. 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.

On February 27, 2014, the Company filed a lawsuit against the FDA that challenges FDA s denial of the Company s request for five-year exclusivity for Vascepa based on the Company s reading of the relevant statute and inconsistency with FDA s past actions. The complaint requests that the court vacate FDA s decision, declare that Vascepa is entitled to the benefits of five-year statutory exclusivity, bar the FDA from accepting any ANDA or similar application for which Vascepa is the reference-listed drug until after the statutory exclusivity period expires, and if necessary, set aside FDA s premature acceptance of any such application.