

AMARIN CORP PLC\UK  
Form 10-K  
February 29, 2012  
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, 2011

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, 2011 was approximately \$1.39 billion, based upon the closing price on the NASDAQ Capital Market reported for such date.

135,745,861 shares held as American Depositary Shares (ADS), each representing one Ordinary Share, 50 pence par value per share, and 313,834 Ordinary Shares, were outstanding as of February 23, 2012.

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>PART I</b>	
Item 1. <u>Business</u>	2
Item 1A. <u>Risk Factors</u>	21
Item 1B. <u>Unresolved Staff Comments</u>	43
Item 2. <u>Properties</u>	44
Item 3. <u>Legal Proceedings</u>	44
Item 4. <u>Mine Safety Disclosures</u>	44
<b>PART II</b>	
Item 5. <u>Market For Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	45
Item 6. <u>Selected Financial Data</u>	49
Item 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	50
Item 7A. <u>Quantitative and Qualitative Disclosures about Market Risk</u>	59
Item 8. <u>Financial Statements and Supplementary Data</u>	60
Item 9. <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	60
Item 9A. <u>Controls and Procedures</u>	60
Item 9B. <u>Other Information</u>	64
<b>PART III</b>	
Item 10. <u>Directors, Executive Officers and Corporate Governance</u>	65
Item 11. <u>Executive Compensation</u>	65
Item 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	65
Item 13. <u>Certain Relationships and Related Transactions, and Director Independence</u>	65
Item 14. <u>Principal Accountant Fees and Services</u>	65
<b>PART IV</b>	
Item 15. <u>Exhibits and Financial Statement Schedules</u>	66
<u>SIGNATURES</u>	73

**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 potential for, and timing of, approval of the AMR101 New Drug Application, or NDA, by the United States Food and Drug Administration, or FDA, and the next steps we may take thereto; the safety and efficacy of our product candidates; the scope of our intellectual property protection and the likelihood of securing additional patent protection and regulatory exclusivity; 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 late-stage biopharmaceutical company with expertise in lipid science focused on the treatment of cardiovascular disease. Our lead product candidate is AMR101, an ultra-pure omega-3 fatty acid, comprising not less than 96% icosapent ethyl, or ethyl-EPA. We are developing AMR101 for the treatment of patients with very high triglyceride levels and high triglyceride levels, or hypertriglyceridemia. Triglycerides are fats in the blood.

In September 2011, we filed a New Drug Application, or NDA, with the U.S. Food and Drug Administration, or FDA, seeking marketing approval for the use of AMR101 in the treatment of patients with very high triglyceride levels ( $\geq 500$  mg/dL), or what we refer to as the MARINE indication. The FDA has assigned a Prescription Drug User Fee Act, or PDUFA, date of July 26, 2012. The PDUFA date is the goal date for the FDA to complete its review of the NDA. The NDA for the MARINE indication is supported by a Special Protocol Assessment, or SPA, agreement with the FDA.

We plan to separately seek approval for the treatment of patients with high triglyceride levels ( $\geq 200$  and  $< 500$  mg/dL) who are also on statin therapy for elevated levels of low-density lipoprotein cholesterol, or LDL-C, (which we refer to as mixed dyslipidemia), or the ANCHOR indication. The ANCHOR indication is also supported by a SPA agreement with the FDA.

The potential efficacy and safety of AMR101 were studied in two Phase 3 clinical trials, the MARINE trial and the ANCHOR trial. These trials showed favorable clinical results in their respective patient populations in reducing triglyceride levels without a statistically significant increase in LDL-C levels and, in the 4 gram AMR101 ANCHOR results, with a statistically significant decrease in LDL-C levels. These trials also showed favorable results, particularly with the 4 gram dose of AMR101, in other important lipid and inflammation biomarkers, including Apo B (apolipoprotein B), non-high-density lipoprotein cholesterol, or non-HDL-C, Total-Cholesterol, very low-density lipoprotein cholesterol, or VLDL-C, Lp-PLA2 (lipoprotein-associated phospholipase), and hs-CRP (high sensitivity C-reactive protein). In each of these trials, AMR101 exhibited a safety profile comparable to placebo.

In November 2010, we announced the favorable results of the Phase 3 MARINE trial, and in April 2011 we announced the favorable results of the Phase 3 ANCHOR trial. The results of both of these studies were submitted to the FDA as part of the NDA for the MARINE indication. To obtain FDA approval of AMR101 for

---

## **Table of Contents**

the ANCHOR indication, based on communications with the FDA, we believe that we must first obtain approval of AMR101 in the MARINE indication and be substantially underway with a cardiovascular outcomes study at the time of the submission of an NDA to the FDA for the ANCHOR indication. Based upon feedback from the FDA and consistent with the respective SPAs for the MARINE trial and ANCHOR trial, we do not believe the final results of an outcomes study are required for FDA approval of AMR101 for either indication.

In December 2011, we announced commencement of patient dosing in our cardiovascular outcomes study of AMR101, titled REDUCE-IT (Reduction of Cardiovascular Events with EPA Intervention Trial), that is designed to evaluate the efficacy of AMR101 in reducing major cardiovascular events in an at-risk patient population on statin therapy. The REDUCE-IT study is also the subject of an SPA agreement with the FDA. If successful, we believe the results of this study could lead to a broadening of the market potential for AMR101 beyond the MARINE and ANCHOR indications.

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 cardiac disease. We estimate that over 40 million adults in the United States have elevated triglyceride levels ( $\geq 200$ mg/dL) and approximately 4.0 million people in the United States have very high triglyceride levels ( $\geq 500$  mg/dL). Triglycerides provide important information as a marker associated with the risk for heart disease and stroke, especially when an individual also has low high-density lipoprotein cholesterol, or HDL-C (often referred to as good cholesterol) and elevated levels of LDL-C (often referred to as bad cholesterol).

We are now preparing for the commercialization of AMR101 for use in the MARINE indication, subject to FDA approval. In preparation for commercialization, during 2011 we secured additional agreements for the clinical and commercial supply of AMR101. We also filed additional patent applications and continued the prosecution of currently pending patent applications as part of a strategy to enhance and extend the proprietary position of AMR101. We will seek to protect the potential commercial exclusivity of AMR101 through a combination of obtaining and maintaining intellectual property rights and regulatory exclusivity, taking advantage of manufacturing barriers to entry and maintaining trade secrets.

We are currently considering three potential paths for the marketing and sale of AMR101: strategic collaboration, acquisition and self-commercialization, the latter of which could include a third-party collaboration. From time to time we have held discussions with larger pharmaceutical companies on potential collaborations and other strategic opportunities, and we may have 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, no assurance can be given as to when or whether we will enter into any such strategic transaction. Until such time that we enter into such a strategic transaction, if ever, we plan to continue to execute on our plans to launch, market and sell AMR101 on our own.

The U.S. market is currently the primary focus of Amarin for the initial commercial launch of AMR101. Opportunities to market and sell AMR101 outside the United States are also under evaluation.

### *January 2012 Financing and Financial Position*

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 3.50% exchangeable senior notes due 2032. The notes are the senior unsecured obligations of Corsicanto and are guaranteed by Amarin Corporation plc. The notes bear interest at a rate of 3.50% 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 Amarin 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

**Table of Contents**

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 Amarin's election, subject to certain conditions, in cash, ADSs or a combination of cash and ADSs.

The proceeds received by Amarin from the January 2012 debt offering were approximately \$144.3 million, net of estimated fees and transaction costs. Together with our cash balance of \$116.6 million at December 31, 2011, we believe that we have sufficient financial resources to fund our projected operations for at least the next twelve months, including the advancement of the REDUCE-IT cardiovascular outcomes study and preparations for and commercial launch of AMR101 on each of the three potential paths we are considering for commercialization subject to timely regulatory approval. Unless we enter into a strategic collaboration in support of a commercial launch, we may need to raise additional capital to support these efforts on our own.

*Phase 3 Clinical Trials*

In November 2010, we reported favorable top-line results from the MARINE trial, the first to complete of our two concurrently run Phase 3 clinical trials of AMR101. In the MARINE trial, AMR101 was investigated as a treatment for patients with triglyceride levels of  $\geq 500$  mg/dL. Patients with this level of triglycerides are characterized as having very high triglyceride levels, as outlined in the National Cholesterol Education Program (NCEP) Expert Panel (Adult Treatment Panel III, 2002), or the NCEP Guidelines. The MARINE trial was a multi-center, placebo-controlled, randomized, double-blind, 12-week pivotal study to evaluate the efficacy and safety of 2 grams and 4 grams of AMR101 in 229 patients with fasting triglyceride levels  $\geq 500$  mg/dL. The primary endpoint in the trial was the percentage change in triglyceride level from baseline compared to placebo after 12 weeks of treatment. Reported top-line results of this study included announcement that AMR101 met the primary endpoint at both the 4 gram and 2 gram doses. In addition to achieving the primary endpoint of the trial, no statistically significant increase in low-density lipoprotein cholesterol, or LDL-C, was observed in this trial at either dose. At both doses AMR101 also showed a decrease in Apo B (Apolipoprotein B) compared to placebo, a sensitive biomarker which is generally considered to be a better predictor of residual cardiovascular risk than LDL-C. The reduction in Apo B compared to placebo was statistically significant at the 4 gram dose, but not the 2 gram dose. Additionally, we observed in the trial a safety profile for AMR101 similar to placebo. See [Our Lead Product Candidate The MARINE Trial](#).

In April 2011, we reported favorable top-line results from the ANCHOR trial, the second of our two Phase 3 clinical trials of AMR101. In the ANCHOR trial, AMR101 was investigated as a treatment for patients with triglyceride levels of  $\geq 200$  and  $< 500$  mg/dL who are also receiving statin therapy. Patients in this trial are characterized as having high triglyceride levels, as outlined in the NCEP Guidelines, with mixed dyslipidemia (two or more lipid disorders). The ANCHOR trial was a multi-center, placebo-controlled, randomized, double-blind, 12-week pivotal study to evaluate the efficacy and safety of 2 grams and 4 grams of AMR101 in 702 patients with high triglycerides who were on optimized statin therapy. The primary endpoint in the trial was the percentage change in triglyceride level from baseline compared to placebo after 12 weeks of treatment. Reported top-line results of this study included an announcement that AMR101 met the study's primary endpoint at both the 4 gram and 2 gram doses. In addition, AMR101 met some of the secondary and exploratory efficacy endpoints in the trial, including at both doses the key secondary endpoint of LDL-C non-inferiority to statin therapy alone (which was observed with a statistically significant decrease in LDL-C at the 4 gram dose), and at both doses statistically significant decreases in Apo B compared to placebo. Additionally, we observed in the trial a safety profile for AMR101 similar to placebo. See [Our Lead Product Candidate The ANCHOR Trial](#).

In addition to achieving the primary endpoints of the MARINE and ANCHOR trials for triglyceride reduction compared to placebo and the LDL-C and Apo B results described above, AMR101, particularly at the 4 gram dose, demonstrated in these trials significant reductions in various secondary and exploratory efficacy endpoints compared to placebo for other lipid and inflammatory biomarkers which we believe are important as they potentially represent additional predictors of cardiovascular risk. These biomarkers include total cholesterol; non-HDL-cholesterol; VLDL-C; Lp-PLA2 (Lipoprotein-phospholipase A2), an enzyme found in blood and



## **Table of Contents**

atherosclerotic plaque and high levels of which have been implicated in the development and progression of atherosclerosis; and high sensitivity C-reactive protein, or hsCRP, an important marker of vascular inflammation.

The MARINE and ANCHOR trials were conducted under separate SPA agreements 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, 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 MARINE and ANCHOR trials adequately address 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 is identified after the testing begins. There is no assurance that the FDA will ultimately consider either of our SPAs to be binding. Moreover, any change to a study protocol can invalidate an SPA. If the FDA does not consider either of the SPAs to be binding or makes a determination that we did not follow the SPA appropriately, the agency could assert that additional studies or data are required to support a regulatory submission.

During 2011, both MARINE and ANCHOR Phase 3 pivotal clinical trial results were presented at a number of medical and scientific meetings, including the National Lipid Association (May), the European Society of Cardiology (August) and the American Heart Association (November). Additionally, the MARINE Phase 3 clinical results were published in the September edition of *The American Journal of Cardiology*, a prominent, peer-reviewed journal. We plan to continue to publish additional data from both the MARINE and ANCHOR trials in peer-reviewed journals.

### *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 December 2011, we announced that the first patient was dosed in the REDUCE-IT study. This study is designed to evaluate the efficacy of AMR101 in reducing major cardiovascular events in an at-risk patient population on statin therapy. REDUCE-IT is a multi-center, prospective, randomized, double-blind, placebo-controlled, parallel-group study to evaluate the effectiveness of AMR101, 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. The active arm of the study is comprised of patients on optimized statin therapy plus AMR101. 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 will be conducted internationally. Based on the results of REDUCE-IT, we may seek additional indications for AMR101 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.

In September 2011, we engaged a clinical research organization, or CRO, and began initial trial and clinical site preparation for REDUCE-IT. We anticipate utilizing approximately 300 clinical sites in connection with the trial, the largest number of which will be in the United States. We, with the support of our CRO, are currently active in qualifying and training such sites. The study is scheduled to be completed in approximately six years and is anticipated to include approximately 8,000 patients. We expect to be substantially underway by the end of 2012.

Consistent with our SPA for the ANCHOR trial, we currently intend to file a supplemental NDA, or sNDA, seeking approval of the ANCHOR indication after the REDUCE-IT cardiovascular outcomes study is substantially underway. The sNDA cannot be filed until after both the initially submitted NDA for the indication studied in the MARINE trial is approved and the cardiovascular outcomes study is substantially underway.

### **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 American Heart Association's *2010 At-A-Glance Report*, over 831,000 deaths in the United States were caused by heart disease and stroke, substantially more than the approximately 560,000 reported deaths caused by cancer.

---

## **Table of Contents**

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, or HDL-C (often referred to as good cholesterol), and elevated levels of LDL-C (often referred to as bad cholesterol).

We estimate that over 40 million adults in the United States have elevated triglyceride levels >200mg/dL and approximately 4.0 million people in the United States have very high triglyceride levels ( $\geq 500$  mg/dL). Since 1976, mean triglyceride levels have increased, in concert with the growing epidemic of obesity, insulin resistance, and type 2 diabetes mellitus. In contrast, mean LDL-C levels have receded.

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

The leading 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 the omega-3 ethyl esters of eicosapentaenoic acid, or EPA, and docosahexaenoic acid, or DHA, and other fatty acids. We believe that DHA may increase LDL-C levels and thereby partially offset one of the typically desired benefits of lipid-lowering therapies, which is lowering LDL-C.

### **Potential Benefits and Market Opportunity for AMR101**

AMR101 is comprised of not less than 96% pure ethyl-EPA and contains no DHA. We believe that the removal of DHA mitigates against the LDL-C raising effect observed in omega-3 formulations that include DHA, as well removing the fishy taste and smell that is sometimes associated with DHA. Based on the results of the MARINE trial, AMR101 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 AMR101's DHA-free composition suggest that AMR101 has the potential to become a best-in-class EPA based triglyceride-lowering agent in the United States and the European Union. In addition, currently no omega-3 based product is approved for lowering high triglycerides in patients with mixed dyslipidemia. If approved by the FDA, we believe that AMR101 has the potential to become first-in-class in the prescription-grade omega-3 market for lowering triglycerides in patients with mixed dyslipidemia.

We believe the potential market for AMR101 is large and growing. We estimate that drug treatment for hypercholesterolemia patients exceeds \$26.5 billion per year in the United States, with sales dominated by statin therapies. U.S. sales of fibrates as a class of products were approximately \$2.6 billion in 2010 with Tricor and Trilipix leading the class. U.S. sales of Lovaza in 2010, as reported by GlaxoSmithKline plc, were over \$900 million, and worldwide sales of Lovaza/Omacor in 2011 exceeded \$1.3 billion, reflecting substantial annual growth both in the United States and Europe.

## **Table of Contents**

### **Our Commercialization Strategy**

Our strategy is to seek FDA approval for AMR101 based on the results of the MARINE and ANCHOR trials while we continue to conduct the REDUCE-IT trial and consider additional trials to further expand the potential indications of use for AMR101. The indication evaluated in the MARINE trial is independent of the ANCHOR trial and can be submitted independently for FDA approval. In September 2011, we filed a NDA with the FDA seeking marketing approval for the MARINE indication. The FDA has assigned a Prescription Drug User Fee Act, or PDUFA, date of July 26, 2012 for the completion of its review of this NDA. In order to obtain a separate indication for AMR101 based on the ANCHOR trial results, the FDA requires that the MARINE indication be approved and that we have a clinical outcomes study substantially underway at the time of the NDA filing for the ANCHOR indication. Based upon feedback from the FDA and consistent with the respective SPAs for the MARINE trial and the ANCHOR trial, we do not believe the final results of an outcomes study are required for FDA approval of AMR101 for either indication.

We are currently considering three potential paths for the marketing and sale of AMR101: strategic collaboration, acquisition and self-commercialization, the latter of which could include a third-party collaboration. From time to time we have held discussions with larger pharmaceutical companies on potential collaborations and other strategic opportunities, and we may have 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, no assurance can be given as to when or whether we will enter into any such strategic transaction.

Until such time that we enter into such a strategic transaction, if ever, we plan to continue to execute on our plans to launch, market and sell AMR101 on our own. This includes making preparations for securing a sufficient commercial supply of AMR101 and expanding sales and marketing capabilities. If we launch AMR101 on our own, assuming a timely FDA approval, we are targeting an early 2013 launch and we expect to begin hiring the majority of the required sales force after NDA approval. In this scenario, we would seek to initially target the clinicians who are top prescribers of other lipid regulating therapies. We believe accomplishing this for the indication studied in the MARINE trial will require a sales force of approximately 200 to 300 representatives in the United States.

We are actively conducting market research to finalize our positioning, pricing and reimbursement strategy with health plans and pharmaceutical benefit managers in preparation for a product launch.

The U.S. market is currently the primary focus of Amarin for the initial commercial launch of AMR101. Opportunities to market and sell AMR101 outside of the United States are also under evaluation.

### **Our Lead Product Candidate**

#### ***The MARINE Trial***

The MARINE trial, the largest study ever conducted with omega-3 fatty acids 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 AMR101 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 SPA agreement with the FDA.

On November 29, 2010, we reported top-line data for the MARINE trial. In the trial, MARINE 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 AMR101 and 2 grams of AMR101, respectively.

**Table of Contents**

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 AMR101 in reducing triglyceride levels from 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 on background statin therapy. These patients had greater median reduction in triglyceride levels, which was also statistically significant.

In addition, patients did not experience 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 [ $p = \text{NS}$ ]). In addition, there was a statistically significant decrease in median non-HDL-C (total cholesterol less so-called good cholesterol) compared to placebo with both of the AMR101 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 markers, 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. The 2 gram dose also showed reductions of Apo B (2.6%), Lp-PLA2 (5.1%), VLDL-C (15.3%), Total Cholesterol (6.8%), and hsCRP (10.1%) compared to placebo. For these achieved endpoints, p-values were not significant for most and  $< 0.05$  for all. Apo B (Apolipoprotein B) is believed to be a sensitive biomarker of residual cardiovascular risk and is generally considered to be a better predictor of residual 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 AMR101 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, AMR101 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 was reduced by 25.6% ( $P < 0.0001$ ) compared with placebo, which is a common risk factor for cardiovascular events in patients with diabetes. AMR101 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.

AMR101 was well tolerated in the MARINE trial with a safety profile comparable to placebo. There were no treatment-related serious adverse events in the MARINE study. No significant changes in fasting blood glucose, hemoglobin A1C, vital signs, electrocardiograms, or liver or kidney function were observed with either AMR101 dose.

Patients enrolled in the MARINE trial were given the option to be treated with AMR101 for a period of up to 40-weeks after their last dose in the pivotal 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 AMR101 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, AMR101 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 AMR101, whether used alone or in combination with other lipid-altering regimens.

**Table of Contents*****The ANCHOR Trial***

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 on optimized statin therapy. Patients were randomized into three arms for treatment with AMR101 4 gram/day, 2 gram/day or placebo. Patient enrollment in this trial began in January 2010, and enrollment and randomization was completed in February 2011 at 702 patients. The primary endpoint in the trial was the percentage change in triglyceride level from baseline compared to placebo after 12 weeks of treatment.

In April 2011, we reported top-line results from the ANCHOR trial. The ANCHOR trial met its primary endpoint at doses of 4 grams and 2 grams per day with median placebo-adjusted reductions in triglyceride levels of 21.5% ( $P<0.0001$  value) for 4 grams and 10.1% ( $P=0.0005$ ) for 2 grams. The median baseline triglyceride levels were 259 mg/dL, 265 mg/dL and 254 mg/dL for the patient groups treated with placebo, 4 grams and 2 grams of AMR101 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 of LDL-C in order to avoid offset to the primary target of cholesterol lowering therapy. The trial's non-inferiority criterion for LDL-C was met at both AMR101 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 AMR101 group, LDL-C decreased significantly by 6.2% from baseline versus placebo, demonstrating superiority over placebo ( $p=0.0067$ ). For the 2 grams per day 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. The 2 gram dose was associated with statistically significant reductions in non-HDL-C (5.5%,  $p<0.01$ ), Apo B (3.8%,  $p<0.05$ ), Lp-PLA2 (8.0%,  $p<0.0001$ ) and a non-statistically significant reduction in high-sensitivity C-reactive protein (hsCRP) (6.8%) at week 12 compared to placebo.

AMR101 was well tolerated in the ANCHOR trial with a safety profile comparable to placebo. There were no treatment-related serious adverse events in the ANCHOR study. No significant changes in fasting blood glucose, hemoglobin A1C, vital signs, electrocardiograms, or liver or kidney function were observed with either AMR101 dose.

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

Prior to commencing Phase 3 trials for AMR101, we did not conduct Phase 2 trials for the patient populations being studied in the MARINE and ANCHOR trials. Such Phase 2 studies were not required as part of the SPAs for either trial. Among the reasons why Phase 2 trials were not conducted or required is that the active ingredient in AMR101, ethyl-EPA of not less than 96% purity with no DHA, has been approved by regulatory authorities in Japan and marketed by Mochida Pharmaceutical Co. for over a decade. In Japan, ethyl-EPA is marketed under the product name of Epadel and is indicated for hyperlipidemia and peripheral vascular disease and which we understand had 2009 revenues in Japan that exceed \$500 million per year. Clinical data from Japan show that Epadel is effective in reducing triglycerides. In addition, in an outcomes study called the Japan EPA Lipid Intervention Study, or JELIS study, which study 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.

## **Table of Contents**

### ***Observed Clinical Safety of AMR101***

Prior to commencing the MARINE and ANCHOR trials, we conducted a pre-clinical program for AMR101, including toxicology and pharmacology studies. In addition, we previously investigated AMR101 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 AMR101 in these studies, with over 100 receiving continuous treatment for a year or more. In all studies performed to date, AMR101 has shown a favorable safety and tolerability profile. In the MARINE trial, the patients dosed with AMR101 demonstrated a safety profile comparable to placebo. In the ANCHOR trial, the patients dosed with AMR101 demonstrated a safety profile comparable to placebo. There were no treatment-related serious adverse events in the MARINE study or in the ANCHOR study.

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 AMR101 in transgenic mice and multiple pharmacokinetic drug-drug interaction studies in healthy subjects in which we evaluated the effect of AMR101 on certain common prescription drugs. All findings from these studies were consistent with our expectations of no AMR101-related inhibition or metabolism of the drugs studied.

### ***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. Currently all such development is in formulative or pre-clinical stages. We believe that AMR101 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.

### **Manufacturing and Supply for AMR101**

We currently use third party manufacturers and suppliers to manufacture clinical quantities of ethyl-EPA, which constitutes the only active pharmaceutical ingredient, or API, within AMR101, to encapsulate, bottle and package AMR101 and to maintain inventory of AMR101. Our existing supplier, Nisshin Pharma, or Nisshin, which is based in Japan, has produced all of the active pharmaceutical ingredient for AMR101 API for Amarin's clinical trials and has filed a U.S. Drug Master File, or DMF, which contains information defining the processes and facilities used in API manufacture and storage. Key aspects of this specification include pharmaceutical grade compound at a level of purity of at least 96% EPA and containing no DHA. 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. We have entered into agreements with additional suppliers beyond Nisshin to potentially manufacture commercial supply of AMR101 API. However, Nisshin is currently our only supplier of ethyl-EPA. We intend to submit supplemental NDAs, or sNDAs, to the FDA, following an NDA approval, requesting approval of such additional API manufacturers to supplement Amarin's commercial needs, subject to regulatory requirements.

Our agreement with Nisshin for the supply of ethyl-EPA was entered into in November 2010. In connection with this agreement, we paid Nisshin a non-refundable upfront payment of \$0.5 million upon execution of the agreement. In addition, the agreement includes the following financial obligations: a milestone payment of \$0.5 million payable on the first marketing approval of AMR101 in the United States, and minimum purchase obligations that vary based on pre-NDA submission, six months after submission, and within six months after first marketing approval. Under the agreement, Nisshin is responsible for any capital costs required to meet the volume demand of Amarin. The supply agreement with Nisshin may be terminated by either party by giving to the other party a notice in writing in the event of a material breach of the agreement and (where such breach is

## **Table of Contents**

capable of remedy) the breaching party fails to remedy such breach within 60 days of receiving a written notice from the terminating party specifying the breach and requiring its remedy. The agreement may also be terminated by either party immediately by giving a written notice to the other, if a petition is filed by or against the other party for commencement of a bankruptcy proceeding, commencement of corporate reorganization proceeding, commencement of civil rehabilitation proceeding, or any other insolvency proceeding or the other party is unable to pay its debts in the normal course of business. Nisshin may terminate this agreement by giving Amarin 30 days notice in writing if Amarin fails to meet its minimum purchase requirements, unless, within such 30 days, Amarin pays to Nisshin the amount corresponding to the unfulfilled purchases.

If Nisshin has expanded its manufacturing capacity in accordance with the agreement, Nisshin may terminate the agreement in the event that Amarin does not receive marketing approval for AMR101 in the United States on or before December 31, 2014 or in the event Amarin abandons development of AMR101 for hypertriglyceridemia in the United States. If terminated, Amarin is required to reimburse Nisshin for the costs incurred to expand its facility less any profits paid to Nisshin for the purchase of ethyl-EPA by Amarin under the agreement, but in any event, not to exceed \$5.0 million. Unless terminated earlier, in accordance with the terms of the agreement, the agreement shall extend for a period of 10 years from the commencement date after which it may be renewed upon mutual agreement for successive three-year periods.

We believe Nisshin is capable of producing sufficient quantities of AMR101 API to support the initial commercial launch of AMR101. However, based on the positive results of our MARINE and ANCHOR clinical trials and the potential for greater than originally expected product demand, we determined in 2011 to add additional suppliers. Our goals in expanding our supply chain were to provide greater capacity to meet anticipated demand, enable supply diversification and flexibility and introduce cost competition. After conducting an extensive global search for manufactures capable of producing API for AMR101 to our technical specifications, we entered into limited exclusivity, long-term agreements with two additional API suppliers in 2011, Chemport Inc. and Equateq Limited. We are currently working to finalize terms and conditions with a fourth supplier. Certain of our API supply agreements contain provisions under which the cost of supply to us decreases as we purchase increased product volume.

The agreements with each of our API suppliers contemplate phased manufacturing capacity expansions designed to create sufficient manufacturing capacity to meet anticipated demand for API material for AMR101 following FDA approval. Accordingly, Nisshin and our other potential suppliers are currently working to expand and qualify their production capabilities to meet regulatory requirements to manufacture the API for AMR101. 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 they will successfully qualify with the FDA.

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 AMR101, 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 NDA filed with the FDA for AMR101 references one supplier of our API, Nisshin, with which we have had the longest relationship and which we believe is qualified to support our initial commercial launch of AMR101. We have defined with the FDA our plan and specifications for qualifying the additional API suppliers. We intend to submit sNDAs for the use of these additional API suppliers after the suppliers successfully complete the specified process and facility qualifications and after the NDA for the MARINE indication is approved.

For API encapsulation, we submitted two commercial encapsulators as part of our AMR101 NDA. We believe that both of these companies, who currently encapsulate Lovaza<sup>®</sup>, have the capacity and sufficient expertise to support our product launch requirements.

## **Table of Contents**

### **Our Marketing Plans**

We currently have minimal marketing, sales and distribution capabilities. In order to commercialize products that are approved for commercial sale, we must either develop a sales, marketing and distribution infrastructure or collaborate with third parties that have such experience. Until such time that we enter into any such collaborations, if ever, we plan to continue to execute on our plans to market, sell and distribute AMR101 on our own. If we launch AMR101 on our own, we expect to begin hiring the majority of the required sales force after NDA approval. In this scenario, we would seek to initially target the clinicians who are top prescribers of other lipid regulating therapies. We believe accomplishing this for the indication studied in the MARINE trial will require a sales force of approximately 200 to 300 representatives in the United States.

### **Historical Product Development Programs**

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 AMR101. In connection with this private placement, our board of directors and executive management underwent significant change, 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 for Huntington's disease, Myasthenia gravis and Parkinson's disease.

#### ***Huntington's disease***

In 2009, we voluntarily withdrew our previously announced European marketing application for AMR101 relating to an Orphan Medicinal Product indication for a subset of Huntington's disease patients. While the safety profile of AMR101 for Huntington's disease was encouraging, feedback from European regulatory authorities indicated that at least one additional study of AMR101 was required to establish the efficacy of this product candidate in treating motor symptoms of Huntington's disease.

#### ***Myasthenia gravis***

In 2007, we purchased Ester Neurosciences Ltd (Ester), an Israeli pharmaceutical company, and its lead product candidate, EN101, an AChE-R mRNA inhibitor for the treatment of myasthenia gravis, or MG, a debilitating neuromuscular disease. In connection with the acquisition, we assumed a license to certain intellectual property assets related to EN101 from the Yissum Research Development Company of The Hebrew University of Jerusalem.

During 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 authorized to seek a partner for EN101. The amendment agreement also provided that any future payment obligations payable by Amarin to the former shareholders of Ester would be made only out of income received from potential partners.

Under the terms of this amendment agreement, the former Ester shareholders had the option of reacquiring the original share capital of Ester if we are unable to successfully partner EN101. In connection with this amendment agreement, in August 2009 we issued 1,315,789 common shares to the former Ester shareholders.

Following our decision to cease development of EN101, Yissum terminated its license agreement with Amarin. 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.



## **Table of Contents**

We have received correspondence on behalf of the former shareholders of Ester asserting that Amarin is in breach of its amended agreement due to the fact that the Yissum terminated its license and Amarin 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.

### ***Parkinson s disease***

Previously we were engaged in the pre-clinical development of AMR103, a novel delivery form of levodopa, for the treatment of patients with Parkinson s disease. The program was part of our development of different types of chemical linkage to attach a range of bioactive lipids either to other lipids or other drugs. This Targeted Lipid Transport Technology, or TLT, platform can result in novel chemical entities, potentially offering substantial and clinically relevant advantages over either compound alone. However, 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 discontinued all further development of AMR103 and the TLT platform.

### **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 very high triglycerides, and Abbott Laboratories, which currently markets Tricor and Trilipix for the treatment of very high triglycerides and mixed dyslipidemia. In March 2011, Pronova BioPharma Norge AS, which owns the patents for Lovaza, entered into an agreement with Apotex Corp. and Apotex Inc. to settle their patent litigation in the United States related to Lovaza. Pursuant to the terms of the settlement agreement, Pronova granted Apotex a license to enter the U.S. market with a generic version of Lovaza in the first quarter of 2015, or earlier depending on circumstances. We expect Apotex to compete against us as well. Other companies are also seeking to introduce generic versions of Lovaza.

In addition, we are aware of other pharmaceutical companies that are developing products that, if approved, would compete with AMR101. These include a free fatty acid form of omega-3 (comprised of 55% EPA and 20% DHA) which is being developed by Omthera Pharmaceuticals, which completed enrollment in a Phase 3 clinical trial in November 2011 and has announced that it expects to disclose initial top-line data by April 2012, and Trygg Pharma, which has completed a Phase 3 study of an omega-3 based drug candidate for hypertriglyceridemia, but we believe Trygg has not yet announced results from that study. In addition, Acasti Pharma, a subsidiary of Neptune Technologies & Bioresources Inc., announced in late 2011 the enrollment of its Phase 2 clinical trial to assess the safety and efficacy of its omega-3 prescription drug candidate for the treatment of hypertriglyceridemia. We believe Resolvix Pharmaceuticals and Catabasis Pharmaceuticals are also developing potential treatments for hypertriglyceridemia based on omega-3 fatty acids, but we believe that neither has initiated a Phase 2 clinical trial of its product.

AMR101, if approved, will also face competition from dietary supplement companies marketing naturally occurring omega-3 fatty acids as nutritional supplements.

---

## **Table of Contents**

### **Regulatory Matters**

#### ***Government Regulation and Regulatory Matters***

Any product development activities related to AMR101 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. There is no assurance that we will receive FDA approval for AMR101 or any other product.

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.

## **Table of Contents**

### ***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. In addition, in order to seek approval for a potentially expanded indication based on the ANCHOR study, we will be required to have substantially enrolled subjects in a medical outcomes study at the time of our NDA submission, and the MARINE indication must be approved. Based upon feedback from the FDA and in accordance with the SPA for the ANCHOR study, we do not believe that the results of the REDUCE-IT outcomes study are required for approval of the indication studied in the ANCHOR trial.

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 AMR101 or a future product is approved, FDA's review will be lengthy and we may encounter significant difficulties or costs during the review process. After approving any drug product, the FDA may require post-marketing testing and surveillance to monitor the effects of approved products or it may place conditions on approvals including potential requirements or risk management plans that could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

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

In the European Union (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

## **Table of Contents**

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 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.

## **Table of Contents**

### ***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 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.

### ***Marketing Exclusivity***

Market-exclusivity provisions under the Food, Drug and Cosmetic Act, or FDCA, also can delay the submission or the approval of certain 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). 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. 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.

---

## **Table of Contents**

With respect to AMR101, we are seeking five-year NCE marketing exclusivity under the FDCA. We believe that the active pharmaceutical ingredient in AMR101, at least 96% ethyl-EPA, may be considered a new chemical entity, and could therefore be eligible for five-year market exclusivity under the FDCA if the NDA is approved. The only other omega-3 based product approved by the FDA is Lovaza. We believe the active moiety in Lovaza and the active moiety in AMR101 are different. Lovaza was approved as a lipid-regulating agent by the FDA in 2004 and has been described in its FDA-approved product label as a combination of ethyl esters of omega-3 fatty acids, principally ethyl-EPA and ethyl-DHA. Our belief that AMR101 should be granted NCE exclusivity is based in part on precedent at the FDA for granting NCE status to a previously uncharacterized active moiety, in this case, potentially ethyl-EPA that was part of a previously approved product. It is currently unclear whether the FDA will view the ethyl-EPA in AMR101 as a previously approved active moiety in Lovaza and deny our request that AMR101 be granted NCE status and the associated period of regulatory exclusivity. We expect the FDA determination on NCE exclusivity will be made in connection with, or soon after, an NDA approval of the MARINE application, if approved, but we cannot assure you that we will be granted NCE exclusivity even if the NDA is approved. If we are not granted NCE exclusivity, we may be granted three-year exclusivity. We also plan to seek regulatory exclusivity for AMR101 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.

Pediatric exclusivity is another type of exclusivity in the United States. Pediatric exclusivity, if granted, provides an additional six months to an existing exclusivity or a statutory delay in approval resulting from a patent certification. This six-month exclusivity, which runs from the end of other exclusivity protections or patent delay, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued Written Request for such a study. If market exclusivity, as described above, is successful, we will consider pursuing pediatric exclusivity, although there can be no assurance that we will be successful.

### **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. We seek to protect our chemical compounds and technologies by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. We also rely on trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position. We, or our licensors, file patent applications directed to our key drug candidates in an effort to establish intellectual property positions regarding new chemical entities relating to our product candidates as well as uses of new chemical entities in the treatment of diseases. Our patenting strategy encompasses pursuing patents for compositions, formulations, indications/uses and combinations with other drugs. Amarin is prosecuting multiple patent applications in an effort to protect the intellectual property developed during the AMR101 cardiovascular program.

We believe that patent protection of our technologies, processes and products is important to our future operations. The success of our products may depend, in part, upon our ability to obtain strong patent protection. There can, however, be no assurance that:

any patents will be granted from our pending patent applications directed to AMR101 or any of our future products in any or all appropriate jurisdictions;

any patents that we or our licensees may obtain will not be successfully challenged in the future;

our technologies, processes or products will not infringe upon the patents of third parties; or

the scope of any patents will be sufficient to prevent third parties from developing similar products.

Our strategy is to file patent applications where we think it is appropriate to protect and preserve the proprietary technology and inventions considered significant to our business. We currently have no patents that directly apply to the use of AMR101 for hypertriglyceridemia, hyperlipidemia or cardiovascular therapy in the

---

## **Table of Contents**

United States or Europe. We have filed and are prosecuting numerous patent applications in the United States and internationally that seek to protect the proprietary position of AMR101. 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 based upon what we believe are unexpected findings from the MARINE and ANCHOR trials. If granted, we believe that many of these resulting patents would expire in 2030 or beyond. However, no assurance can be given that any of our patent applications will be granted or, if they are granted, that they will prevent competitors from competing with AMR101. Securing patent protection for a product is a complex process involving many legal and factual questions. The patent applications we have filed in the United States and internationally are at varying stages of examination, the timing of which is outside our control. The process to getting a patent granted can be lengthy and claims initially submitted are often modified in order to satisfy the requirements of the patent office. This process includes written and public communication with the patent office. The process can also include direct discussions with the patent examiner. There can be no assurance that the patent office will accept our arguments with respect to any patent application or with respect to any claim therein. The timing of the patent review process is independent of and has no effect on the timing of the FDA's review of our NDA. To our knowledge, the U.S. Patent and Trademark Office or other international patent offices have not yet commenced examining certain of these applications. While examination of certain of these applications is anticipated during 2012, we cannot predict the timing or results of such examination. In addition, we may elect to submit, or the patent office may require, additional evidence to support certain of the claims we are pursuing. Providing such additional evidence could result in us incurring additional costs. We cannot be certain what commercial value any granted patent in our patent portfolio will provide to us.

We will also rely upon trade secrets and know-how to retain our competitive position.

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 in the United States, it is possible that those parties will obtain patents that will be sufficiently broad so as to prevent us from utilizing such technology. In addition, we may use unpatented proprietary technology, in which case there would be no assurance that others would not develop similar technology. See Item 1A

**Risk Factors** **Risks Related to our Intellectual Property and Regulatory Exclusivity** We are dependent on patents, proprietary rights and confidentiality, and **Risk Factors** **Risks Related to our Business** Potential technological changes in our field of business create considerable uncertainty .

### **Patent Term Restoration**

Depending upon the timing, duration and specifics of FDA approval of the use of AMR101, if the NDA is approved, we believe that some of our U.S. patents may be eligible for a limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and the extension must be applied for prior to expiration of the patent. The United States Patent and Trademark Office, in consultation with the FDA, reviews and approves the applications for any patent term extension or restoration for an approved NDA. In the future, we intend to apply for restorations of patent term for some of our currently owned or licensed patents to add patent life beyond their current expiration date, depending on the expected length of clinical trials and other factors involved in the filing of the relevant NDA.

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

At December 31, 2011, we had 31 full-time employees employed in marketing, general and administrative and research and development functions. We believe our relations with our employees are good.

**Organizational Structure**

At December 31, 2011, we had the following subsidiaries:

<b>Subsidiary Name</b>	<b>Country of Incorporation or Registration</b>	<b>Proportion of Ownership Interest and Voting Power Held</b>
Amarin Pharmaceuticals Ireland Limited	Ireland	100%
Amarin Pharma Inc.	United States	100%
Amarin Neuroscience Limited	Scotland	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 activity being conducted by Amarin Neuroscience Limited 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 3.50% 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 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.



---

## **Table of Contents**

### **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, the progress and timing of our clinical programs, the safety and efficacy of our product candidates, regulatory filings and commercialization activities, the potential clinical benefits and market potential of our product candidates, commercial market estimates, future development efforts, patent protection, effects of healthcare reform, reliance on third parties, and other risks set forth below.*

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

*We have a history of losses and anticipate that we will incur continued losses for the foreseeable future.*

We have not been profitable in any of the last five fiscal years. For the fiscal years ended December 31, 2011, 2010, and 2009, we reported losses of approximately \$69.1 million, \$249.6 million, and \$30.6 million, respectively. Substantially all of our operating losses resulted from costs incurred in connection with our research and development programs, from general and administrative costs associated with our operations, and from non-cash losses on changes in the fair value of warrant derivative liabilities. We expect to incur additional and increasing operating losses over the next several years. These losses, combined with expected future losses, have had and will continue to have an adverse effect on our cash resources, shareholders' deficit and working capital. We expect our research and development expenses to significantly increase in connection with our proposed clinical outcomes study for AMR101 and any other studies for our product candidates. In addition, if we obtain regulatory approval for any of our product candidates, we may incur significant sales, marketing, in-licensing and outsourced manufacturing expenses, as well as continued research and development expenses. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all.

*We have not generated any revenue from our product candidates and may never be profitable.*

Our ability to become profitable depends upon our ability to generate revenue. Unless and until marketing approval is obtained from either the FDA or European Medicines Agency, which we refer to as the EMA, for any of our product candidates, or we are otherwise able to acquire rights to products or product candidates that have received regulatory approval or are at an advanced stage of development and can be readily commercialized, we may not be able to generate sufficient revenue to attain profitability. In addition, our ability to generate profits after any FDA or EMA approval of our product candidates is subject to our ability to contract for the manufacture of commercial quantities of our product candidates at acceptable cost levels and establish sales and marketing capabilities or identify and enter into one or more strategic collaborations to effectively market and sell any approved product candidate.

Even if one of our product candidates is approved for commercial sale, any approved product candidate may not gain market acceptance or achieve commercial success. In addition, we would anticipate incurring significant costs associated with commercializing any approved product. We may not achieve profitability soon after generating product sales, if ever. If we are unable to generate product revenues, we will not become profitable and may be unable to continue operations without continued funding.

*Our ability to generate revenue depends on obtaining regulatory approvals for our products.*

In order to successfully commercialize a product, we or our potential partners are required to conduct tests and successfully complete clinical trials needed in order to meet regulatory requirements and to obtain applicable regulatory approvals. The costs of developing and obtaining regulatory approvals for pharmaceutical products

## **Table of Contents**

can be substantial. Our ability to commercialize any of our products in development is dependent upon the success of development efforts in clinical studies. If these clinical trials fail to produce satisfactory results, or if we are unable to maintain the financial and operational capability to complete these development efforts, we may be unable to generate revenues. Even if we obtain regulatory approvals, the timing or scope of any approvals may prohibit or reduce our ability to commercialize products successfully. For example, if the approval process 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 may not have the scope or breadth needed for us to commercialize products successfully.

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

As a consequence of our decision in 2009 to focus on product development for cardiovascular indications and the discontinuation of development work related to other product candidates, 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 if we require additional clinical trials to obtain regulatory approval of AMR101, as a result of the initiation of the REDUCE-IT cardiovascular outcomes study and as we prepare for the commercialization of AMR101. Accordingly, our historical financial results reflect a substantially different business from that currently being conducted. In addition, we have not yet demonstrated an ability to obtain regulatory approval for or 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.

***We will require substantial additional resources to fund our operations and to develop our product candidates. 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. At December 31, 2011, we had cash and cash equivalents of approximately \$116.6 million. We believe that our current resources will be sufficient to fund our projected operations for the next twelve months, which projected operations contemplate not only working capital and general corporate needs but also commercial preparation of AMR101 and the continuation of the REDUCE-IT cardiovascular outcomes study. In order to commercialize AMR101, we must either develop a sales, marketing and distribution infrastructure or collaborate with third parties that have such experience. We plan to consider collaboration opportunities with larger pharmaceutical companies for the launch, marketing and sale of AMR101. Although from time to time we are in discussions with pharmaceutical companies regarding such collaboration, there can be no assurance that these discussions will result in any such transaction. Accordingly, we are also developing plans to launch, market and sell AMR101 in the United States on our own.

If we do not enter into a strategic collaboration in connection with the launch, marketing and sale of AMR101, we will likely need to raise additional capital to fully support these efforts. We will also need additional capital to fully complete our REDUCE-IT cardiovascular outcomes trial.

## **Table of Contents**

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

whether or not we enter into a strategic collaboration in connection with the launch, marketing and sale of AMR101;

the time and costs involved in obtaining regulatory approvals for AMR101;

the continued cost associated with the REDUCE-IT outcomes study to support the filing of an NDA for the clinical indication evaluated in the ANCHOR trial;

the number of additional product candidates we may pursue;

the costs involved in filing and prosecuting patent applications and enforcing or defending patent claims; and

the costs associated with commercializing our product candidates if they receive regulatory approval, including the cost and timing of developing sales and marketing capabilities, or the cost and timing of securing commercial supply of AMR101 and the timing of entering into strategic collaboration with others relating to the commercialization of our product candidates, if at all.

If we do not enter into a collaboration agreement to support the commercialization of AMR101, or if adequate funds are not available to us in amounts or on terms acceptable to us or on a timely basis, or at all, we may be required to terminate or delay our development efforts in support of our product candidates, or delay the advancement of the REDUCE-IT cardiovascular outcomes trial, or delay our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize AMR101, in the event we obtain regulatory approval for this product candidate.

***Continued negative economic conditions would likely have a negative impact on Amarin's 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 any of our product candidates, 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.

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

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

As of December 31, 2011, there were warrants outstanding for the purchase of up to 21,106,363 American Depositary Shares, or ADSs, each representing one of our ordinary shares, with a weighted average exercise price of \$1.48 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 an initial exchange rate of 113.4752 ADS per \$1,000 principal amount of notes, if we elected physical settlement, the notes would initially be exchangeable into 17,021,280 ADS.

## **Table of Contents**

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 or product candidates, or grant licenses on terms that are not favorable to us.

### ***We are dependent upon the success of AMR101.***

If development efforts for AMR101, including regulatory approval, are not successful for the MARINE, ANCHOR or any other indication, or if adequate demand for AMR101 is not generated, 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 AMR101. If we are not successful in developing any future product or products, or if there is not adequate demand AMR101 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. As a result, the limited range of products we develop could constrain our ability to generate revenues and achieve profitability.

### **Risks Related to the Development and Commercialization of our Product Candidates**

***There can be no assurance that our NDA submitted to the FDA seeking approval to market AMR101 will be approved and there can be no assurance that the FDA will complete its review of our NDA by the PDUFA date.***

On September 26, 2011, we submitted an NDA to the FDA seeking approval to market AMR101 in the United States for use in the treatment of patients with very high triglyceride levels, or the MARINE indication, and the FDA has assigned a Prescription Drug User Fee Act, or PDUFA, date of July 26, 2012 for the completion of its review. The PDUFA date is the goal date for the FDA to complete its review of the NDA. However, there can be no assurance that the FDA will complete its review of the NDA by this date. The FDA may deny approval of the application and require additional testing or data. In the event the FDA takes any such action, such actions would have a material adverse effect on our operations and financial condition.

***Our SPA agreements with the FDA are not guarantees of FDA approval of AMR101 for the subject indications.***

An SPA agreement is an evaluation by the FDA of a protocol with the goal of reaching an agreement that the Phase 3 trial protocol design, clinical endpoints, and statistical analyses are acceptable to support regulatory approval of the drug product candidate with respect to effectiveness for the indication studied. The MARINE trial and ANCHOR trial were each conducted under an SPA with the FDA. The REDUCE-IT trial is also being conducted under an SPA with the FDA. The FDA agreed that, based on the information we submitted to the agency, the design and planned analysis of the MARINE and ANCHOR trials are adequate to support use of the studies as the primary basis for approval with respect to effectiveness. An 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 is identified after the study begins, or if the study sponsor fails to follow the protocol that was agreed upon with the FDA. There is no assurance that the FDA will not identify a scientific issue and deem either or both of our SPAs no longer binding. Moreover, any change to a study protocol after agreement with the FDA is reached can invalidate an SPA. While we amended the protocol for the ANCHOR trial after the initial SPA evaluation was completed, we obtained the FDA's evaluation of, and agreement to, the amendment. If, for example, the FDA does not consider the applicable SPA to be binding during its review of our regulatory approval applications, or if the FDA determines that we did not follow the SPAs appropriately, the agency could assert that additional studies or data are required to support approval of the application.

---

## **Table of Contents**

***Even if we obtain marketing approval for AMR101 in the United States, there can be no assurance as to the final indication or indications approved by the FDA, and the commercial value to us of any approved indication may be smaller than we anticipate.***

There can be no assurance as to the final indication approved by the FDA, in the event that marketing approval is obtained. Even if marketing approval is obtained, the number of actual patients with the condition included in such approved indication may be smaller than we anticipate. For example, the FDA could approve the MARINE indication and not the ANCHOR indication. Even if we obtain marketing approval, 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. If any such approved indication is narrower than we anticipate, the market potential for our product candidate would suffer.

***Even if we obtain marketing approval for AMR101 in the United States, it may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community necessary for commercial success.***

If AMR101 receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors and others in the medical community. Gaining market acceptance for our product may be particularly difficult. If AMR101 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 our product candidates, if approved for commercial sale, will depend on a number of factors, including:

efficacy and potential advantages compared to alternative treatments;

the ability to offer AMR101 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 strength of marketing and distribution support;

sufficient third-party coverage or reimbursement; and

the prevalence and severity of any side effects.

***Even if our products are approved, we may not be able to compete effectively against our competitors' pharmaceutical products.***

The pharmaceutical industry is highly competitive. If we are successful in completing the development of any of our products, we may face competition to the extent other pharmaceutical companies have on the market or are able to develop products for the treatment of similar indications. Potential competitors in this market include companies with greater resources and name recognition than we have. Furthermore, to the extent we are able to acquire or develop additional marketable products in the future, such products will compete with a variety of other products within the United States or elsewhere, possibly including established drugs and major brand names. Competitive factors, including generic competition, could force us to lower prices or could result in reduced sales. In addition, new products developed by others could emerge as competitors to our future products. Products based on new technologies or new drugs could render our products obsolete or uneconomical.

The success of our future products will also depend in large part on the willingness of physicians to prescribe these products to their patients. Our future products may compete against products that have achieved broad recognition and acceptance among medical professionals. In order to achieve an acceptable level of prescriptions for our future products, we must be able to meet the needs of both the medical community and end users with respect to cost, efficacy and other factors.



---

## **Table of Contents**

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 very high triglycerides, and Abbott Laboratories, which currently markets Tricor and Trilipix for the treatment of very high triglycerides and mixed dyslipidemia. In March 2011, Pronova BioPharma Norge AS, which owns the patents for Lovaza, entered into an agreement with Apotex Corp. and Apotex Inc. to settle their patent litigation in the United States related to Lovaza. Pursuant to the terms of the settlement agreement, Pronova 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. We expect Apotex to compete against us as well. Other companies are also seeking to introduce generic versions of Lovaza. These competitors have 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, would compete with AMR101. These include a free fatty acid form of omega-3 (comprised of 55% EPA and 20% DHA) which is being developed by Omthera Pharmaceuticals, which completed enrollment in a Phase 3 clinical trial in November 2011 and has announced that it expects to disclose initial top-line data by April 2012, and Trygg Pharma, which has completed a Phase 3 study of an omega-3 based drug candidate for hypertriglyceridemia, but we believe Trygg has not yet announced results from that study. In addition, Acasti Pharma, a subsidiary of Neptune Technologies & Bioresources Inc., announced in late 2011 the enrollment of its Phase 2 clinical trial to assess the safety and efficacy of its omega-3 prescription drug candidate for the treatment of hypertriglyceridemia. We believe Resolvix Pharmaceuticals and Catabasis Pharmaceuticals are also developing potential treatments for hypertriglyceridemia based on omega-3 fatty acids, but neither has initiated a Phase 2 clinical trial of its product.

AMR101, if approved, will also face competition from dietary supplement companies marketing naturally occurring omega-3 fatty acids as nutritional supplements.

***Our current lead product candidate 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, our lead product candidate, if approved, would be subject to non-prescription competition and consumer substitution.***

Our current lead product candidate, AMR101, is a prescription-only omega-3 fatty acid. Mixtures of omega-3 fatty acids are naturally occurring substances in various foods, including fatty fish. Omega-3 fatty acids are also marketed by others as non-prescription dietary supplements. We believe the pharmaceutical grade purity of AMR101, if approved, will have a superior therapeutic profile to naturally occurring omega-3 fatty acids and dietary supplements. However, we cannot be sure physicians will view AMR101, if approved, as superior. To the extent the price of AMR101, if approved, is significantly higher than the prices of commercially available omega-3 fatty acids marketed by other companies as dietary supplements, physicians may recommend these commercial alternatives instead of writing prescriptions for AMR101 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 AMR101.

***To maximize the commercial potential of AMR101, if approved, we may need to find collaborative partners to help market and sell the product.***

To commercialize AMR101, we must either develop a sales, marketing and distribution infrastructure or collaborate with third parties that have such experience. We plan to consider collaboration opportunities with larger pharmaceutical companies for the launch, marketing and sale of AMR101. If we do complete such a collaboration agreement, we will be reliant on one or more of these strategic partners to generate revenue on our behalf.

---

## **Table of Contents**

We may not be successful in finding a collaborative partner to help market and sell our products, or may be delayed in doing so, in which case we would not receive revenue or royalties on the timeframe and to the extent that we currently anticipate. 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. If that were to occur, we may have to curtail the development of a particular product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of our sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we will need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we cannot raise sufficient funds, we will not be able to bring our product candidates to market effectively and generate as much product revenue as we could under a collaboration.

***If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market AMR101, we may not be successful in commercializing AMR101 on our own, if and when AMR101 is approved.***

To achieve commercial success for any approved product, we must either develop a sales and marketing organization or outsource these functions to third parties. Until such time as we complete a strategic transaction with a third party to market and sell AMR101, if ever, we are continuing to develop plans to launch, market and sell AMR101 on our own. This includes making preparations for securing a sufficient commercial supply of AMR101 and expanding sales and marketing capabilities and would require that we build a substantial commercialization infrastructure in order to compete with larger companies with established marketing and sales capabilities. We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical products. There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our products on our own include:

our inability to recruit and retain adequate numbers of effective sales and marketing personnel;

the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe any future products;

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 creating an independent sales and marketing organization.

If we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenues or the profitability of these product revenues to us are likely to be lower than if we were to market and sell any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our product candidates or doing so on terms that are favorable to us. 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 we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.



---

**Table of Contents**

*If approved, 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 by our partners, 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. 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. Application holders must obtain FDA approval for product and manufacturing changes, depending on the nature of the change. 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 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. If we receive marketing approval for AMR101, physicians may nevertheless prescribe AMR101 to their patients in a manner that is inconsistent with the approved 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.

*Our cardiovascular outcomes study, REDUCE-IT, may take longer than we anticipate to be determined by the FDA to be substantially underway, which could delay FDA review and approval of the ANCHOR indication and cost more than we expect. The FDA may not approve our request to consider the indication studied in the ANCHOR trial in conjunction with the FDA's review of the indication studied in the MARINE trial.*

Based on our communications with the FDA, in order to obtain FDA marketing approval of a separate indication for the use of AMR101 in the treatment of patients with high triglyceride levels who are also on statin

---

**Table of Contents**

therapy for elevated LDL-cholesterol levels (which we refer to as mixed dyslipidemia), or the ANCHOR indication, we believe that we must first obtain approval in the MARINE indication and have a cardiovascular outcomes study substantially underway at the time of the NDA submission. In August 2011, we reached an agreement with the FDA on an SPA for the design of the REDUCE-IT cardiovascular outcomes study of AMR101, and we began dosing patients in December 2011. In the event we do not receive approval of the MARINE indication or experience delays in initiating or achieving substantial enrollment for REDUCE-IT or the FDA requires that we enroll more patients, our filing of an sNDA seeking approval of the ANCHOR indication will be delayed. We currently intend to file an sNDA seeking approval of the indication studied in the ANCHOR trial after we receive FDA marketing approval for the MARINE indication and after we believe the REDUCE-IT study will be determined to be substantially underway by the FDA.

***The REDUCE-IT cardiovascular trial may fail to achieve its clinical endpoints, and the long-term clinical results of AMR101 may not be consistent with the clinical results we observed in our Phase 3 pivotal trials.***

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 AMR101 on lipids and no outcomes study has been conducted evaluating AMR101. Outcomes studies of certain other lipid modifying therapies have failed to achieve the endpoints of such studies. 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 AMR101 in REDUCE-IT or any other study of AMR101 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 current good manufacturing practices for use in clinical trials;

slower than expected rates of patient recruitment;

---

**Table of Contents**

the inability to observe patients adequately after treatment;

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. Similarly, positive results from studies in Japan of a product containing the same active ingredient in AMR101 may not be predictive of success for AMR101 in trials outside of Japan. 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 AMR101 Phase 3 clinical trials for the treatment of Huntington's disease were negative. As a result, we stopped development of that product candidate, we revised our clinical strategy and shifted our focus to develop AMR101 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 our products, if approved.***

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;



---

**Table of Contents**

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.

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 pharmaco-economic study that compares the cost-effectiveness of our product candidates to other available therapies. Such pharmaco-economic 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 potentially involved in commercialization, we may encounter difficulties in managing our growth and expanding our operations successfully.***

Although certain of our employees have commercialization experience, as a company we currently have no sales, marketing or distribution capabilities. Accordingly, as we advance AMR101 through the development stage towards commercialization, we will need to expand our organization, including marketing and sales capabilities or contract with third parties to provide these capabilities for us, which will be expensive and time consuming. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of AMR101 in the event it receives regulatory approval. If we are not successful in commercializing AMR101 or our other product candidates in the event they receive regulatory approval, our future product revenue will suffer and we may incur significant additional losses.

As our operations expand, 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. Our future financial performance and our ability to commercialize AMR101 and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts effectively, and hire, train and integrate 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.

---

## **Table of Contents**

### **Risks Related to our Reliance on Third Parties**

***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 supply of ethyl-EPA it would have a material adverse affect on our ability to commercialize AMR101.

We currently purchase all of our supply of the bulk compound (ethyl-EPA), which constitutes the only active pharmaceutical ingredient, or API, of AMR101, from a single supplier with a single manufacturing facility, Nisshin Pharma, or Nisshin, located in Japan. Nisshin currently obtains its supply of the key raw material to manufacture API from another third party single source of supply. While we have contractual freedom to source the API for AMR101 elsewhere and have entered into supply agreements with additional suppliers who rely on other third party suppliers of the key raw material to manufacture the API for AMR101, Nisshin is the only supplier submitted for approval with our pending NDA to the FDA. Further, our agreements with our suppliers typically include minimum purchase obligations. Moreover, there is no guarantee that additional other suppliers with which we have contracted to supply 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 AMR101. 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.

***The manufacture and packaging of pharmaceutical products such as AMR101 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 AMR101, are regulated by the FDA and similar foreign regulatory bodies and must be conducted in accordance with the FDA's current good manufacturing practices and comparable requirements of foreign regulatory bodies. There are a limited number of manufacturers that operate under these current good manufacturing practices regulations who are both capable of manufacturing AMR101 and willing to do so. Failure by us or our third party manufacturers to comply with applicable regulations, requirements, or guidelines could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our products, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business. For example, our NDA filed with the FDA has only one supplier of API for AMR101, Nisshin, and Nisshin has plans to expand its capacity to supply API to us by building a new facility. If Nisshin facilities used for the manufacturing and testing of AMR101 API are delayed in passing FDA pre-approval inspection to ensure substantial compliance with current good manufacturing practices and other FDA standards, or if we are not able to manufacture

---

## **Table of Contents**

AMR101 to required specifications through Nisshin, our FDA marketing approval of AMR101 may be delayed, we may be delayed in launching the product and our anticipated future revenues and financial results may be materially adversely affected. The same requirements and risks are applicable to the suppliers of the key raw material used to manufacture the API for AMR101.

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 current good manufacturing practices. Any new facility is 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, after FDA approval of AMR101, we plan to file a supplemental NDA to add new manufacturing facilities from other third party suppliers to manufacture API for AMR101. If these third parties cannot establish, to the satisfaction of the FDA, that they are in substantial compliance with current good manufacturing practices, and that the products manufactured at the new site meet FDA requirements, we may not be able to manufacture API from that site, our supply of API for AMR101 may be delayed, and our anticipated future revenues and financial results may be materially adversely affected.

Furthermore, in order to obtain approval of our products, including AMR101, by the FDA and foreign regulatory agencies, we will be required to consistently produce the active pharmaceutical ingredient and the finished product in commercial quantities and of specified quality on a repeated basis and document our ability to do so. This requirement is referred to as process validation. We have completed a validation process for the API for AMR101 at Nisshin, but have not yet done so at any other contract supplier. Each of our potential API suppliers use a different method to manufacture API, which has the potential to increase the risk to us that our manufacturers will meet applicable regulatory requirements. We also need to complete process validation on the finished product in the packaging we propose for commercial sales. This includes testing of stability, 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, we may not obtain approval to launch the product or approval, launch or commercial supply after launch may be delayed.

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.

During 2012, we intend to increase our purchases of API and finished capsules of AMR101 in preparation of commercial launch. We plan to make certain of these purchases prior to NDA approval with the aim to further expand purchase levels of supply after NDA approval. We may elect to make API purchases from certain of our suppliers after we are satisfied that the material they produce and their facilities are qualified. However, in the event that we make such purchases, we will not be able to use such material for commercial sale until the sNDA for the applicable supplier is approved by the FDA. Similarly, if we are not compliant with other regulations with regard to this intended purchase of supply, our launch may be delayed.

***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 trial. 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

## **Table of Contents**

contractual duties or meet expected deadlines, we may be delayed in obtaining regulatory approvals for our product candidates and may be delayed in our efforts to successfully commercialize our product candidates for targeted diseases.

### **Risks Related to our Intellectual Property and Regulatory Exclusivity**

#### ***We are dependent on patents, proprietary rights and confidentiality.***

Because of the significant time and expense involved in developing new products and obtaining regulatory approvals, it is very important to obtain patent and trade secret protection for new technologies, products and processes. Our ability to successfully implement our business plan will depend in large part on our ability to:

acquire patented or patentable products and technologies;

obtain and maintain patent protection or market exclusivity for our current and acquired products;

preserve any trade secrets relating to our current and future products; and

operate without infringing the proprietary rights of third parties.

We currently have no issued patents that directly apply to the use of AMR101 for hypertriglyceridemia, hyperlipidemia or cardiovascular therapy in the United States or Europe. Although we are currently prosecuting a number of patent applications in this area, we will also rely upon trade secrets and know-how to retain our competitive position. When deemed appropriate, we intend to vigorously enforce our patent protection and intellectual property rights. We file patent applications either on a country-by-country basis or by using the European or international patent cooperation treaty systems.

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 go 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.

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 upon patents that we own or that have been licensed to us. 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 patent applications to delay the approval process or to challenge granted patents, even if the opposition or challenge has little or no merit. Patent opposition proceedings and challenges are generally highly technical, time consuming and expensive to pursue. Were we to be subject to one or more patent oppositions or challenges, that effort could consume substantial time and resources, with no assurances of success, even when holding an issued patent.



---

**Table of Contents**

*There can be no assurance that any of our pending patent applications relating to AMR101 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 AMR101. 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 positive 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 patent applications will be granted or, if they grant, that they will prevent competitors from competing with AMR101. Securing additional patent protection for a product is a complex process involving many legal and factual questions. The patent applications we have filed in the United States and internationally are at varying stages of examination, the timing of which is outside our control. The process to getting a patent granted can be lengthy and claims initially submitted are often modified in order to satisfy the requirements of the patent office. This process includes written and public communication with the patent office. The process can also include direct discussions with the patent examiner. There can be no assurance that the patent office will accept our arguments with respect to any patent application or with respect to any claim therein. The timing of the patent review process is independent of and has no effect on the timing of the FDA's review of our NDA. To our knowledge, the U.S. Patent and Trademark Office or other international patent offices have not yet commenced examining certain of these applications. While examination of certain of these applications is anticipated during 2012, we cannot predict the timing or results of such examination. In addition, we may elect to submit, or the patent office may require, additional evidence to support certain of the claims we are pursuing. Providing such additional evidence could result in us incurring additional costs. We cannot be certain what commercial value any granted patent in our patent estate will provide to us.

*If AMR101 is not granted new chemical entity exclusivity protection from the FDA our business may be materially harmed.*

Under sections 505(c)(3)(E)(ii) and 505(j)(5)(F)(ii) of 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, a new chemical entity that is granted regulatory approval may be eligible for five years of marketing exclusivity in the United States following regulatory approval. A drug can be classified as a new chemical entity if the FDA has not previously approved any other drug containing the same active moiety.

We believe that the active pharmaceutical ingredient in AMR101, at least 96% ethyl-EPA, may be considered a new chemical entity under the Hatch-Waxman Amendments and would therefore be eligible for five-year market exclusivity under the FDCA. The only other omega-3 based product approved by the FDA is Lovaza. We believe the active moiety in Lovaza and the active moiety in AMR101 are different. Lovaza was approved as a lipid-regulating agent by the FDA in 2004 and has been described in its FDA-approved product label as a combination of ethyl esters of omega-3 fatty acids, principally ethyl-EPA and ethyl-DHA. Our belief that AMR101 should be granted NCE exclusivity is based in part on precedent at FDA for granting NCE status to a previously uncharacterized active moiety, in this case, potentially ethyl-EPA, that was part of a previously approved product. It is currently unclear whether the FDA will view the ethyl-EPA in AMR101 as a previously approved active moiety in Lovaza and deny our request that AMR101 be granted new chemical entity status and the associate period of regulatory exclusivity. We expect the FDA determination on NCE exclusivity will be made in connection with, or soon after, an NDA approval of the MARINE application, and cannot assure you that we will be granted NCE exclusivity.

This marketing exclusivity, if granted, would preclude approval during the exclusivity period of certain 505(b)(2) applications or certain abbreviated new drug applications submitted by another company for another version of the drug. If we are not able to gain or exploit the period of marketing exclusivity, we may face significant competitive threats to our commercialization of these compounds from other manufacturers, including

## **Table of Contents**

the manufacturers of generic alternatives. Further, even if AMR101 is considered to be a new chemical entity and we are able to gain five-year marketing exclusivity, another company could also gain such marketing exclusivity under the provisions of the FDCA, as amended by the Hatch-Waxman Amendments, if such company can, under certain circumstances, complete a human clinical trial process and obtain regulatory approval of its product.

*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 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**

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

We are engaged in the biopharmaceutical field, which is characterized by extensive research efforts and rapid technological progress. New developments in research are expected to continue at a rapid pace in both industry and academia. We cannot assure you that research and discoveries by others will not render some or all of our programs or product candidates uncompetitive or obsolete. Our business strategy is based in part upon new and unproven technologies to the development of biopharmaceutical products for the treatment of cardiovascular diseases. 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.*

Prior to 2005, we had commercial revenue and remain subject to the potential risk of product liability claims relating to the manufacturing and marketing of our former products during the period prior to their divestiture. Any person who is injured as a result of using one of our former products during our period of ownership 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 can not 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

## **Table of Contents**

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 correspondence on behalf of the former shareholders of Ester asserting that we are in breach of its amended agreement due to the fact that the 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.

***We will incur significant, increased costs as a result of provisions of the Sarbanes-Oxley Act of 2002, and our management will be required to devote substantial time to new compliance initiatives.***

The Sarbanes-Oxley Act of 2002 requires, among other things, that we maintain effective internal controls for financial reporting and disclosure. In particular, we perform system and process evaluation and testing of our internal controls over financial reporting and our independent registered public accounting firm reports on the effectiveness of our internal controls over financial reporting, as required by Section 404 of The Sarbanes-Oxley Act of 2002. Based on this evaluation and testing, our management identified a material weakness in internal control over financial reporting as of December 31, 2009 which persisted on December 31, 2010 and which was remediated as of December 31, 2011. Our testing, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be new material weaknesses. We expect to incur significant expense and devote substantial management effort toward ensuring compliance with Section 404. We currently do not have an internal audit function, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. Moreover, the identification by us or our independent registered public accounting firm of deficiencies in our internal controls that are deemed to be additional material weaknesses could cause the market price of the ADSs to decline, and we could be subject to sanctions or investigations by The NASDAQ Stock Market, the SEC or other regulatory authorities, which would entail expenditure of additional financial and management resources.

***We have previously identified a material weakness in our internal control over financial reporting in the past and cannot assure you that material weaknesses will not occur in the future.***

As part of the annual financial statement review under International Financial Reporting Standards for the period ended December 31, 2009, management concluded that as of December 31, 2009 there was a deficiency in the company's internal control over financial reporting relating to the technical expertise and review over the accounting for complex, non-routine transactions that could result in a material misstatement of the consolidated financial statements that would not be prevented or detected on a timely basis. Accordingly, management determined that this control deficiency constituted a material weakness. During 2010, we did not engage in any new non-routine transactions. Nevertheless, based on management's evaluation of our internal control over financial reporting as of December 31, 2010, management determined that this material weakness in our internal control over financial reporting remained. Specifically, our management concluded there was a deficiency in the company's internal control over financial reporting relating to the technical expertise and review over the accounting for complex, non-routine transactions that could result in a material misstatement of the consolidated financial statements that would not be prevented or detected on a timely basis.

## **Table of Contents**

In response to this material weakness, our management, with the input, oversight, and support of the Audit Committee, identified and took the following steps to remediate the control deficiency: non-ordinary course transactions are now considered and evaluated by senior finance management; we continue to prepare accounting position papers for all complex transactions; and, where appropriate, management seeks the advice of outside consultants on accounting matters related to the application of U.S. GAAP to complex, non-ordinary course transactions and in other instances as warranted. Any future deficiencies could materially and adversely affect our ability to provide timely and accurate financial information, and the current and future deficiencies may impact investors' confidence in our internal controls and our company, which could cause our stock price to decline.

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

Under current U.K. legislation, a company incorporated in England and Wales, or which is centrally managed and controlled in the U.K., is regarded as resident in the U.K. 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 U.K. and Ireland then the provisions of article 4(3) of the Double Tax Convention between the U.K. 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. There is intense competition for qualified personnel in the areas of our activities. In this environment, we may not be able to attract and retain the personnel necessary for the development of our business, particularly if we do not achieve profitability. The failure to recruit key scientific, technical and management personnel would be detrimental to our ability to implement our business plan.

## 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 January 31, 2012 we had 135,929,996 common shares outstanding. As of January 31, 2012 there were 135,612,162 shares held as ADSs and 317,834 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:

the status of our patent prosecution efforts;

developments or disputes concerning any future patent or proprietary rights;

innovation by us or our competitors;

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;

currency exchange rate fluctuations; and

period-to-period variations in our results of operations.

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

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

***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;

## **Table of Contents**

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

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

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

---

## **Table of Contents**

While we cannot provide any assurance that we are, are not, or will or will not be, a PFIC now or in the future, we believe it prudent to assume that the we were classified as a PFIC in 2011 and that we could be classified as such in 2012 or 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.

***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



---

**Table of Contents**

owned. Under U.S. law, each shareholder typically is entitled to one vote per share at all meetings. Under English law, it is only on a poll that the number of shares determines the number of votes a holder may cast. You should be aware, however, that the voting rights of ADSs are also governed by the provisions of a deposit agreement with our depositary bank.

Under English law, subject to certain exceptions and disapplications, each shareholder generally has preemptive rights to subscribe on a proportionate basis to any issuance of ordinary shares or rights to subscribe for, or to convert securities into, ordinary shares for cash. Under U.S. law, shareholders generally do not have preemptive rights unless specifically granted in the certificate of incorporation or otherwise.

Under English law and our Articles of Association, certain matters require the approval of 75% of the shareholders who vote (in person or by proxy) on the relevant resolution, 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 representing 75% of the ordinary shares.

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 effect 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**

***Our directors, management and affiliated investment funds exercise significant control over our company, which will limit your ability to influence corporate matters.***

As of February 15, 2012 our executive officers, directors and affiliated investment funds collectively controlled approximately 15.11% of our outstanding ordinary shares, excluding any shares subject to ADSs that such persons may have the right to acquire upon exercise of outstanding options or warrants. As a result, these shareholders, if they act together, will be able to influence our management and affairs and all matters requiring shareholder approval, including the election of directors and approval of significant corporate transactions.

In addition, we entered into an agreement with various participants in the October 2009 private placement under which investment funds affiliated with Orbimed Advisors LLC, Sofinnova Ventures and Abingworth LLP have the ability to designate persons for Amarin to nominate to its Board of Directors and the other participants have given these investments funds a proxy to vote their securities in favor of these nominees. We have a continuing obligation to nominate one (1) designee of investment funds affiliated with Sofinnova Ventures to its Board of Directors for so long as such funds beneficially own at least fifty percent (50%) of the ADSs they purchased in the October 2009 private placement. Dr. James I. Healy was designated by investment funds affiliated with Sofinnova Ventures pursuant to this arrangement. In addition, we have agreed to nominate one (1) designee of investment funds affiliated with Abingworth LLP to its Board of Directors for so long as such funds beneficially own at least five percent (5%) of our outstanding voting securities. Dr. Joseph Anderson was designated by investment funds affiliated with Abingworth LLP under this arrangement.

This concentration of ownership and the above-described arrangement may have the effect of delaying or preventing a change in control of our company that other shareholders may desire and might negatively affect the market price of the ADSs.

***U.S. holders of the ADSs or ordinary shares may be subject to U.S. 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.

**Table of Contents****Item 2. Properties**

The following table lists the location, use and ownership interest of our principal properties as of December 31, 2011:

Location	Use	Ownership	Size (sq. ft.)
Dublin, Ireland	Offices	Leased	320
Bedminster, New Jersey, USA	Offices	Leased	11,889
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 June 30, 2014, 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.

Effective November 1, 2011, we leased 320 square feet of office space in Dublin, Ireland. The lease terminates on October 31, 2012 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 in December 2013 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.

In January 2007, we leased 3,251 square feet of office space in Dublin, Ireland. In accordance with the lease provisions, we terminated this lease effective January 2012 and in December 2011, paid a sum equivalent to six months rent, rates, service fees and insurance premiums and customary dilapidation charges.

On November 28, 2008, we leased 2,725 square feet of office space at 12 Roosevelt Avenue, Mystic, Connecticut, USA and on March 4, 2010 we leased an additional 1,350 square feet at the same location. Both leases expired on October 31, 2011.

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**

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, 2011, we are not a 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 2011		Fiscal 2010	
	High	Low	High	Low
First Quarter	\$ 9.66	\$ 6.92	\$ 1.60	\$ 0.93
Second Quarter	\$ 19.87	\$ 7.21	\$ 2.95	\$ 1.46
Third Quarter	\$ 15.02	\$ 8.63	\$ 3.23	\$ 2.02
Fourth Quarter	\$ 10.20	\$ 5.99	\$ 8.64	\$ 2.43

**Shareholders**

As of February 1, 2012, there were approximately 493 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 depositary, Citibank, N.A., constitutes a single record holder of our ordinary shares.

**Dividends**

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

**Table of Contents****Performance Graph 2 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.*

In the opinion of the Board of Directors, 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	12/31/2009	12/31/2010	12/31/2011
Amarin Corporation PLC	\$ 100.00	\$ 573.43	\$ 523.78
NASDAQ Composite Index	\$ 100.00	\$ 118.15	\$ 117.22
NASDAQ Biotechnology Index	\$ 100.00	\$ 115.22	\$ 129.13

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.

As depicted above, over the last two years Amarin has out-performed relative to the NASDAQ and NASDAQ Bio indices to give a cumulative shareholder return of 524%, while the NASDAQ index gave a return of 17% and the NASDAQ Bio index a return of 29%.

**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, 2006 and its relative performance is tracked through December 31, 2011.

Company/Market/Peer Company	12/31/2006	12/31/2007	12/31/2007	12/31/2009	12/31/2010	12/31/2011
Amarin Corporation PLC	\$ 100.00	\$ 11.40	\$ 3.11	\$ 6.27	\$ 35.96	\$ 32.85
NASDAQ Composite Index	\$ 100.00	\$ 110.66	\$ 66.41	\$ 96.54	\$ 114.06	\$ 113.16
NASDAQ Biotechnology Index	\$ 100.00	\$ 104.64	\$ 91.77	\$ 106.42	\$ 122.62	\$ 137.42

**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 ( 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*

Except in relation to persons whose business is or includes the issue of depositary receipts or the provision of clearance services or their nominees (whose particular circumstances are not considered further in this report), 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 ending December 31, 2011, 2010, 2009 and 2008 have been derived from the audited consolidated financial statements of Amarin, included elsewhere in this Annual Report on Form 10-K. The selected financial data set forth below as of and for the year ending December 31, 2007 is unaudited. 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.

On January 18, 2008, our common shares were consolidated on a 1-for-10 basis whereby ten common shares of £0.05 each became one common share of £0.5. Unless otherwise specified, all shares and share related information have been adjusted to give effect to this 1-for-10 common share consolidation.

	2011	Years Ended December 31,			2007
		2010	2009	2008	
(In thousands, except per share amounts)					
<b>Consolidated Statements of Operations Data:</b>					
Revenues	\$	\$	\$	\$	\$
<b>OPERATING EXPENSES:</b>					
Research and development	21,602	28,014	20,892	7,899	10,349
General and administrative (1)	22,559	17,087	13,152	19,622	18,093
Purchased in-process research & development					19,916
Total operating expenses	44,161	45,101	34,044	27,521	48,358
Operating loss	(44,161)	(45,101)	(34,044)	(27,521)	(48,358)
(Loss) gain on change in fair value of derivative liability (2)	(22,669)	(205,153)	5,137	9,289	397
Interest expense	(1)	(19)	(2,832)	(836)	(180)
Interest income	231	53	199	431	1,252
Other income (expense), net	(10)	130	33	(900)	205
Loss from continuing operations before taxes	(66,610)	(250,090)	(31,507)	(19,537)	(46,684)
(Provision for) benefit from income taxes	(2,516)	501	901	1,048	837
Net loss applicable to common stockholders	\$ (69,126)	\$ (249,589)	\$ (30,606)	\$ (18,489)	\$ (45,847)
Loss per basic and diluted share:	\$ (0.53)	\$ (2.49)	\$ (0.72)	\$ (0.84)	\$ (4.69)
<b>Weighted average shares:</b>					
Basic and diluted	130,247	100,239	42,424	22,086	9,784
<b>Consolidated Balance Sheet Data:</b>					
	2011	2010	As of December 31,		2007
			2009	2008	
(In thousands)					
Cash, cash equivalents	\$ 116,602	\$ 31,442	\$ 52,258	\$ 14,239	\$ 18,303
Total assets	126,379	35,367	55,444	17,135	22,507
Long-term obligations	123,889	230,157	42,090	1,591	7,714
Stockholders' (deficit) equity	(5,962)	(202,367)	6,597	8,416	4,563

(1) Includes 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) Includes non-cash charges resulting from changes in the fair value of warrant 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 the potential for, and timing of, approval of the AMR101 New Drug Application by the United States Food and Drug Administration 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 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 late-stage biopharmaceutical company with expertise in lipid science focused on the treatment of cardiovascular disease. Our lead product candidate is AMR101, an ultra-pure omega-3 fatty acid, comprising not less than 96% ultra pure icosapent ethyl, or ethyl-EPA. We are developing AMR101 for the treatment of patients with very high triglyceride levels and high triglyceride levels, or hypertriglyceridemia. Triglycerides are fats in the blood.

In September 2011, we filed a New Drug Application, or NDA, with the U.S. Food and Drug Administration, or FDA, seeking marketing approval for the use of AMR101 in the treatment of patients with very high triglyceride levels ( $\geq 500$  mg/dL), or what we refer to as the MARINE indication. The FDA has assigned a Prescription Drug User Fee Act, or PDUFA, date of July 26, 2012 for the completion of its review of this NDA. The NDA for the MARINE indication is supported by a Special Protocol Assessment, or SPA, agreement with the FDA.

We plan to separately seek approval for AMR101 for the treatment of patients with high triglyceride levels ( $\geq 200$  and  $< 500$  mg/dL) who are also on statin therapy for elevated low-density lipoprotein cholesterol, or LDL-C, levels (which we refer to as mixed dyslipidemia), or what we refer to as the ANCHOR indication. The ANCHOR indication is also supported by a SPA agreement with the FDA.

The potential efficacy and safety of AMR101 was studied in two Phase 3 clinical trials, the MARINE trial and the ANCHOR trial. These trials showed favorable clinical results in their respective patient populations in reducing triglyceride levels without a statistically significant increase in LDL-C levels, and in the 4 gram AMR101 ANCHOR results, with a statistically significant decrease in LDL-C levels. These trials also showed favorable results, particularly with the 4 gram dose of AMR101, in other important lipid and inflammation biomarkers, including Apo B (apolipoprotein B), non-high-density lipoprotein cholesterol, or HDL-C, Total-Cholesterol, very low-density lipoprotein cholesterol, or VLDL-C, Lp-PLA2 (lipoprotein-associated phospholipase), and hs-CRP (high sensitivity C-reactive protein). In each of these trials, AMR101 exhibited a safety profile comparable to placebo.

In November 2010, we announced the favorable results of the Phase 3 MARINE trial, and in April 2011 we announced the favorable results of the Phase 3 ANCHOR trial. The results of both of these studies were submitted to the FDA as part of the NDA for the MARINE indication. To obtain FDA approval of AMR101 for the ANCHOR indication, based on communications with the FDA, we believe that we must first obtain approval

---

## **Table of Contents**

of AMR101 in the MARINE indication and be substantially underway with a cardiovascular outcomes study at the time of the submission of an NDA to the FDA for the ANCHOR indication. Based upon feedback from the FDA and consistent with the respective SPAs for the MARINE trial and ANCHOR trial, we do not believe the final results of an outcomes study are required for FDA approval of AMR 101 for either indication.

In December 2011, we announced commencement of patient dosing in our cardiovascular outcomes study of AMR101, titled REDUCE-IT (Reduction of Cardiovascular Events with EPA Intervention Trial), that is designed to evaluate the efficacy of AMR101 in reducing major cardiovascular events in an at-risk patient population on statin therapy. The REDUCE-IT study is also the subject of an SPA agreement with the FDA. If successful, we believe the results of this study could lead to a broadening of the market potential for AMR101 beyond the MARINE and ANCHOR indications.

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 cardiac disease. We estimate that over 40 million adults in the U.S. have elevated triglyceride levels ( $\geq 200$ mg/dL) and approximately 4.0 million people in the United States have very high triglyceride levels ( $\geq 500$  mg/dL). Triglycerides provide important information as a marker associated with the risk for heart disease and stroke, especially when an individual also has low high-density lipoprotein, or HDL-C (often referred to as good cholesterol), and elevated levels of LDL-C (often referred to as bad cholesterol).

### *Manufacturing and Supply*

We entered 2011 with one active pharmaceutical ingredient, or API, supplier, Nisshin Pharma. We believe this supplier is capable of producing API to support the initial commercial launch of AMR101. However, based on the positive results of our MARINE and ANCHOR clinical trials and the potential for greater than originally expected product demand, we determined in 2011 to add additional suppliers. Our goals in expanding our supply chain were to provide greater capacity to meet anticipated demand, enable supply diversification and flexibility and introduce cost competition. After conducting an extensive global search for manufactures capable of producing AMR101 API to our technical specifications, we entered into limited exclusivity, long-term agreements with two additional API suppliers in 2011. We are currently working to finalize terms and conditions with a fourth supplier. Certain of our API supply agreements contain provisions under which the cost of supply to us decreases as we purchase increased product volume.

The agreements with each of our API suppliers contemplate phased capacity expansion aimed at creating sufficient capacity to meet anticipated demand for API material for AMR101 following FDA approval. Accordingly, Nisshin and our other potential suppliers are currently working to expand and qualify their production capabilities to meet regulatory requirements to manufacture the API for AMR101. 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 they will successfully qualify with the FDA.

Our NDA for AMR101 references supply from Nisshin with which we have had the longest relationship and is best qualified to support our launch of AMR101. We have defined with the FDA our plan and specifications for qualifying the additional API suppliers. We intend to submit sNDAs for the use of these additional API suppliers after the suppliers successfully complete the qualification process and the NDA is approved. For API encapsulation, we submitted two commercial encapsulators as part of our NDA. We believe that both of these companies have the capacity to support our product launch requirements.

During 2012, we intend to increase our purchases of API and finished capsules of AMR101 in preparation of commercial launch. We plan to make certain of these purchases prior to NDA approval with the aim to further expand purchase levels of supply after NDA approval. We may elect to make API purchases from certain of our suppliers after we are satisfied that the material they produce and their facilities are qualified. However, in the event that we make such purchases, we will not be able to use such material for commercial sale until the sNDA for the applicable supplier is approved by the FDA. Similarly, if we are not compliant with other regulations with regard to this intended purchase of supply, our launch may be delayed.

---

## **Table of Contents**

### *Commercialization Strategy*

We are currently considering three potential paths for the marketing and sale of AMR101: strategic collaboration, acquisition and self-commercialization, that latter of which could include a third-party collaboration. From time to time we have held discussions with larger pharmaceutical companies on potential collaborations and other strategic opportunities with larger pharmaceutical companies and we may have 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 such potential collaborations. 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 launch, market and sell AMR101 on our own.

The U.S. market is currently our primary focus for the initial commercial launch of AMR101. Opportunities to market and sell AMR101 outside of the United States are also under evaluation.

### *January 2012 Financing and Financial Position*

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 3.50% exchangeable senior notes due 2032. The notes are the senior unsecured obligations of Corsicanto and are guaranteed by Amarin Corporation plc. The notes bear interest at a rate of 3.50% 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 Amarin 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 Amarin's election, subject to certain conditions, in cash, ADSs or a combination of cash and ADSs.

The proceeds received by Amarin from the January 2012 debt offering were approximately \$144.3 million, net of estimated fees and transaction costs. Together with our cash balance of \$116.6 million at December 31, 2011, we believe that we have sufficient financial resources to fund our projected operations at least for the next twelve months, including advancement of the REDUCE-IT cardiovascular outcomes study and preparations for and commercial launch of AMR101 on each of the three potential paths we are considering for commercialization, subject to regulatory approval. Unless we enter into a strategic collaboration in support of a commercial launch, we may need to raise additional capital to support these efforts on our own.

### **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

## **Table of Contents**

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.

*Derivative Financial Liabilities* Derivative financial liabilities on initial recognition are 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, or a Monte Carlo simulation depending on the nature of the instrument. 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 warrants 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.

*Inventory Capitalization* Until AMR101 is approved for commercial marketing and sale, it is considered a product candidate under development. As such, until an NDA for AMR101 is approved, all supply of AMR101 purchased will not be capitalized and will be included as a component of research and development expense. Upon NDA approval, we plan to capitalize subsequent AMR101 purchases as inventory. Purchases of AMR101 received and expensed before NDA approval will not be subsequently capitalized.

### **Recent Accounting Pronouncements**

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, 2011 versus December 31, 2010*

*Revenue.* We recorded no revenue in 2011 or 2010.

*Research and Development Expense.* Research and development expense for the year ended December 31, 2011 was \$21.6 million, versus \$28.0 million in the prior year period, a decrease of \$6.4 million, or 22.9%. Research and development expenses for the years ended December 31, 2011 and 2010 are summarized in the table below:

	2011	2010
Research and development expenses (1)	\$ 20,138	\$ 26,480
Non-cash stock based compensation expense (2)	1,464	1,534
	\$ 21,602	\$ 28,014

- (1) Research and development expense, excluding non cash charges, for the year ended December 31, 2011 was \$20.1 million, versus \$26.5 million in the prior year period, a decrease of \$6.4 million, or 24.2%. The decrease in research and development expense was primarily due to decreased costs in 2011 for our



**Table of Contents**

AMR101 cardiovascular program, primarily costs associated with the MARINE and ANCHOR trials, our two Phase 3 clinical trials, the top-line results of which were reported in December 2010 and April 2011, respectively. The decrease in costs for these trials in 2011 versus 2010 were partially offset by increased clinical costs for the REDUCE-IT cardiovascular outcomes study, which was initiated in the second half of 2011, and costs associated with submitting our NDA in September 2011 for AMR101.

- (2) Stock based compensation expense included within research and development was \$1.5 million for the years ended December 31, 2011 and 2010, respectively.

Although clinical costs for the MARINE and ANCHOR trials have decreased as a result of their completion in 2011, we expect these cost reductions to be offset in 2012 by costs for the REDUCE-IT cardiovascular outcomes study as part of which dosing of initial patients commenced in December 2011. We currently estimate that cumulative costs incurred through a CRO for REDUCE-IT will approximate \$25 million in 2012 and \$125 million through the estimated six year term of the study. We also anticipate increases in research and development costs during 2012 related to the purchase of supply of AMR101, which supply we intend to include as a component of research and development expense for accounting purposes prior to NDA approval. The amount of expense we incur for AMR101 supply during 2012 depends upon the timing of receipt of API from our suppliers and the timing of an NDA approval.

*General and Administrative Expense.* General and administrative expense for the year ended December 31, 2011 was \$22.6 million, versus \$17.1 million in the prior year, an increase of \$5.5 million, or 32.2%. General and administrative expenses for the years ended December 31, 2011 and 2010 are summarized in the table below:

	2011	2010
General and administrative expenses (1)	\$ 14,825	\$ 7,237
Non-cash warrant related compensation (income) expense (2)	(96)	5,713
Non-cash stock based compensation expense (3)	7,830	3,673
Restructuring, severance and lease exit costs (4)		464
	\$ 22,559	\$ 17,087

- (1) General and administrative expense, excluding restructuring, severance and non-cash compensation charges for stock compensation and warrants, for the year ended December 31, 2011 was \$14.8 million, versus \$7.2 million in the prior year, an increase of \$7.6 million, or 105.6%. The increase was primarily due to higher staffing levels in 2011, increased overhead costs for increased office space and higher costs in 2011 for marketing studies and other pre-commercial activities.
- (2) Warrant related compensation (income) expense for the year ended December 31, 2011 was \$0.1 million of income, versus \$5.7 million of expense in the prior year, a change of \$5.8 million. Warrant related compensation income for the period ended December 31, 2011 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 income in 2011 was due primarily to the decrease in the fair value of these warrants, the decrease in the fair value of the warrants is due primarily to a decrease in our stock price between December 31, 2010 and December 31, 2011.
- (3) Stock based compensation expense for the year ended December 31, 2011 was \$7.8 million, versus \$3.7 million in the prior year period, an increase of \$4.1 million due primarily to an increase in option awards granted in late 2010 and during the year ended December 31, 2011 to attract and retain qualified employees.
- (4) Restructuring, severance and lease exit costs for the year ended December 31, 2010 represented costs for severance, office consolidation and the relocation of certain operations to our U.S. offices.

We expect general and administrative costs in 2012 to increase as we prepare for the commercialization of AMR101, including costs for market research, sales force preparation and development of management information systems. The extent of such increases will depend in large part on the timing of NDA approval for AMR101 and whether we launch AMR101 on our own or with a strategic collaborator. If we launch AMR101 on our own, we anticipate that this launch will occur, subject to NDA approval, in early 2013 and that we would not hire the majority of the anticipated number of sales representatives until the fourth quarter of 2012.

**Table of Contents**

*(Loss) Gain on Change in Fair Value of Derivative Liability.* (Loss) gain on change in fair value of derivative liability for the year ended December 31, 2011 was expense of \$22.7 million versus \$205.2 million in the prior year period. (Loss) gain 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, 2010 was \$230.1 million and we recognized a \$205.2 million loss on change in fair value of derivative liability for the period ended December 31, 2010 for these warrants. 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. The decrease in the warrant derivative liability value was due primarily to the decrease in the price of our common shares. See further discussion of the warrant derivative liability in Note 2 and Note 7 of the Notes to the Consolidated Financial Statements.

*Interest Income (Expense), net.* Interest income includes interest earned on cash balances. Interest expense for the year ended December 31, 2011 was \$1,000 versus \$19,000 in the prior year.

*Other (Expense) Income, net.* Other (expense) income primarily includes gains and losses on foreign exchange transactions. Other (expense) income for the year ended December 31, 2011 was a net expense of \$10,000 versus income of \$130,000 in the prior year.

*(Provision for) benefit from Income Taxes.* Provision for the year ending December 31, 2011 was a \$2.5 million provision versus a \$0.5 million benefit in the prior year. The increase in the 2011 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, 2010 versus December 31, 2009**

*Revenue.* We recorded no revenue in 2010 or 2009.

*Research and Development Expense.* Research and development expense for the year ended December 31, 2010 was \$28.0 million, versus \$20.9 million in the prior year period, an increase of \$7.1 million, or 34.0%. Research and development expenses for the years ended December 31, 2010 and 2009 are summarized in the table below:

	2010	2009
Research and development expenses (1)	\$ 26,480	\$ 18,509
Non-cash stock based compensation expense (2)	1,534	1,481
Non-cash change in fair value of Ester share based liability (3)		902
	\$ 28,014	\$ 20,892

- (1) Research and development expense, excluding non cash charges, for the year ended December 31, 2010 was \$26.5 million, versus \$18.5 million in the prior year period, an increase of \$8.0 million, or 43.2%. The increase in research and development expense was primarily due to increased costs in 2010 for our AMR101 cardiovascular program, primarily costs associated with our two Phase III clinical trials incurred through Medpace, the CRO we engaged in late 2009 to help us set up and manage the two trials. We began enrolling patients in these trials in early 2010 and announced the completion of enrollment in both trials during the second half of 2010. These clinical trial cost increases were partially offset by lower costs for non-cardiovascular development programs which were discontinued during the fourth quarter of 2009.
- (2) Stock based compensation expense included within research and development was \$1.5 million for the years ended December 31, 2010 and 2009, respectively.
- (3) Non-cash change in fair value of Ester share based liability for the year ended December 31, 2009 reflects the change in the fair value from December 31, 2008 to the May 2009 settlement date of the liability associated with Milestone Ia of the Ester share purchase agreement (see further discussion in Note 8 of the Notes to the Consolidated Financial Statements).



**Table of Contents**

*General and Administrative Expense.* General and administrative expense for the year ended December 31, 2010 was \$17.1 million, versus \$13.2 million in the prior year, an increase of \$3.9 million, or 29.5%. General and administrative expenses for the years ended December 31, 2010 and 2009 are summarized in the table below:

	2010	2009
General and administrative expenses (1)	\$ 7,237	\$ 8,593
Non-cash warrant related compensation expense (2)	5,713	1,040
Non-cash stock based compensation expense (3)	3,673	1,378
Restructuring, severance and lease exit costs (4)	464	2,141
	\$ 17,087	\$ 13,152

- (1) General and administrative expense, excluding restructuring, severance and non-cash compensation charges for stock compensation and warrants, for the year ended December 31, 2010 was \$7.2 million, versus \$8.6 million in the prior year, a decrease of \$1.4 million, or 16.3%. The decrease was primarily due to lower staffing and overhead expenses in 2010, due to a reduction in office locations in 2009 as a result of a restructuring in late 2009 in conjunction with the October 2009 private placement, which also included the termination of non-cardiovascular development programs.
- (2) Warrant related compensation expense for the year ended December 31, 2010 was \$5.7 million, versus \$1.0 million in the prior year, an increase of \$4.7 million. Warrant related compensation expense for the period ended December 31, 2010 reflects a non-cash expense 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 increase in the fair value of the warrants is due primarily to an increase in our stock price between December 31, 2009 and December 31, 2010.
- (3) Stock based compensation expense for the year ended December 31, 2010 was \$3.7 million, versus \$1.4 million in the prior year period, an increase of \$2.3 million due primarily to an increase in option awards for the year ended December 31, 2010 to attract and retain qualified employees.
- (4) Restructuring, severance and lease exit costs were \$0.5 million for the year ended December 31, 2010 versus \$2.1 million in the prior year. Restructuring, severance and lease exit costs includes primarily costs for severance, office consolidation and the relocation of certain operations to the Company's U.S. offices.

*(Loss) Gain on Change in Fair Value of Derivative Liability.* (Loss) gain on change in fair value of derivative liability for the year ended December 31, 2010 was expense of \$205.2 million versus income of \$5.1 million in the prior year period. (Loss) gain 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, 2009 was \$41.5 million and we recognized a \$6.6 million gain on change in fair value of derivative liability for the period ended December 31, 2009 for these warrants. The fair value of the warrant derivative liability at December 31, 2010 was \$230.1 million and we recognized a \$205.2 million loss on change in fair value of derivative liability for the period ended December 31, 2010. The increase in the warrant derivative liability value was due primarily to the increase in the price of our common shares. See further discussion of the warrant derivative liability in Note 2 and Note 7 of the Notes to the Consolidated Financial Statements.

*Interest Income (Expense), net.* Interest income includes interest earned on cash balances. Interest expense for the year ended December 31, 2010 was \$19,000 versus \$2.8 million in the prior year. The decrease was due primarily to the amortization of the difference between the fair value of the June and July 2009 bridge loans at their date of issue and their face value at the time of repayment in October 2009. The bridge notes were repaid in conjunction with our October 2009 private placement.

**Table of Contents**

*Other Income (Expense), net.* Other income primarily includes gains and losses on foreign exchange transactions. Other income for the year ended December 31, 2009 also included \$0.7 million from the sale of intellectual property.

**Liquidity and Capital Resources**

Our sources of liquidity as of December 31, 2011 include cash and cash equivalents of \$116.6 million. In addition, in January 2012 we completed a convertible debt offering from which we received approximately \$144.3 million in net proceeds. Our projected uses of cash include the continued funding of the REDUCE-IT study, commercial preparation and launch of AMR101, 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,		
	2011	2010	2009
Cash (used in) provided by continuing operations:			
Operating activities	\$ (39.4)	\$ (33.9)	\$ (28.4)
Investing activities	(2.0)		0.6
Financing activities	126.6	13.1	65.8
(Decrease) increase in cash and cash equivalents	\$ 85.2	\$ (20.8)	\$ 38.0

We had no debt obligations at December 31, 2011.

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 in aggregate principal amount of its 3.50% exchangeable senior notes due 2032. The proceeds received by Amarin from the January 2012 debt offering were approximately \$144.3 million, net of fees and transaction costs. These notes were issued pursuant to an indenture dated as of January 9, 2012, by and among Corsicanto, Amarin Corporation plc as guarantor, and Wells Fargo Bank, National Association, as trustee. The notes are the senior unsecured obligations of Corsicanto and are guaranteed by Amarin Corporation plc. The notes bear interest at a rate of 3.50% 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 Amarin 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 Amarin's election, subject to certain conditions, in cash, ADSs or a combination of cash and ADSs.

In January 2011, we sold 13.8 million shares of our common shares, par value £0.50 per share, at a price of \$7.60 per share, resulting in net proceeds of approximately \$98.7 million after deducting underwriting commissions and expenses payable by us associated with this transaction.

We believe that our cash, including the net proceeds from the January 2012 financing, will be sufficient to fund our projected operations for at least the next twelve months, including advancement of the REDUCE-IT cardiovascular outcomes study, commercial preparations and projected launch of AMR101, working capital and other general corporate activities. This is based on our current operational plans and activities at normal levels and does not assume any cash inflows from partnerships, warrant exercises or other dilutive or non-dilutive financings in the longer-term.

**Table of Contents****Contractual Obligations**

The following table summarizes our contractual obligations at December 31, 2011 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	2012	2013 to 2014	2015 to 2016	After 2016
<b>Contractual Obligations:</b>					
Purchase obligations (1)	\$ 13.3	\$ 13.3	\$	\$	\$
Operating lease obligations (2)	1.3	0.6	0.7		
<b><u>Total contractual cash obligations</u></b>	<b>\$ 14.6</b>	<b>\$ 13.9</b>	<b>\$ 0.7</b>	<b>\$</b>	<b>\$</b>

(1) Represents minimum purchase obligations with Nisshin, our supplier of AMR 101 active pharmaceutical ingredient, ethyl-EPA. We purchased \$2.1 million of materials during the year ended December 31, 2011 and have additional purchase obligations of \$13.3 million in 2012. Not included in this obligation is a non-refundable milestone payment of \$0.5 million payable upon the first marketing approval of AMR101 in the United States. Additional future minimum purchases will be required, subject to an NDA approval, and in preparation for commercialization of AMR101 we may purchase more than the minimum amount.

In addition, provided the supplier has expanded its manufacturing capacity in accordance with the agreement, the supplier may terminate the agreement in the event that (i) Amarin does not receive marketing approval for AMR101 in the United States on or before December 31, 2014 or (ii) in the event that Amarin abandons development of AMR101 for hypertriglyceridemia in the United States. In either case, Amarin will be required to reimburse the supplier for certain costs incurred by the supplier in connection with its manufacturing expansion, less the amount of profit received as a result of purchases of ethyl-EPA by Amarin, not to exceed \$5.0 million.

We anticipate incurring certain costs associated with the qualification of product produced by Nisshin. In an effort to further expand production capacity at this supplier or through the addition of supplemental suppliers, we may make capital commitments to support their expansion, particularly if such commitments further reduce the cost to us of the manufactured product.

(2) Represents operating lease costs, primarily consisting of leases for facilities in Dublin, Ireland, Bedminster, NJ and Groton, CT. We do not enter into financial instruments for trading or speculative purposes.

The above table also does not reflect potential material purchases under active pharmaceutical ingredient, or API, supply agreements signed during 2011 with two additional API suppliers. We are currently working to finalize terms and conditions with a fourth supplier. These agreements provide access to additional API supply that is incremental to supply from Nisshin, our existing API supplier. Each of these three API agreements contemplates a phased capacity expansion plan aimed at creating sufficient capacity to meet anticipated demand for API material for AMR101 following FDA approval. These API suppliers are self-funding these expansion plans with contributions from Amarin. These agreements include requirements for the suppliers to qualify their materials and facilities. We anticipate incurring certain costs associated with the qualification of product produced by these suppliers. Following FDA approval of AMR101, these agreements include annual purchase levels enabling Amarin to maintain supply exclusivity with each respective supplier, and to prevent potential termination of the agreements. Because we have not yet obtained FDA approval for AMR101, these amounts are excluded from the above table. The 2011 supply agreements 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 Amarin 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.

---

## **Table of Contents**

Concurrent with one of these supply agreements, our agreement with Chemport located in South Korea, we agreed to make a minority share equity investment in Chemport of up to \$3.3 million. In July 2011, we paid to Chemport \$1.7 million under this agreement, which has been included in other long term assets at December 31, 2011. Subject to Chemport meeting certain milestones, we anticipate making the remaining \$1.6 million investment during 2012.

Under our 2004 share repurchase agreement with Laxdale Limited, in connection with commercialization of AMR101 for cardiovascular indications, prior to the end of 2012 we are required to pay potential royalties to a former employee of Laxdale of 1% on net sales up to £100 million (approximately \$155 million at December 31, 2011); 0.5% for net sales between £100 million (approximately \$155 million at December 31, 2011) and £500 million (approximately \$773 million at December 31, 2011); and 0.25% for sales in excess of £500 million (approximately \$773 million at December 31, 2011). After 2012, we have no royalty obligations.

Under this same agreement with Laxdale Limited, upon receipt of marketing approval in the U.S. and/or Europe for the first indication for AMR101 (or first indication of any product containing Amarin Neuroscience intellectual property acquired from Laxdale Limited in 2004), we must make an aggregate stock or cash payment (at the sole option of each of the sellers) of £7.5 million (approximately \$11.6 million at December 31, 2011) for each of the two potential marketing approvals (i.e., £15 million maximum, or approximately \$23.2 million at December 31, 2011). In addition, upon receipt of a marketing approval in the U.S. or Europe for a further indication of AMR101 (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 \$7.7 million at December 31, 2011) for each of the two potential market approvals (i.e. £10 million maximum, or approximately \$15.5 million at December 31, 2011).

In addition to the obligations in the table above, we have approximately \$0.7 million of liability for uncertain tax positions that have been recorded in long-term liabilities at December 31, 2011. 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.

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

We are exposed to market risks, which include changes in interest rates, changes in credit worthiness and liquidity of our marketable securities. We do not use derivative financial instruments in our investment portfolio and have no foreign exchange contracts. At December 31, 2011, we record as a liability the fair value of warrants to purchase 18.7 million shares of our common stock issued to investors. The fair value of this warrant 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

**Table of Contents**

market price of our common shares (\$8.24 based on the \$7.49 market price of our stock at December 31, 2011) on which the December 31, 2011 valuation was based, the value of the derivative liability would have increased by \$13.6 million. Such increase would have been reflected as additional loss on change in fair value of the warrant derivative liability 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 and Sterling. The majority of our vendor relationships are denominated in U.S. dollar. We therefore believe that the risk of a significant impact on our operating income from foreign currency fluctuations is not substantial.

*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, 2011, the fair value of our cash and cash equivalents maturing in one year or less was \$116.6 million and represented 100% of our cash, cash equivalents and investment portfolio. A hypothetical 50 basis point increase 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. At December 31, 2011, 2010 and 2009 there was no outstanding debt.

**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, 2011 (the Evaluation Date), our management, with the participation of our Principal Executive Officer and Principal Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our Principal Executive Officer and Principal Financial Officer have concluded based upon the evaluation described above that, as of the Evaluation Date, our disclosure controls and procedures were effective at the reasonable assurance level.

## **Table of Contents**

### **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, 2011. 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, 2011, 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, 2011. 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 2011 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting, other than described below.

#### *Remediation of Material Weakness*

As previously described in Item 9A *Controls and Procedures* in our Annual Report on Form 10-K filed for the year ended December 31, 2010, our management identified a material weakness in internal control over financial reporting as of December 31, 2009, which persisted as of December 31, 2010. Specifically, our management concluded there was a deficiency in the company's internal control over financial reporting relating to the technical expertise and review over the accounting for complex, non-routine transactions that could result in a material misstatement of the consolidated financial statements that would not be prevented or detected on a timely basis.

**Table of Contents**

During the fourth quarter ended December 31, 2011, we completed remediation efforts to address the material weakness identified above. Specifically, our management, with the input, oversight, and support of the Audit Committee, identified and took the following steps beginning during the second half of 2010, all of which efforts continued into the fourth quarter of 2011: non-ordinary course transactions are considered and evaluated by senior finance management; we continue to prepare accounting position papers for all complex transactions; and, where appropriate, management seeks the advice of outside consultants on accounting matters related to the application of U.S. GAAP to complex, non-ordinary course transactions and in other instances as warranted. Management tested the design and operating effectiveness of these redesigned controls during our year-end closing process for 2011, and we believe that we have remediated the material weakness as described above, as of December 31, 2011.

---

**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 subsidiaries (the Company) as of December 31, 2011, based on criteria established in *Internal Control – Integrated Framework* 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 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, 2011, based on the criteria established in *Internal Control – Integrated Framework* 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, 2011 of the Company and our report dated February 29, 2012 expressed an unqualified opinion on those financial statements.

/s/ DELOITTE & TOUCHE LLP

Boston, Massachusetts

February 29, 2012



**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 2012 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, Attn: Investor Relations.

**Item 11. *Executive Compensation***

The information required by this item will be contained in our Proxy Statement, which will be filed with the SEC in connection with our 2012 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 Proxy Statement, which will be filed with the SEC in connection with our 2012 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 Proxy Statement, which will be filed with the SEC in connection with our 2012 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 Proxy Statement, which will be filed with the SEC in connection with our 2012 Annual General Meeting of Shareholders. Such information is incorporated herein by reference.

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

## (a) Financial Statements and Schedules

See index to the financial statements on page F-1.

## (b) Exhibits

The following exhibits are incorporated by reference or filed as part of this report.

<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	Registration Statement on Form F-3, File No. 170505, as Exhibit 3.1	November 10, 2010
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	Filed herewith	
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 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 21, 2002, as Exhibit 2.4	April 24, 2003
4.4	Form of American Depositary Receipt evidencing ADSs	Filed herewith	
10.1	The Company 2002 Stock Option Plan	Annual Report on Form 20-F for the year ended December 31, 2006, as Exhibit 4.17	March 5, 2007
10.2	The Company 2011 Stock Option Plan	Quarterly Report on Form 10-Q for the period ended June 30, 2011 as Exhibit 10.4	August 8, 2011
10.3	Form of Incentive Stock Option Award Agreement	Filed herewith	

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

10.4	Form of Non-Qualified Stock Option Award Agreement	Filed herewith	
10.5	Form of Restricted Stock Unit Award Agreement	Filed herewith	
10.6	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 21, 2002, as Exhibit 4.22	April 24, 2003

**Table of Contents**

Exhibit Number	Description	Incorporated by Reference Herein	
		Form	Date
10.7	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
10.8	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, as Exhibit 4.62	May 19, 2008
10.9	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, as Exhibit 4.71	March 5, 2007
10.10	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, as Exhibit 4.67	May 19, 2008
10.11	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, as Exhibit 4.69	May 19, 2008
10.12	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, as Exhibit 99.5	December 17, 2007
10.13	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, as Exhibit 99.6	December 17, 2007
10.14	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, as Exhibit 99.7	December 17, 2007
10.15	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, as Exhibit 99.1	January 28, 2008
10.16	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, as Exhibit 99.1	February 1, 2008

**Table of Contents**

<b>Exhibit</b>		<b>Incorporated by Reference Herein</b>	
<b>Number</b>	<b>Description</b>	<b>Form</b>	<b>Date</b>
10.17	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, as Exhibit 4.79	May 19, 2008
10.18	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, as Exhibit 4.80	October 22, 2009
10.19	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, as Exhibit 4.81	May 19, 2008
10.20	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, as Exhibit 4.88	December 4, 2009
10.21	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, as Exhibit 4.90	October 22, 2009
10.22	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, as Exhibit 4.93	October 22, 2009
10.23	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, as Exhibit 4.92	October 22, 2009
10.24	Letter Agreement dated August 1, 2008 with Paresh Somi	Annual Report on Form 10-K for the year ended December 31, 2010, as Exhibit 10.20	March 16, 2011
10.25	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, as Exhibit 10.21	March 16, 2011
10.26	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, as Exhibit 4.94	October 22, 2009
10.27		Registration Statement on Form F-1,	December 14, 2009

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

	Letter Agreement dated October 12, 2009 with Dr. Declan Doogan	File No. 333-163704, as Exhibit 4.101	
10.28	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

**Table of Contents**

<b>Exhibit</b>		<b>Incorporated by Reference Herein</b>	
<b>Number</b>	<b>Description</b>	<b>Form</b>	<b>Date</b>
10.29	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, as Exhibit 4.97	October 22, 2009
10.30	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, as Exhibit 4.95	October 22, 2009
10.31	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, as Exhibit 4.96	October 22, 2009
10.32	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
10.33	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, as Exhibit 4.100	June 25, 2010
10.34	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
10.35	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
10.36	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, as Exhibit 10.35	March 16, 2011
10.37	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
10.38		Report of Foreign Private Issuer filed	December 14, 2009



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

	Compromise Agreement dated December 10, 2009 with Tom Maher	on Form 6-K, as Exhibit 99.3	
10.39	Transitional Employment Agreement, dated August 10, 2010, between the Company and Declan Doogan	Annual Report on Form 10-K for the year ended December 31, 2010, as Exhibit 10.38	March 16, 2011
10.40	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, as Exhibit 10.39	March 16, 2011
10.41	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, as Exhibit 10.40	March 16, 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>
10.42	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, as Exhibit 10.41	March 16, 2011
10.43	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, as Exhibit 10.42	March 16, 2011
10.44	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, as Exhibit 10.43	March 16, 2011
10.45	Amarin Corporation plc Management Incentive Compensation Plan	Annual Report on Form 10-K for the year ended December 31, 2010, as Exhibit 10.44	March 16, 2011
10.46	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, as Exhibit 10.45	March 16, 2011
10.47	Letter Agreement dated March 1, 2010 with Frederick W. Ahlholm	Annual Report on Form 10-K for the year ended December 31, 2010, as Exhibit 10.46	March 16, 2011
10.48	Letter Agreement dated January 28, 2011 with Paul Huff	Quarterly Report on Form 10-Q for the period ended March 31, 2011 as Exhibit 10.1	May 10, 2011
10.49	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 as Exhibit 10.2	August 8, 2011
10.50	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 as Exhibit 10.1	August 8, 2011
10.51		Filed herewith	

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

Amendment to API Commercial Supply Agreement, dated October 19, 2011, between Amarin Pharmaceuticals Ireland Ltd. and Equateq Limited

10.52	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 as Exhibit 10.3	August 8, 2011
10.53	Amended and Restated Employment Agreement with Joe Zakrzewski, dated October 20, 2011	Current Report on Form 8-K dated October 20, 2011 as Exhibit 10.1	October 20, 2011

**Table of Contents**

Exhibit Number	Description	Incorporated by Reference Herein	
		Form	Date
10.54	Stuart Sedlack offer letter, dated August 1, 2007.	Quarterly Report on Form 10-Q for the period ended September 30, 2011 as Exhibit 10.1	November 8, 2011
10.55	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 as Exhibit 10.2	November 8, 2011
10.56	Letter Agreement with Joseph Kennedy, dated December 13, 2011	Current Report on Form 8-K dated December 23, 2011 as Exhibit 10.5	December 23, 2011
10.57	Letter Agreement with Stuart Sedlack, dated December 23, 2011	Current Report on Form 8-K dated December 23, 2011 as Exhibit 10.3	December 23, 2011
10.58	Letter Agreement with John Thero, dated December 23, 2011	Current Report on Form 8-K dated December 23, 2011 as Exhibit 10.1	December 23, 2011
10.59	Letter Agreement with Paul Huff, dated December 23, 2011	Current Report on Form 8-K dated December 23, 2011 as Exhibit 10.2	December 23, 2011
10.60	Letter Agreement with Paresh Soni, dated December 23, 2011	Current Report on Form 8-K dated December 23, 2011 as Exhibit 10.4	December 23, 2011
10.61	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	Filed herewith	
10.62	Letter Agreement with Steve Ketchum, dated February 8, 2012	Current Report on Form 8-K dated February 16, 2012 as Exhibit 10.1	February 16, 2012
14.1	Code of Ethics	Registration Statement on Form F-3, 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 Chief Executive Officer (Principal Executive Officer) pursuant to Section 302 of Sarbanes-Oxley Act of 2002	Filed herewith	
31.2	Certification of President (Principal Financial Officer) pursuant to Section 302 of Sarbanes-Oxley Act of 2002	Filed herewith	



**Table of Contents**

<b>Exhibit</b>		<b>Incorporated by Reference Herein</b>	
<b>Number</b>	<b>Description</b>	<b>Form</b>	<b>Date</b>
32.1	Certification of Chief Executive Officer (Principal Executive Officer) and President (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		
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.

**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*

Date: February 29, 2012

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

Signature	Title	Date
/s/ John F. Thero John F. Thero	President (Principal Financial and Accounting Officer)	February 29, 2012
/s/ Joseph Zakrzewski Joseph Zakrzewski	Chief Executive Officer and Director (Principal Executive Officer)	February 29, 2012
/s/ Joseph Anderson, Ph.D. Joseph Anderson, Ph.D.	Director	February 29, 2012
/s/ Lars Ekman Lars Ekman	Director	February 29, 2012
/s/ Carl Gordon, Ph.D, CFA Carl Gordon, Ph.D, CFA	Director	February 29, 2012

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

	Director	February 29, 2012
/s/ James Healy, M.D., Ph.D.		
James Healy, M.D., Ph.D.		
	Director	February 29, 2012
/s/ Kristine Peterson		
Kristine Peterson		
	Director	February 29, 2012
/s/ Patrick O Sullivan		
Patrick O Sullivan		
	Director	February 29, 2012
/s/ Jan van Heek		
Jan van Heek		



**Table of Contents**

AMARIN CORPORATION PLC

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

	<b>Page</b>
<u>Report of Independent Registered Public Accounting Firm</u>	F-1
<u>Financial Statements:</u>	
<u>Consolidated Balance Sheets</u>	F-2
<u>Consolidated Statements of Operations and Comprehensive Loss</u>	F-3
<u>Consolidated Statements of Stockholders' (Deficit) Equity</u>	F-4
<u>Consolidated Statements of Cash Flows</u>	F-5
<u>Notes to Consolidated Financial Statements</u>	F-6
<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, 2011 and 2010, and the related consolidated statements of operations and comprehensive loss, stockholders' (deficit) equity, and cash flows for each of the three years in the period ended December 31, 2011. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the 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, 2011 and 2010, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2011, 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, 2011, based on the criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 29, 2012 expressed an unqualified opinion on the Company's internal control over financial reporting.

/s/ DELOITTE & TOUCHE LLP

Boston, Massachusetts

February 29, 2012

**Table of Contents**

## AMARIN CORPORATION PLC

**CONSOLIDATED BALANCE SHEETS**

	December 31, 2011                      2010 (in thousands, except  share and per share  amounts)	
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 116,602	\$ 31,442
Deferred tax asset	533	608
Other current assets	1,837	1,063
Total current assets	118,972	33,113
Property, plant and equipment, net	432	88
Deferred tax asset	4,734	2,166
Other long term assets	2,241	
<b>TOTAL ASSETS</b>	<b>\$ 126,379</b>	<b>\$ 35,367</b>
<b>LIABILITIES AND STOCKHOLDERS (DEFICIT) EQUITY</b>		
Current Liabilities:		
Accounts payable	\$ 4,419	\$ 4,449
Accrued expenses and other liabilities	4,033	3,128
Total current liabilities	8,452	7,577
Long-Term Liabilities:		
Warrant derivative liability	123,125	230,069
Lease obligations and other long-term liabilities	764	88
Total liabilities	132,341	237,734
Commitments and contingencies (Note 9)		
Stockholders' Deficit:		
Common stock, £0.50 par value, unlimited authorized; 135,832,542 issued, 135,812,463 outstanding at December 31, 2011; 106,856,731 issued, 106,836,652 outstanding at December 31, 2010	113,321	90,465
Additional paid-in capital	449,393	206,718
Treasury stock; 20,079 shares at December 31, 2011 and 2010	(217)	(217)
Accumulated deficit	(568,459)	(499,333)
Total stockholders' deficit	(5,962)	(202,367)
<b>TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT</b>	<b>\$ 126,379</b>	<b>\$ 35,367</b>

See the notes to the consolidated financial statements.



**Table of Contents**

## AMARIN CORPORATION PLC

**CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**

	Years Ended December 31,		
	2011	2010	2009
	(In thousands, except share and per share amounts)		
Revenues	\$	\$	\$
Operating Expenses:			
Research and development	21,602	28,014	20,892
General and administrative	22,559	17,087	13,152
Total operating expenses	44,161	45,101	34,044
Operating loss	(44,161)	(45,101)	(34,044)
(Loss) gain on change in fair value of derivative liability	(22,669)	(205,153)	5,137
Interest expense	(1)	(19)	(2,832)
Interest income	231	53	199
Other (expense) income, net	(10)	130	33
Loss from operations before taxes	(66,610)	(250,090)	(31,507)
(Provision for) benefit from income taxes	(2,516)	501	901
Net and comprehensive loss	\$ (69,126)	\$ (249,589)	\$ (30,606)
Loss per basic and diluted share:	\$ (0.53)	\$ (2.49)	\$ (0.72)
Weighted average shares:			
Basic and diluted	130,247	100,239	42,424
	See the notes to the consolidated financial statements.		

**Table of Contents**

## AMARIN CORPORATION PLC

**CONSOLIDATED STATEMENTS OF STOCKHOLDERS (DEFICIT) EQUITY****FOR THE YEARS ENDED DECEMBER 31, 2011, 2010 and 2009****(in thousands, except share data)**

						Total
	Common Shares	Common Stock	Additional Paid-in Capital	Treasury Stock	Accumulated Deficit	Shareholders (Deficit) Equity
<b>At January 1, 2009</b>	<b>27,046,724</b>	<b>\$ 25,664</b>	<b>\$ 202,107</b>	<b>\$ (217)</b>	<b>\$ (219,138)</b>	<b>\$ 8,416</b>
Shares issued under Ester amendment	1,315,789	1,046	755			1,801
Shares issued under Proseed agreement	39,473	31	20			51
Shares issued in October private placement	66,400,000	54,212	8,041			62,253
Fair value of October 2009 warrant derivative liability			(47,105)			(47,105)
Shares issued in repayment of bridge loans	3,999,996	3,266	334			3,600
Transfer of fair value of bridge loan and December 2007 warrants from liabilities to equity			5,328			5,328
Stock-based compensation			2,859			2,859
Loss and comprehensive loss					(30,606)	(30,606)
<b>At December 31, 2009</b>	<b>98,801,982</b>	<b>84,219</b>	<b>172,339</b>	<b>(217)</b>	<b>(249,744)</b>	<b>6,597</b>
Exercise of warrants	6,344,136	4,906	3,998			8,904
Exercise of stock options	1,706,016	1,336	2,306			3,642
Tax benefits realized from stock-based compensation			543			543
Fair value of October 2009 warrants reclassified from derivative liability to equity			22,317			22,317
Share issuances for services	4,597	4	8			12
Stock-based compensation			5,207			5,207
Loss and comprehensive loss					(249,589)	(249,589)
<b>At December 31, 2010</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
Fair value of October 2009 warrants reclassified from derivative liability to equity			129,517			129,517
Share issuances for services	14,221	11	60			71
Stock-based compensation			9,294			9,294
Loss and comprehensive 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>

See the notes to the consolidated financial statements.



**Table of Contents**

## AMARIN CORPORATION PLC

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

	Years Ended December 31,		
	2011	2010	2009
	(in thousands)		
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net loss	\$ (69,126)	\$ (249,589)	\$ (30,606)
Adjustments to reconcile loss to net cash used in operating activities:			
Depreciation and amortization	76	63	583
Gain on sale of intellectual property			(700)
Stock-based compensation	9,294	5,207	2,859
Stock-based compensation Ester			902
Stock-based compensation warrants	(96)	5,713	1,040
Excess tax benefit from stock-based awards	(4,199)	(543)	
Non-cash interest			2,803
Loss (gain) on changes in fair value of derivative liability	22,669	205,153	(5,137)
Deferred income taxes	(2,493)	(1,691)	(689)
Change in lease liability	(21)	(583)	(290)
Shares issued for services	71	12	
Changes in assets and liabilities:			
Other current assets	(774)	912	(68)
Other non-current assets	(591)		
Accounts payable and other current liabilities	5,751	1,476	897
Net cash used in operating activities	(39,439)	(33,870)	(28,406)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Purchases of equipment	(398)	(23)	(116)
Purchase of long term investment	(1,650)		
Sale of lorazepam			700
Net cash (used in) provided by investing activities	(2,048)	(23)	584
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Proceeds from issuance of common stock, net of transaction costs	98,654		62,253
Proceeds from exercise of stock options, net of transaction costs	5,094	3,642	
Proceeds from exercise of warrants, net of transaction costs	18,702	8,904	
Proceeds on issuance of convertible debt			5,600
Repayment of convertible debt			(2,000)
Excess tax benefit from stock-based awards	4,199	543	
Repayment of finance leases	(2)	(12)	(12)
Net cash provided by financing activities	126,647	13,077	65,841
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	85,160	(20,816)	38,019
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	31,442	52,258	14,239
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 116,602	\$ 31,442	\$ 52,258
Supplemental disclosure of cash flow information:			
Cash paid during the year for:			
Interest	\$	\$ 2	\$ 125
Income taxes	\$ 761	\$ 230	\$
Supplemental disclosure of non-cash items:			
Reclass of warrant liability to additional paid-in capital	\$ 129,517	\$ 22,317	\$ 5,328



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

Reclass of additional paid-in capital to warrant liability	\$	\$	\$ 47,105
Conversion of bridge loans	\$	\$	\$ 3,600
Issuance of Ester Shares	\$	\$	\$ 1,842
Issuance of Proseed Shares	\$	\$	\$ 51

See notes to the consolidated financial statements.

F-5

---

**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 public limited company with its primary stock market listing in the United States on the NASDAQ Global Market. Amarin 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.

Amarin is a clinical-stage biopharmaceutical company focused on developing improved treatments for cardiovascular disease by capitalizing on its expertise in the field of lipid science and the known therapeutic benefits of essential fatty acids in cardiovascular disease. The Company is currently focusing its efforts on AMR101 (icosapent ethyl), a prescription-only omega-3 fatty acid, comprising not less than 96% ultra pure icosapent ethyl (ethyl-EPA).

The Company has evaluated subsequent events from December 31, 2011 through the date of the issuance of these consolidated financial statements and has determined that no material subsequent events have occurred, except as disclosed below (see footnote 16 Subsequent Event) that would affect the information presented in these consolidated financial statements or to require additional disclosure.

**Basis of Presentation**

The accompanying consolidated financial statements of the Company and subsidiaries have been prepared on a basis which assumes that the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. 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 development and commercialization of AMR101, which is still under development and not available for sale. However, the Company is not considered a development stage business, as the release and sale of the previous product represented the exit of the Company from the development stage.

At December 31, 2011, the Company had cash and cash equivalents of \$116.6 million. The Company's consolidated balance sheet also includes a significant derivative liability (see footnote 7 Warrants and Derivative Liability) reflecting the fair value of outstanding warrants to purchase shares of the Company's common stock. This liability can only be settled in shares of the Company's stock and, as such, would only result in cash inflows upon the exercise of the warrants not a cash outflow. Accordingly, this warrant derivative liability presents neither a short nor long-term claim on the liquid assets of the Company.

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 3.50% exchangeable senior notes due 2032 resulting in net proceeds to the Company of \$144.3 million. The notes are the senior unsecured obligations of Corsicanto and are guaranteed by Amarin.

The Company believes its cash, including the net proceeds from the January 2012 financing, will be sufficient to fund its projected operations for at least the next twelve months which contemplates commercial preparation of AMR101, working capital and other general corporate activities. This is based on management's current operational plans and activities at normal levels and does not assume any cash inflows from partnerships, warrant exercises or other dilutive or non-dilutive financings in the long-term.

**Table of Contents****(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 accounting principles generally accepted in the United States of America 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.

**Cash and Cash Equivalents**

Cash and cash equivalents consist of cash, deposits held at call with banks and short term highly liquid instruments with remaining maturities at the date of purchase of 90 days or less.

**Property & 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 their estimated useful lives. 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. 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 undiscounted forecasted cash flows or appraised values, depending on the nature of the assets.

**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.

**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.

## **Table of Contents**

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.

## **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 or a Monte Carlo simulation depending on the nature of instrument.

If the terms of warrants that initially require the warrant to be classified as a derivative financial liabilities 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 derecognised 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.

## **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.

## **Stock-Based Compensation**

Stock-based compensation cost is measured at the grant date, based on the fair value of the award, and is recognized as compensation cost 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. The Company maintains substantially all of its cash and cash equivalents in financial institutions believed to be of high-credit quality.

## **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 year-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 financial statements of operations. For transactions settled during the period, gains and losses are included in other (expense) income, net in the consolidated statements of operations. Foreign exchange gains and losses have not been significant in the periods presented.

**Table of Contents****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 (expenses), net in the consolidated statements of operations. Unamortized debt issuance costs are recorded in other assets in the consolidated balance sheets.

**Fair Value of Financial Instruments**

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

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

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

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

The following table presents information about the Company's liability as of December 31, 2011 and 2010 that is 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 thousands</i>		<b>December 31, 2011</b>		
	<b>Total</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>
<b>Asset:</b>				
Cash equivalents	\$ 39	\$ 39	\$	\$
<b>Liability:</b>				
Warrant derivative liability	\$ 123,125	\$	\$	\$ 123,125

<i>In thousands</i>		<b>December 31, 2010</b>		
	<b>Total</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>
<b>Liability:</b>				
Warrant derivative liability	\$ 230,069	\$	\$	\$ 230,069

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

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.

**Table of Contents**

As of December 31, 2010, the fair value of the warrant derivative liability was determined to be \$230.1 million using the Black-Scholes option valuation applying the following assumptions: (i) risk-free rate of 1.52%, (ii) remaining term of 3.8 years, (iii) no dividend yield (iv) volatility of 117%, and (v) the stock price on the date of measurement. The \$210.9 million increase in the fair value of the warrants was recognized as a \$205.2 million loss on change in fair value of derivative liability and \$5.7 million compensation expense for change in fair value of warrants issued to former employees, both amounts are included in the consolidated statement of operations for the year ended December 31, 2010. At December 31, 2011, the fair value of the warrant derivative liability was determined to be \$123.1 million using the Black-Scholes option valuation model applying the following assumptions: (i) risk-free rate of 0.36%, (ii) remaining term of 2.8 years, (iii) no dividend yield (iv) volatility of 118%, and (v) the stock price on the date of measurement. The \$22.6 million increase in the fair value of the warrants, net of exercises, was recognized as a \$22.7 million loss on change in fair value of derivative liability and \$(0.1) million compensation income for change in fair value of warrants issued to former employees, both amounts are included in the consolidated statement of operations for the year ended December 31, 2011. The change in the fair value of the warrant derivative liabilities is as follows (in thousands):

	October 2009 Warrants	June and July 2009 Warrants	May 2008 Participation Rights	December 2007 Warrants	Totals
<b>Balance at December 31, 2008</b>	<b>\$</b>	<b>\$</b>	<b>\$ 504</b>	<b>\$ 533</b>	<b>\$ 1,037</b>
Initial measurement, June and July 2009 warrants		2,803			2,803
Initial measurement, October 2009 financing warrants	47,105				47,105
Initial measurement, October 2009 warrants issued to employees	1,210				1,210
(Gain) loss on change in fair value of derivative liability	(6,625)	1,513	(504)	479	(5,137)
Compensation income for change in fair value of warrants issued to former employees	(170)				(170)
Transfers to equity		(4,316)		(1,012)	(5,328)
<b>Balance at December 31, 2009</b>	<b>\$ 41,520</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>	<b>\$ 41,520</b>
Loss on change in fair value of derivative liability	205,153				205,153
Compensation expense for change in fair value of warrants issued to former employees	5,713				5,713
Transfers to equity	(22,317)				(22,317)
<b>Balance at December 31, 2010</b>	<b>\$ 230,069</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>	<b>\$ 230,069</b>
Loss on change in fair value of derivative liability	22,669				22,669
Compensation income for change in fair value of warrants issued to former employees	(96)				(96)
Transfers to equity	(129,517)				(129,517)
<b>Balance at December 31, 2011</b>	<b>\$ 123,125</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>	<b>\$ 123,125</b>

The fair value of the June and July 2009 warrant derivative liability, using a Monte Carlo valuation model, was determined to be \$2.8 million at initial measurement and \$4.3 million at termination, applying the following assumptions: (i) risk-free rates of 2.35% and 2.55%, (ii) remaining terms of 5.0 and 4.8 years, (iii) no dividend yield, (iv) volatility of 112%, and (v) the stock price on the date of measurement. The fair value of the warrant derivative liability of \$4.3 million was reclassified from liabilities during 2009 and included as a component of equity at December 31, 2009.

The fair value of the December 2007 warrant derivative liability, using a Monte Carlo valuation model, was determined to be \$2.5 million at initial measurement and \$1.0 million at termination, applying the following



**Table of Contents**

assumptions: (i) risk-free rates of 3.32% and 1.32%, (ii) remaining terms of 5.0 and 3.0 years, (iii) no dividend yield, (iv) volatility of 113% and 131%, and (v) the stock price on the date of measurement. The fair value of the warrant derivative liability of \$1.0 million was reclassified from liabilities during 2009 and included as a component of equity at December 31, 2009.

The fair value of the December 2008 derivative liability, using a Monte Carlo valuation model, was determined to be \$8.2 million at initial measurement and \$0.5 million at termination, applying the following assumptions: (i) risk-free rates of 2.24 to 0.04%, (ii) remaining terms of 0.6 and 0.2 years, (iii) no dividend yield, (iv) volatility of 90% and 131% and (v) the stock price on the date of measurement. The fair value of the warrant derivative liability of \$0.5 million was recognized in the statement of operations as a gain on fair value of change in derivative liabilities at December 31, 2009.

**Segment and Geographical Information**

For the years ended December 31, 2011, 2010 and 2009, the Company has reported its business as a single reporting segment. The Company's chief decision maker, who is the Chief Executive Officer, regularly evaluates the Company on a consolidated basis.

**Recent Accounting Pronouncements**

From time to time, new accounting pronouncements are issued by FASB 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 consolidated financial position, results of operations, and cash flows, or do not apply to the Company's operations.

**(3) Other Current Assets**

Other current assets consist of the following at December 31:

	2011	2010
	(in thousands)	
Research and development credits receivable (1)	\$	\$ 351
Prepaid expenses and other	1,837	712
	\$ 1,837	\$ 1,063

(1) Represents refunds receivable in the U.K. for research and development expenditures incurred in 2009 at Amarin Neuroscience Ltd (ANL).

**(4) Property, Plant & Equipment**

Property, plant and equipment consist of the following at December 31:

	2011	2010
	(in thousands)	
Leasehold improvements	\$ 42	\$ 14
Computer equipment	201	163
Furniture and fixtures	77	26
	320	203
Accumulated depreciation and amortization	(176)	(115)
Construction in Progress	288	
	\$ 432	\$ 88



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

Depreciation expense for the years ended December 31, 2011, December 31, 2010, and December 31, 2009 was \$0.1 million, \$0.1 million, \$0.6 million, respectively.

F-11

**Table of Contents****(5) Ester Asset Purchase**

In December 2007, the Company purchased 100% of the outstanding share capital of Ester Neurosciences Ltd (Ester). In conjunction with the purchase of Ester, Amarin primarily received the rights to Ester's intellectual property related to EN101. The Ester transaction was accounted for as an asset purchase with the purchase price consisting of an upfront payment of \$5.2 million, \$10.0 million in common stock (with a fair value of \$9.0 million) and a variable contingent payment, payable in common stock, of up to \$5.0 million, based on the achievement of a performance milestone called Milestone Ia. The achievement of Milestone Ia was considered probable and, as a result, the Company recorded a stock based liability with a fair value of \$4.8 million. The stock based liability was remeasured at each reporting date with changes in the fair value recorded as compensation expense (income) as a component of research and development expense. The fair value of this liability was determined to be approximately \$3.4 million at December 31, 2007 and the Company recognized a reduction of compensation expense of \$1.4 million for the period ended December 31, 2007. The fair value of this liability was determined to be approximately \$0.9 million at December 31, 2008 and the company recognized a reduction of compensation expense of \$2.5 million for the period ended December 31, 2008.

In June 2009, the Company amended the terms of its 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 authorized to seek a partner to continue the research and development for EN101. The amendment also provided that any future payment obligations payable by Amarin to the former shareholders of Ester would be made only out of income received from potential partners. Under the terms of this amendment agreement, the former Ester shareholders have the option of reacquiring the original share capital of Ester if Amarin is unable to successfully partner EN101. In August 2009, in connection with this amendment agreement, the Company settled the liability and issued 1,315,789 common shares to the former Ester shareholders, with a fair value on the settlement date of approximately \$1.8 million. The \$0.9 million difference between the \$1.8 million fair value of the common shares issued at settlement and the \$0.9 million fair value of the stock based liability at the settlement date was recognized as compensation expense within research and development for the period ended December 31, 2009.

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

Accrued expenses consist of the following at December 31, 2011 and 2010:

	2011	2010
	(in thousands)	
Payroll and payroll-related expenses	\$ 1,120	\$ 1,631
Research and development expenses	1,132	340
Income taxes payable		585
All other	1,781	572
	\$ 4,033	\$ 3,128

**(7) Warrants and Derivative Liability**

The Company had 21,106,363 warrants to purchase common shares outstanding at December 31, 2011 at a weighted-average exercise price of \$1.48, as summarized in the following table:

Issue Date	Amount	Exercise Price	Expiration Date
4/27/07	17,500	17.90	1/17/14
6/1/07	55,737	7.20	5/31/12
12/5/07	516,300	1.17	12/3/12
7/31/09	138,888+	1.00	7/30/14
7/31/09	1,666,000	1.00	7/30/14
10/16/09	18,064,888	1.50	10/15/14
10/16/09	647,050	1.50	10/15/14

**21,106,363**

**\$ 1.48**

F-12

---

**Table of Contents****October 2009 Warrants**

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 (see footnote 8 Debt). 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 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 an exercise price of \$1.50 per ADS. The total number of warrants issued in conjunction with the financing was 35.2 million.

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 initial fair value of these warrants was determined to be approximately \$47.1 million using the Black-Scholes option pricing model. The Company recorded the warrant issuances as a reduction to additional paid-in capital.

In conjunction with the October 2009 financing, the Company issued an additional 0.9 million warrants to three former officers. The initial fair value of the warrant derivative liability associated with these warrants was determined to be \$1.2 million using the Black-Scholes option pricing model. The Company recorded a warrant derivative liability of \$1.2 million for these warrants and a corresponding charge to compensation expense of \$1.2 million for the period ended December 31, 2009.

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. The fair value of the warrants at December 31, 2009 was determined to be approximately \$41.5 million using the Black-Scholes option pricing model and the Company recognized a gain of approximately \$6.6 million for a change in fair value of warrant derivative liability and a reduction to compensation expense of \$0.2 million for the period ended December 31, 2009.

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. During the year ended December 31, 2010, approximately 5.3 million of these October 2009 warrants were exercised, resulting in gross proceeds to the Company of approximately \$8.0 million. Upon exercise, the fair value of the warrants exercised is remeasured and reclassified from warrant liability to additional paid-in capital. The \$22.3 million fair value of the exercised warrants was transferred from warrant liability to additional paid in capital with the change in the fair value on the exercise date recognized in the statement of operations. The fair value of the warrant liability at December 31, 2010 for the remaining warrants was determined to be approximately \$230.1 million. The Company recognized a loss on change in fair value of derivative liability of \$205.2 million and compensation expense of \$5.7 million for the period ended December 31, 2010.

During the year ended December 31, 2011, approximately 12.1 million of these October 2009 warrants were exercised, resulting in gross proceeds to the Company of approximately \$18.1 million. Upon exercise, the fair value of the warrants exercised is remeasured and reclassified from warrant liability to additional paid-in capital. The \$129.5 million fair value of the exercised warrants was transferred from warrant liability to additional paid in capital with the change in the fair value on the exercise date recognized in the statement of operations. The fair value of the warrant liability at December 31, 2011 for the remaining warrants was determined to be approximately \$123.1 million. The Company recognized a loss on change in fair value of derivative liability of \$22.7 million and compensation income of \$0.1 million for the period ended December 31, 2011.

---

**Table of Contents****June and July 2009 Warrants**

In conjunction with the \$2.6 million private placement of 8% convertible bridge loans due August 2009 in June 2009 the Company issued 1,444,442 warrants with an exercise price of \$1.00. In July 2009, the Company completed a second private placement of \$3.0 million of 8% convertible bridge loans due September 30, 2009. In conjunction with the July loan (i) \$0.1 million of the June 2009 bridge notes were repaid, (ii) the maturity date of the June 2009 bridge notes was extended to September 30, 2009, (iii) the Company cancelled and reissued 1,388,887 of the June 2009 warrants with an exercise price of \$1.00 and (iv) the Company issued an additional 1,666,666 warrants with an exercise price of \$1.00.

The initial fair value of the warrants issued in conjunction with the June 2009 and July 2009 bridge loans was approximately \$1.3 million and \$1.5 million, respectively. Due to the lack of a fixed conversion feature, the warrants were classified as a derivative and the fair value of these warrants of \$2.8 million was recorded in warrant derivative liability at the date of the transaction, with the remaining fair value of the proceeds received of \$2.8 million recorded as loan payable. The difference between the loan payable of \$2.8 million and the face value of the bridge notes of \$5.6 million was recognized over the remaining term of the loan as interest expense of \$2.8 million, and is included in the statement of operations for the period ended December 31, 2009.

In conjunction with the \$70.0 million October 2009 private placement, \$3.6 million of the \$5.5 million outstanding bridge loan notes were converted into 3,999,996 common shares and new warrants were issued to purchase 1,999,996 common shares at an exercise price of \$1.50. On October 16, 2009, the date of the conversion, the fair value of the June and July 2009 warrant derivative liability was \$4.3 million. The resulting increase in the fair value of the bridge loan warrants of \$1.5 million was recognized as a loss on change in fair value of derivative liabilities during the period ended December 31, 2009. At October 2009, the number and value of the underlying shares became fixed and determinable, therefore, the warrants were no longer classified as derivative liability and were remeasured to fair value and reclassified from derivative liability to additional paid-in capital with the change in the fair value on the exercise date recognized in the statement of operations.

**December 2007 Warrants**

In conjunction with a registered direct offering in December 2007, the Company issued approximately 1.0 million warrants to purchase common stock at an initial exercise price of \$4.80 per share, which was later adjusted to \$1.17 based on a price protection provision in the warrant. Due to the pricing variability feature, the warrants were classified as derivative liabilities. The initial fair value of these warrants at December 31, 2007 was calculated to be approximately \$2.1 million. The warrant liability was re-measured at each reporting date with subsequent changes in fair value recognized in the statement of operations.

At December 31, 2008, the fair value of these warrants was \$0.5 million and the Company recognized a gain on change in fair value of derivative liability of approximately \$1.6 million for the period ended December 31, 2008, due to the decrease in the fair value of these warrants from December 31, 2007.

At December 6, 2009, in accordance with the December 2007 purchase agreement, the pricing variability feature of these warrants expired and the number and value of the underlying shares became fixed. As such, the warrants were no longer considered a derivative liability and the fair value of the warrants at December 6, 2009 was determined to be \$1.0 million. The resulting increase in the fair value of the warrants of \$0.5 million was recognized as a loss on change in fair value of derivative liability for the period ended December 31, 2009, and the \$1.0 million fair value of the warrants was reclassified from derivative liability to additional paid-in capital.

**Pre-December 2007 Warrants**

The Company issued several warrants in January 2006, April 2007, June 2007 and November 2007. These have been classified as equity instruments and have been included in the Company's consolidated balance sheet within equity at December 31, 2011 and 2010.

**Table of Contents****(8) Debt**

As of December 31, 2011 and 2010, the Company had no borrowings.

June and July 2009 Bridge Notes

In June 2009 Amarin completed a \$2.6 million private placement of 8% convertible bridge loans due August 2009. In conjunction with the June 2009 bridge loan, the Company issued 1,444,442 warrants with an exercise price of \$1.00. In July 2009, the Company completed a second private placement of \$3.0 million of 8% convertible bridge loans due September 30, 2009. In conjunction with the July 2009 bridge loan (i) \$0.1 million of the June 2009 bridge notes were repaid, (ii) the maturity date of the June 2009 bridge notes was extended to September 30, 2009, (iii) the Company cancelled and reissued 1,388,887 of the June 2009 warrants with an exercise price of \$1.00 and (iv) issued an additional 1,666,663 warrants with an exercise price of \$1.00 (see Note 7 Warrants). The warrants were classified as a derivative and the fair value of these warrants of \$2.8 million was recorded as a warrant derivative liability, with the remaining fair value of the proceeds received of \$2.8 million recorded as loan payable. The difference between the loan payable of \$2.8 million and the face value of the bridge notes of \$5.6 million was recognized over the remaining term of the loan as interest expense of \$2.8 million, and is included in the statement of operations for the period ended December 31, 2009.

In conjunction with the \$70.0 million October 2009 private placement, \$3.6 million of the \$5.5 million outstanding bridge loan notes were converted into 3,999,996 common stock and new warrants were issued to purchase 1,999,996 common shares at an exercise price of \$1.50. The holders of the remaining bridge loans elected to have their principal of \$1.9 million and accrued interest of \$0.1 million which was repaid in cash in 2009.

**(9) Commitments and Contingencies**Litigation

The Company is, from time to time, subject to disputes arising in the normal course of business. While ultimate results of any such disputes cannot be predicted with certainty, at December 31, 2011, there were no asserted claims against the Company which in the opinion of management, would have a material effect on the consolidated financial statements.

Operating 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, 2011 are as follows (in thousands):

Year Ending December 31,	Operating	Capital
2012	\$ 556	\$ 7
2013	465	7
2014	267	7
Total	\$ 1,288	21
Less: interest		2
Total principal obligations		19
Less: current portion		6

Long-term capital lease

\$ 13

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 commenced on November 28, 2011, with payment obligations to begin on the later of January 15, 2012 or the date that certain improvements are completed (the Commencement



---

**Table of Contents**

Date ). The Lease shall terminate on the last day of the month in which the third anniversary of the Commencement Date occurs, but may be extended by Amarin for a period of three years. Under the Lease, Amarin will pay monthly rent of approximately \$8,500 for the first three years and, if Amarin chooses to extend the lease, monthly rent would increase 3% in each of years four, five and six, respectively.

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, 2012 but 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.

In May 2011, the Company entered into an agreement for 9,747 square feet of office space in Bedminster, NJ. Monthly rent is approximately \$21,931. The agreement began July 1, 2011 and terminates on June 30, 2014. The agreement can be terminated by either party with six months prior written notice. In December 2011, the Company leased an additional 2,142 square feet in the same location under the same terms as the previous lease.

As previously disclosed in Amarin's Annual Report on Form 10-K filed on March 16, 2011 for the year ended December 31, 2010, Amarin Pharmaceuticals Ireland Limited, a subsidiary of Amarin, previously gave notice of its intent to terminate the lease agreement for the Company's offices at Block 3, The Oval, Shelbourne Road, Dublin 4, effective as of January 2012. This lease was terminated in December 2011.

On November 1, 2008 the Company entered into a three year operating lease for office space in Mystic, CT. This lease expired on October 31, 2011.

Total rent expense during the years ended 2011, 2010 and 2009 was approximately \$0.5 million, \$0.3 million, and \$0.3 million, respectively.

**Lease Liability**

In December 2005 the Company ceased using the 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. Liabilities for exited lease facilities at December 31, 2011 and 2010 were \$0.1 million and \$0.1 million respectively, and are included on the consolidated balance sheet 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 2010 supply agreement with the Company's existing Japan-based supplier: (i) a one-time non-refundable payment of \$0.5 million is due to the supplier upon the first marketing approval of AMR101 in the United States (ii) the Company is subject to minimum supply purchase commitments; and (iii) if the Company is not successful in obtaining NDA approval for AMR101, a penalty equal to the facility expansion costs incurred by the supplier to meet the supply demands, not to exceed \$5.0 million, less any profits paid to the supplier for purchased materials under the existing agreement;

The Company signed two agreements in 2011 for the supply of API materials for AMR101. These agreements provide access to additional API supply that is incremental to supply from its existing Japan-based API supplier. These agreements include requirements for the suppliers to qualify their materials and facilities. The Company anticipates incurring certain costs associated with the qualification of product produced by these suppliers. Following FDA approvals of AMR101, these agreements include annual purchase levels to enable Amarin to maintain exclusivity with each



**Table of Contents**

respective supplier, and to prevent potential termination of the agreements. Because the Company has not yet obtained FDA approval for AMR101, no liability has been recorded. The 2011 supply agreements also includes (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 Amarin if the supplier does not successfully develop and qualify the API by a certain date and (iii) a raw material purchase commitment of \$1.1 million.

Concurrent with the agreement with a supplier noted above for commercial supply, Amarin agreed to make a noncontrolling minority share equity investment in the supplier of up to \$3.3 million. In July 2011, the Company invested \$1.7 million under this agreement, which has been included in other long term assets and accounted for under the cost method at December 31, 2011.

The 2009 Lorazepam sale agreement with Elan, whereunder Elan did not assume any obligations under a related Neurostat development agreement and, as a result, Amarin retained a potential obligation to make two milestone payments to Neurostat, contingent upon future events: (i) a \$0.2 million payment if the drug is administered to human subjects by Elan and (ii) a \$0.2 million payment if the drug is tested by Elan in an efficacy study. During 2011 the Company was notified that the first milestone was completed and \$0.2 million was paid in cash in October 2011.

Under the 2004 share repurchase agreement with Laxdale Limited, in connection with commercialization of AMR101 for cardiovascular indications, prior to the end of 2012 the Company is required to pay potential royalties to a former employee of Laxdale of 1% on net sales up to £100 million (approximately \$155 million at December 31, 2011); 0.5% for net sales between £100 million (approximately \$155 million at December 31, 2011) and £500 million (approximately \$773 million at December 31, 2011); and 0.25% for sales in excess of £500 million (approximately \$773 million at December 31, 2011).

In addition, under this same agreement with Laxdale Limited, upon receipt of marketing approval in the U.S. and/or Europe for the first indication for AMR101 (or first indication of any product containing Amarin Neuroscience intellectual property acquired from Laxdale Limited in 2004), the Company must make an aggregate stock or cash payment to the former shareholders of Laxdale Limited (at the sole option of each of the sellers) of £7.5 million (approximately \$11.6 million at December 31, 2011) for each of the two potential marketing approvals (i.e. £15 million maximum, or approximately \$23.2 million at December 31, 2011). In addition, upon receipt of a marketing approval in the U.S. or Europe for a further indication of AMR101 (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 \$7.7 million at December 31, 2011) for each of the two potential market approvals (i.e. £10 million maximum, or approximately \$15.5 million at December 31, 2011).

The Company has no provision for any of the obligations above since the amounts are either not probable or estimable at December 31, 2011. The royalty obligation noted above terminates on December 31, 2012.

**(10) Equity****Common stock**

In January 2011, Amarin sold 13.8 million common shares to both existing and new investors at a price of \$7.60 per share, resulting in gross proceeds of \$104.9 million and net proceeds of \$98.7 million.

During the year ended December 31, 2011, the Company issued 2,273,221 shares as a result of the exercise of stock options, resulting in gross proceeds of \$5.2 million and net proceeds of \$5.1 million. In addition the Company issued 12,888,369 shares as a result of the exercise of warrants, resulting in gross proceeds of \$19.0 million and net proceeds of \$18.7 million.

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

**Table of Contents**

conjunction with the private placement. In consideration for the \$62.3 million in net proceeds Amarin issued 66.4 million units, each unit consisting of (i) one ADS (representing one ordinary share) at 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 conjunction with the \$70.0 million October 2009 private placement, \$3.6 million of the \$5.5 million outstanding bridge loan notes were converted into 3,999,996 shares of common stock and new warrants were issued to purchase 1,999,996 common shares at an exercise price of \$1.50.

In October 2009, the Company issued 39,473 common shares pursuant to an agreement with Proseed Capital Holdings, for a success fee related to the settlement of the Ester milestone Ia amendment.

In June 2009, the Company amended the terms of its 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 authorized to seek a partner for EN101. In connection with this amendment agreement, in August 2009 the Company issued 1,315,789 common shares to the former Ester shareholders, with a fair value on the settlement date of approximately \$1.8 million.

**(11) Income Taxes**

As of December 31, 2011, interest and penalties related to any uncertain tax positions have been insignificant. The Company recognizes interest and penalties related to uncertain tax positions in the provision for income taxes. The total amount of unrecognized tax benefits that would affect the Company's effective tax rate if recognized is \$1.0 million as of December 31, 2011, compared to \$0.5 million as of December 31, 2010.

The following is a reconciliation of the total amounts of unrecognized tax benefits for the years ended December 31, 2011, 2010 and 2009:

	2011	2010	2009
	(In thousands)		
Beginning uncertain tax benefits	\$ 558	\$ 304	\$ 48
Current year increases	439	254	256
Current year decreases			
Ending uncertain tax benefits	\$ 997	\$ 558	\$ 304

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 at December 31, 2011:

Jurisdiction	Tax Years
United States	2008-2011
Ireland	2006-2011
United Kingdom	2010-2011

The Company expects gross liabilities of \$48,000 to expire in 2012.

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

	2011	2010	2009
	(In thousands)		
United States	\$ 1,019	\$ 1,987	\$ 162
Ireland and United Kingdom	(67,629)	(252,077)	(31,669)
	\$ (66,610)	\$ (250,090)	\$ (31,507)



**Table of Contents**

The expense (benefit) from income taxes shown in the accompanying consolidated statements of operations consists of the following for fiscal 2011, 2010 and 2009:

	2011	2010 (In thousands)	2009
<b>Current:</b>			
Federal-U.S.	\$ 3,908	\$ 1,068	\$ 121
State-U.S.	1,101	122	32
United Kingdom			(365)
<b>Total Current</b>	<b>\$ 5,009</b>	<b>\$ 1,190</b>	<b>\$ (212)</b>
<b>Deferred:</b>			
Federal-U.S.	(1,936)	(1,604)	(353)
State-U.S.	(557)	(87)	(336)
Ireland and United Kingdom	(5,566)	(6,035)	(3,540)
Change in valuation allowance	5,566	6,035	3,540
<b>Total Deferred</b>	<b>\$ (2,493)</b>	<b>\$ (1,691)</b>	<b>\$ (689)</b>
	<b>\$ 2,516</b>	<b>\$ (501)</b>	<b>\$ (901)</b>

The expense (benefit) from income taxes differs from the amount computed by applying the statutory income tax rate to income before taxes due to the following for fiscal 2011, 2010 and 2009:

	2011	2010 (In thousands)	2009
Benefits from taxes at statutory rate	\$ (16,652)	\$ (62,523)	\$ (7,877)
Rate differential	3,952	3,871	1,945
Research credits		(1,014)	(897)
Change in valuation reserves	7,120	6,035	3,540
Permanent & other	2,209	17	3,433
Warrant derivative liabilities	5,643	52,761	(1,406)
Other	244	352	361
	<b>\$ 2,516</b>	<b>\$ (501)</b>	<b>\$ (901)</b>

The tax residency of Amarin Corporation plc migrated from the United Kingdom (UK) to Ireland in April 2008. As a result of the migration, unutilized UK trading losses at the date of migration are no longer available for offset against taxable profits. 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, 2011, 2010 and 2009, 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:

	2011	2010 (In thousands)
Deferred tax assets:		

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

Net operating losses	\$ 32,841	\$ 27,171
Stock based compensation	5,706	2,997
Depreciation	40	132
Tax credits	6	30
Other reserves and accrued liabilities	53	422
Net deferred tax asset	38,646	30,752
Less: valuation allowance	(33,379)	(27,978)
	\$ 5,267	\$ 2,774

F-19

**Table of Contents**

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 \$175.7 million, which begin to expire in 2011. In addition, the Company has available U.S. Federal tax credit carryforwards of \$1.2 million and state tax credit carryforwards of \$1.4 million. These carryforwards which will expire between 2028 and 2030 may be used to offset future taxable income, if any. The Company believes that net operating losses attributable to Ester of \$12.0 million are not likely to be realized in the future.

**(12) Stock Incentive Plans and Stock Based Compensation**

On April 29, 2011 the Board, upon the recommendation of the Remuneration Committee, adopted the 2011 Stock Incentive Plan ( 2011 Plan ), which was approved by the Company's shareholders on July 12, 2011. The 2011 Plan replaced the Company's 2002 Stock Option Plan ( 2002 Plan ), which expired on January 1, 2012. The maximum number of the Company's Ordinary Shares of £0.50 each or any ADS's, as to be issued under the 2011 Plan 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, on December 16, 2011, the Company granted nonqualified stock options to an employee to purchase 600,000 shares of the Company's ordinary shares with a 10-year term and an exercise price equal to \$6.35 per share, the closing price of the Company's American Depositary Receipts on the grant date. Twenty-five percent of the options vest on the first anniversary of the grant date with the remaining seventy-five percent to vest ratably over the subsequent 36-month period, subject to continued employment with the Company. These grants were made pursuant to an employment agreement on terms consistent with the 2011 Plan.

Under the terms of the 2011 Plan, options are exercisable at various periods and expire as set forth in the grant document. In the case where an incentive stock option is granted, the maximum expiration date is not later than 10 years from the date of grant. The following table summarizes all stock option activity for the year ended December 31, 2011:

	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, 2011	10,028	\$ 2.69		
Granted	4,445	10.53		
Cancelled/Expired	(328)	16.43		
Exercised	(2,274)	2.27		
Outstanding, December 31, 2011	11,871	\$ 5.33	8.68 years	\$ 40,475
Exercisable, December 31, 2011	3,495	\$ 2.69	8.09 years	\$ 17,972
Vested and Expected to Vest, December 31, 2011	11,787	\$ 5.32	8.68 years	\$ 40,250
Available for future grant at December 31, 2011	2,231			

**Table of Contents**

The weighted average fair value of the stock options granted during the year ended December 31, 2011, 2010 and 2009 was \$8.61, \$2.21, and \$1.12, respectively.

During the year ended December 31, 2011, the Company received cash of \$5.2 million from the exercise of options. The intrinsic value of options exercised during fiscal 2011 was \$11.9 million and \$10.3 million during fiscal 2010. As of December 31, 2011 and 2010, there was \$36.9 million and \$9.6 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 2.5 years. There was an impact of \$0.5 million, on the presentation in the consolidated statement of cash flows relating to excess tax benefits on the federal level that have been realized as a reduction in taxes payable for the year ended December 31, 2010. The Company recognizes compensation expense for the fair values of those awards which have graded vesting on a straight line basis. There were no option exercises during fiscal year 2009. The following table presents the stock-based compensation expense related to option awards for the period ended December 31:

	2011	2010	2009
	(in thousands)		
Research and development	\$ 1,464	\$ 1,534	\$ 1,481
General and administrative	7,830	3,673	1,378
<b>Stock-based compensation expense</b>	<b>\$ 9,294</b>	<b>\$ 5,207</b>	<b>\$ 2,859</b>

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 expected holding period of an industry peer group due to lack of history of employee exercises. 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.

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.

For 2011, 2010 and 2009, the Company used the following assumptions to estimate the fair value of share-based payment awards:

	2011	2010	2009
Risk free interest rate	2.03% - 2.56%	1.5% - 3.1%	2.5% - 3.0%
Expected dividend yield	0.00%	0.00%	0.00%
Expected option life (years)	6.25	5.75 - 6.25	5.75 - 6.25
Expected volatility	105% - 112%	105% - 110%	105% - 110%

**(13) Defined Contribution Plans**

The Company sponsored a defined contribution plan for certain of its employees and makes available a 401(k) plan for its U.S. employees to which it made contributions in prior years. Contributions made by the Company for the years ended December 31, 2011, 2010 and 2009 amounted to \$-0-, \$21,000, and \$306,000, respectively.

**Table of Contents****(14) Related Party Transactions****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 Director of Amarin, is a partner; (ii) 7 million ADSs purchased by Orbimed Advisors LLC, where Dr. Carl L. Gordon, a 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 \$123.1 million warrant derivative liability at December 31, 2011, the fair value of the warrants held by the current and former directors of the Company and their related investment funds amounted to \$102.0 million.

**June 2009 Convertible Bridge Notes**

Sunninghill Ltd, a company controlled by Dr. John Climax, a non-executive director of Amarin until October 2009, purchased \$2.0 million of the Company's June 2009 convertible bridge loans and \$1.0 million of the Company's July 2009 convertible bridge loans. In addition, Mr. Thomas Lynch, then an executive director of Amarin, purchased \$0.3 million of the Company's June 2009 bridge loans. These loans were retired in October 2009 in conjunction with the private placement.

**Elan**

In February 2007 Amarin signed a development and license agreement with Elan Pharma International Ltd, a subsidiary of Elan Corporation, plc (Elan), licensing the rights to develop and market a nasal formulation of lorazepam (NanoCrystal<sup>®</sup>). Mr. Shane Cooke, chief financial officer of Elan is related to Mr. Alan Cooke, former president of Amarin. In 2009 we sold all rights in lorazepam back to Elan for \$0.7 million, which has been included in other income at December 31, 2009.

**Transactions with Directors and Executive officers****Mr. Thomas Lynch**

In March 2007 Amarin's Remuneration Committee approved an agreement between the Company and Dalriada Ltd for consultancy services relating to financing and other corporate matters. Under the agreement, the Company paid Dalriada Ltd £240,000 per annum through June 30, 2010, at which time the agreement terminated. An additional amount of £195,000 was approved by the remuneration committee of which £75,000 (\$121,500) was paid during the year ended December 31, 2007 for consultancy services, with the remainder being paid during the year ended December 31, 2008. In January 2009, the annual consultancy fee was revised to 300,000 (\$400,000) per annum and an additional performance related payment of \$100,000 was paid. Dalriada Ltd is owned by a family trust, the beneficiaries of which include Mr. Thomas Lynch, former Amarin Chairman and Chief Executive Officer.

On October 16, 2009, Mr. Lynch was issued 500,000 warrants to purchase common shares of Amarin upon the completion of the \$70.0 million financing. The fair value of these warrants on the date of grant was \$669,000, which was included in stock compensation expense for the year ended December 31, 2009. In conjunction with Mr. Lynch's participation in the June and July 2009 bridge loans, he received 277,777 shares and 277,776 warrants. The warrants are exercisable for five years from issuance, 138,888 warrants have an exercise price of \$1.00 and 138,888 warrants have an exercise price of \$1.50.



**Table of Contents****Mr. Alan Cooke**

On October 16, 2009, Mr. Cooke, Amarin's former President, entered a compromise agreement with the Company. Pursuant to the compromise agreement, Mr. Cooke received a termination payment of 375,000 (\$607,500) and his options to purchase shares in the Company became fully vested. These options were exercised during 2010. Also on October 16, 2009, Mr. Cooke was issued 247,050 warrants to purchase shares in Amarin. The fair value of these warrants on the date of grant was \$331,000, which was included in stock compensation expense for the year ended December 31, 2009. The warrant exercise price is \$1.50 and they are exercisable for five years from the issuance date.

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

	Fiscal year ended December 31, 2011			
	1st	2nd	3rd	4th
	Quarter	Quarter	Quarter	Quarter
	(In thousands, except per share amounts)			
Revenue	\$	\$	\$	\$
Net income (loss)(1)	18,294	(202,103)	96,345	18,338
Net income (loss) per share:				
Basic	\$ 0.15	\$ (1.58)	\$ 0.72	\$ 0.14
Diluted	\$ 0.12	\$ (1.58)	\$ 0.62	\$ 0.12

	Fiscal year ended December 31, 2010			
	1st	2nd	3rd	4th
	Quarter	Quarter	Quarter	Quarter
	(In thousands, except per share amounts)			
Revenue	\$	\$	\$	\$
Net loss(2)	(9,211)	(41,357)	(11,209)	(187,812)
Net loss per basic and diluted share:	\$ (0.09)	\$ (0.42)	\$ (0.11)	\$ (1.82)

- (1) The net income generated in the first, third and fourth quarters of 2011 were due to the change in the fair value of the warrant derivative liability at each respective quarterly reporting period in 2011. As a result of a decrease in the Company's stock price at each respective quarter end versus the previous quarter end, the value of the derivative liability decreased, resulting in non-cash income for change in the fair value of the warrant derivative. The loss in the second quarter of 2011 was also due primarily to the change in the fair value of the warrant derivative liability, which was due to the Company's stock price increasing in value at June 30, 2011, versus March 31, 2011.
- (2) The increase in net loss in the fourth quarter of 2010 is primarily due to the change in the fair value of the warrant derivative liability as a result of the change in the Company's stock price at December 31, 2010.

**(16) Subsequent Event**

In January 2012, the Company completed the sale of \$150.0 million in aggregate principal amount of 3.5% Convertible Senior Notes due 2032. 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 Corporation plc. The general, unsecured, senior obligations are guaranteed by the parent. Net proceeds to us, after payment of underwriting fees and estimated expenses, were approximately \$144.3 million. The notes bear cash interest at a 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 mature on January 15, 2032. The notes are subject to repurchase by us 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 fundamental change repurchase date.

---

**Table of Contents**

Holders may convert their notes at their option at any time prior to the close of business on the business day immediately preceding October 15, 2031 only under the following circumstances: (1) during any calendar quarter commencing after March 31, 2012 (and only during such calendar quarter), if the last reported sale price of the Company's common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day; (2) during the five consecutive business day period immediately following any five consecutive trading day period, or the measurement period, in which the trading price per \$1,000 principal amount of notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of the Company's common stock and the conversion rate on each such trading day; (3) if the Company calls any or all of the notes for redemption, at any time prior to the close of business on the scheduled trading day immediately preceding the redemption date; or (4) upon the occurrence of specified corporate events. On or after October 15, 2031 until the close of business on the second scheduled trading day immediately preceding the maturity date, holders may convert their notes at any time, regardless of the foregoing conditions have been satisfied. Upon conversion, the Company will pay or deliver, as the case may be, cash, shares of its common stock (and cash in lieu of any fractional share) or a combination of cash and shares of its common stock, at the Company's election. The conversion rate will initially be 113.4572 shares of common stock per \$1,000 principal amount of notes (equivalent to an initial conversion price of approximately \$8.8125 per share of common stock). The conversion rate will be subject to adjustment in some events but will not be adjusted for any accrued and unpaid interest. In addition, following certain corporate events that occur prior to the maturity date, the Company will increase the conversion rate for a holder who elects to convert its notes in connection with such a corporate event in certain circumstances and will pay to such holder any accrued and unpaid interest on the notes to but excluding the conversion date.

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 note. 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. No sinking fund is 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 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 in right of payment to future secured indebtedness to the extent of the value of the assets securing such indebtedness.