

AMARIN CORP PLC\UK  
Form 10-K  
March 16, 2011  
[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, 2010

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)

Not applicable  
(I.R.S. Employer

Identification No.)

First Floor, Block 3, The Oval

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

**Shelbourne Road, Ballsbridge, Dublin 4, 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:**

| <b>Title of Each Class</b>                                       | <b>Name of Each Exchange on Which Registered</b> |
|------------------------------------------------------------------|--------------------------------------------------|
| American Depositary Shares, each representing one Ordinary Share |                                                  |
| Ordinary shares, 50 pence par value per share                    | The NASDAQ Capital Market                        |

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

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, 2010 was approximately \$132.6 million, based upon the closing price on the NASDAQ Capital Market reported for such date.

125,110,493 shares held as American Depositary Shares (ADS), each representing one Ordinary Share, 50 pence par value per share, and 337,768 ordinary shares, were outstanding as of March 1, 2011.

**DOCUMENTS INCORPORATED BY REFERENCE**

Certain information required to be disclosed in Part III of this report is incorporated by reference from the registrant's definitive proxy statement to be filed not later than 120 days after the end of the fiscal year covered by this report.

**Table of Contents**

**Table of Contents**

|                                                                                                                             | <b>Page</b> |
|-----------------------------------------------------------------------------------------------------------------------------|-------------|
| <b>PART I</b>                                                                                                               |             |
| Item 1. <u>Business</u>                                                                                                     | 1           |
| Item 1A. <u>Risk Factors</u>                                                                                                | 16          |
| Item 1B. <u>Unresolved Staff Comments</u>                                                                                   | 32          |
| Item 2. <u>Properties</u>                                                                                                   | 32          |
| Item 3. <u>Legal Proceedings</u>                                                                                            | 33          |
| Item 4. <u>Removed and Reserved</u>                                                                                         | 33          |
| <b>PART II</b>                                                                                                              |             |
| Item 5. <u>Market For Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u> | 34          |
| Item 6. <u>Selected Financial Data</u>                                                                                      | 37          |
| Item 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>                        | 38          |
| Item 7A. <u>Quantitative and Qualitative Disclosures about Market Risk</u>                                                  | 48          |
| Item 8. <u>Financial Statements and Supplementary Data</u>                                                                  | 48          |
| Item 9. <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>                         | 48          |
| Item 9A. <u>Controls and Procedures</u>                                                                                     | 49          |
| Item 9B. <u>Other Information</u>                                                                                           | 52          |
| <b>PART III</b>                                                                                                             |             |
| Item 10. <u>Directors, Executive Officers and Corporate Governance</u>                                                      | 53          |
| Item 11. <u>Executive Compensation</u>                                                                                      | 53          |
| Item 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>              | 53          |
| Item 13. <u>Certain Relationships and Related Transactions, and Director Independence</u>                                   | 53          |
| Item 14. <u>Principal Accountant Fees and Services</u>                                                                      | 53          |
| <b>PART IV</b>                                                                                                              |             |
| Item 15. <u>Exhibits and Financial Statement Schedules</u>                                                                  | 54          |
| <u>SIGNATURES</u>                                                                                                           | 61          |

**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*, *expects*, *plans*, *anticipates*, *believes*, *estimates*, *predicts*, *potential*, or *continue*; the negative of these terms; or other comparable terminology.

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* and elsewhere in this Annual Report on Form 10-K.

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 products 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 are based on assumptions made by us based on such data and our knowledge of such industry, which we believe to be reasonable. None of the sources cited in this Annual Report on Form 10-K has consented to the inclusion of any data from its reports, nor have we sought their consent. Our internal research has not been verified by any independent source, and we have not independently verified any third-party information. While we believe that such information included in this Annual Report on Form 10-K is generally reliable, such information is inherently imprecise. In addition, projections, assumptions, and estimates of our future performance are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in *Risk Factors* in Item 1A of Part I of this Annual Report on Form 10-K and elsewhere in this Annual Report on Form 10-K. These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

**Item 1. *Business***

*References in this report to Amarin, the Company, we, our and us refer to Amarin Corporation plc and its subsidiaries, on a consolidated basis, unless otherwise indicated.*

Amarin and AMR101 are trademarks of Amarin Corporation plc. This Annual Report on Form 10-K also 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

---

## **Table of Contents**

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 First Floor, 110 Cannon Street, London, EC4N 6AR, England. Our principal executive offices are located at First Floor, Block 3, The Oval, Shelbourne Road, Ballsbridge, Dublin 4, Ireland. Our principal research and development facility and certain of our executive offices are located at 12 Roosevelt Avenue, 3<sup>rd</sup> Floor, Mystic, CT 06355, USA. Our U.S. telephone number is (860) 572-4979.

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 clinical-stage biopharmaceutical company focused on developing improved treatments for cardiovascular disease. We are currently focusing our efforts on AMR101, a prescription-grade omega-3 fatty acid, comprising not less than 96% ultra pure icosapent ethyl (ethyl-EPA). Icosapent ethyl is the ethyl ester of the essential omega-3 fatty acid eicosapentaenoic acid (EPA). In November 2010 we reported top-line results from the MARINE trial, the first of our two planned Phase 3 clinical trials of AMR101. In the MARINE trial, AMR101 was investigated as a treatment for very high triglycerides ( $\geq 500$  mg/dL). AMR101 is presently being investigated in a second Phase 3 clinical trial, the ANCHOR trial, for the treatment of patients with high triglycerides ( $\geq 200$  and  $< 500$  mg/dL) who are also receiving statin therapy. Elevated triglyceride levels have been associated with the increased risk of developing cardiac disease as well as being a component of certain other metabolic disorders, such as diabetes and obesity.

The MARINE trial was conducted under a Special Protocol Assessment, or SPA, with the U.S. Food and Drug Administration, or FDA. The ANCHOR trial is currently being conducted under a separate SPA. An SPA is an evaluation by the FDA of a protocol with the goal of reaching an agreement that the Phase III 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.

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. 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 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 trial 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. Additionally, we observed in the trial a safety profile for AMR101 similar to placebo.

The ANCHOR trial is 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 patients with high triglycerides ( $\geq 200$  and  $< 500$  mg/dL) who are on 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 primary endpoint in the trial is the percentage change in triglyceride level from baseline compared to placebo after 12 weeks of treatment. No prescription omega-3 based drug, such as AMR101, is currently approved in the United States for treating high triglyceride levels in statin-treated patients who have mixed dyslipidemia. In December

## **Table of Contents**

2010, we announced that we completed patient enrollment and randomization with 702 patients enrolled and randomized to the 2 gram, 4 gram and placebo arms of the trial. We expect to announce top-line results from the ANCHOR trial in the second quarter of 2011.

We expect to submit a New Drug Application, or NDA, to the FDA in the third quarter of 2011 requesting approval to market and sell AMR101 for the indication being studied in the MARINE trial in the United States. Depending on the timing of the NDA and the results of the ANCHOR trial, we may elect to add the ANCHOR trial results to the NDA we are preparing. If the ANCHOR results are added to the NDA, the NDA would seek approval for the indication studied in the MARINE trial with the ANCHOR results either as a separate indication for use or referenced in the label as data supporting the safe use of AMR101 in the treatment of high triglyceride levels in statin-treated patients who have mixed dyslipidemia. In order to obtain a separate indication for AMR101 based on the ANCHOR trial results, the FDA requires that we have a clinical outcomes study substantially underway at the time of the NDA filing. The results of an outcomes study are not required for FDA approval of the broader indication and an outcomes study is not required for the indication being studied in the MARINE trial. Opportunities to market and sell AMR101 outside the United States are currently under evaluation.

In January 2011, we completed an equity offering from which we received approximately \$98.7 million in proceeds, net of fees and transaction costs. Together with our cash balance of \$31.4 million at December 31, 2010, we believe we have sufficient financial resources to enable us to file an NDA and begin commercial preparation of AMR101 regardless of the NDA submission strategy we choose.

## **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.

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 >200 mg/dL and approximately 4.0 million people in the United States have very high triglyceride levels (≥500 mg/dL). In patients with severely elevated levels of triglycerides, the risk of cardiovascular events is generally overshadowed by the risk of acute pancreatitis, a life-threatening disease.

Mixed dyslipidemia refers to a condition in which patients have a combination of two or more lipid abnormalities including elevated triglycerides, low high-density lipoprotein cholesterol, or 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 adults with triglyceride levels ≥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. Patients with high levels of LDL-C are referred to as having hypercholesterolemia. As estimated by Data Monitor, drug treatment for hypercholesterolemia patients exceeds \$30 billion per year in the United States, with sales dominated by statin therapies.

The leading treatments to lower triglyceride levels are fibrates (fenofibrate and gemfibrozil) and a prescription only omega-3 fatty acid. Currently there is only one FDA approved prescription-only omega-3 fatty

## **Table of Contents**

acid, known as Lovaza® (Omacor® in Europe). Lovaza consists predominantly of the omega-3 ethyl esters of EPA and DHA (Docosahexaenoic Acid) and was launched in the United States in 2005. Marketed in the United States by GlaxoSmithKline, or GSK, U.S. sales of Lovaza in 2010 as reported by GSK were over \$886 million, and worldwide sales of Lovaza/Omacor in 2009 exceeded \$1.0 billion, reflecting substantial annual growth both in the United States and Europe.

### **Market Opportunities for Amarin and Commercial Strategy**

Unlike, Lovaza, which is comprised of the omega-3 ethyl esters of EPA and DHA, AMR101 is comprised of not less than 96% pure ethyl-EPA and no DHA. 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. We believe that the removal of DHA results in removal of this DHA-associated LDL-C raising effect as well removing the fishy taste and smell that is often associated with DHA. Based on the results of the MARINE trial, AMR101 is the first omega-3 based product outside of Japan to demonstrate statistically significant triglyceride reduction without an 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 European Union. Currently no omega-3 based product is approved for lowering high triglycerides in patients with mixed dyslipidemia. If the results of the ANCHOR trial are successful, we believe that AMR101 has the potential to become first-in-class in the prescription-grade omega-3 market.

Our strategy is to seek FDA approval for AMR101 based on the results of the MARINE and ANCHOR trials while considering additional trials to further expand the indication of use potential for AMR101. The indication evaluated in the MARINE trial is independent of the ANCHOR trial and can be submitted independently for FDA approval. We are currently preparing our NDA for AMR101 based on the MARINE trial results. Depending on the timing of the NDA and the results of the ANCHOR trial, we may elect to add the ANCHOR trial results to the NDA we are preparing. If the ANCHOR results are added to the NDA, the NDA would seek approval for the indication studied in the MARINE trial with the ANCHOR results either as a separate indication for use or referenced in the label as data supporting the safe use of AMR101 in the treatment of high triglyceride levels in statin-treated patients who have mixed dyslipidemia. In order to obtain a separate indication for AMR101 based on the ANCHOR trial results, the FDA requires that we have a clinical outcomes study substantially underway at the time of the NDA filing. The results of an outcomes study are not required for FDA approval of the broader indication and an outcomes study is not required for the indication being studied in the MARINE trial.

### **Our Product Candidates**

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

Patient enrollment in this trial began in December 2009, and enrollment and randomization was completed in August 2010 at 229 patients. On November 29, 2010, we reported top-line data for the MARINE trial, where AMR101 was shown to effectively lower triglyceride levels in patients with very high triglycerides (>500 mg/dL) without significantly increasing LDL-C. The MARINE trial results also included favorable findings with respect to significant reductions in total cholesterol, non-HDL-C, Apo B (Apolipoprotein B), and Lp-PLA2 levels, together with a safety profile for AMR101 comparable to placebo. The MARINE trial was conducted in a population representative of millions of people with very high triglyceride levels, which is estimated to include approximately 4.0 million people in the United States.

The trial's primary endpoint, the percent change in triglyceride, or TG, levels from baseline to week 12 compared to placebo, was met for both the 4 gram and 2 gram dose groups. The MARINE trial was required to meet a stringent level of statistical significance of 1% ( $p < 0.01$ ), as agreed in our SPA with the FDA.

## **Table of Contents**

Twenty-five percent of patients in this trial were on background statin therapy. The patient group treated with 4 grams of AMR101 showed a significant median TG decrease of 33% ( $p < 0.0001$ ) compared to placebo, and the patient group treated with 2 grams of AMR101 showed a significant median TG decrease of 20% ( $p = 0.0051$ ) compared to placebo. The median baseline TG 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.

In a pre-specified analysis in the subgroup of patients with baseline TG  $> 750$  mg/dL, representing 39% of all patients, the effect of AMR101 in reducing TG 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 TG levels in this subgroup were 1052 mg/dL, 902 mg/dL and 948 mg/dL for placebo, 4 gram and 2 gram groups, respectively. In addition, the subgroup of patients on background statin therapy had much greater median reductions in TG than those not on statin therapy.

AMR101 did not result in a 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 [ $p=NS$ ]). This is the first and only triglyceride-lowering therapy studied in this population with very high triglyceride levels to show a lack of significant elevation in LDL-C. In addition, there was a statistically significant decrease in median non-HDL-C (total cholesterol less good cholesterol) compared to placebo with both of the AMR101 treated groups (-18% for the 4 gram group [ $p < 0.0001$ ] and -8% for the 2 gram group [ $p < 0.05$ ]).

MARINE trial results also included statistically significant reductions, particularly at 4 grams, in several important lipid and inflammatory markers, including Apo B, Lp-PLA2 (Lipoprotein-phospholipase A2), VLDL-C and Total Cholesterol. For these achieved endpoints, p-values were  $<0.01$  for most and  $<0.05$  for all. Apo B (Apolipoprotein B) is a sensitive index of residual cardiovascular risk and is generally considered to be a better predictor 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.

AMR101 appeared to be well tolerated in the MARINE trial with a safety profile comparable to placebo. There were no treatment-related serious adverse events observed in the MARINE trial.

We plan to provide more details of these results at scientific meetings in 2011.

Patients enrolled in the MARINE trial were given the option to continue on with AMR101 treatment for a period of up to 40-weeks after their last dose in the pivotal trial. The results from this 40-week open label extension period are not part of the MARINE trial primary endpoints.

The MARINE trial was conducted under a SPA with the FDA. An SPA is an evaluation by the FDA of a protocol with the goal of reaching an agreement that the Phase III 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 trial 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. However, there can be no assurance that this will be the case. If the FDA does not consider the SPA to be binding, the agency could assert that additional studies or data are required to support a regulatory submission.

### ***The ANCHOR Trial***

The ANCHOR trial is a multi-center, placebo-controlled, randomized, double-blind, 12-week study to evaluate the efficacy and safety of 2 grams and 4 grams of AMR101 in patients with high triglyceride levels of  $\geq 200$  mg/dL and  $<500$  mg/dL who are on stable statin therapy. Patients in this trial are classified as having high triglyceride levels with mixed dyslipidemia. The primary endpoint in the trial is the percent change in

## **Table of Contents**

triglyceride level from baseline to week 12 compared to placebo. An important secondary endpoint in the ANCHOR trial, necessary in order for us to achieve the broad indication sought from this trial, is to show that the addition of AMR101 to statin therapy does not increase LDL-cholesterol (LDL-C or "bad cholesterol") compared to placebo in this population. Patient enrollment in this trial began in early 2010. On December 16, 2010, we announced that we completed patient enrollment and randomization with 702 patients enrolled and randomized to the 2 gram, 4 gram and placebo arms of the trial. We expect that the 702 patients randomized will be sufficient to demonstrate statistical significance in accordance with the trial protocol. Prior to randomization into the 12-week treatment period, all patients underwent a six-to-eight week washout period of lipid altering drugs, as well as diet and lifestyle stabilization. We expect to announce top-line results from the ANCHOR trial in the second quarter of 2011.

If the results from the ANCHOR trial are positive, we intend to use those results as the basis for broadening the label for AMR101 beyond treatment for very high triglycerides to include treatment for high triglycerides in patients with mixed dyslipidemia on background statin therapy. This should enable the treatment of the majority of patients clinically indicated for hypertriglyceridemic therapy, as outlined by the NCEP Guidelines. In order to seek approval of this potentially expanded indication, we will be required to have substantially enrolled subjects in a medical outcomes study at the time of our NDA submission. We are in the process of defining the clinical trial design for the outcome study. We do not anticipate initiating the outcome study until after the ANCHOR trial is complete. The results of this outcomes study are not required for approval of the indication studied in the ANCHOR trial; the only requirement is that the outcome study is substantially underway.

The ANCHOR trial is being conducted under an SPA with the FDA and all of the clinical sites in the trial are located in the United States. Our principal investigator for the MARINE trial was Harold Bays, M.D., Medical Director and President of Louisville Metabolic and Atherosclerosis Research Center. Our principal investigator for the ANCHOR trial is Christie M. Ballantyne, M.D., Methodist DeBakey Heart and Vascular Center, Houston, Texas. We also engage Medpace, a clinical research organization and other consultants for advice regarding clinical matters.

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

Prior to commencing Phase III trials for AMR101, we did not conduct Phase II trials for the patient populations being studied in the MARINE and ANCHOR trials. Such Phase II studies were not required as part of the SPAs for either trial. Among the reasons why Phase II 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 Epanol and is indicated for hyperlipidemia and peripheral vascular disease and which we understand has 2009 revenues in Japan that exceed \$500 million per year. Clinical data from Japan shows that Epanol is effective in reducing TGs. In addition, in an outcomes study called the Japan EPA Lipid Intervention Study (JELIS) study, which study consisted of more than 18,000 patients followed over multiple years, Epanol, 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.

### ***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 III trials in Huntington's disease. Over 1,000 patients have received 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 positive safety

## **Table of Contents**

and tolerability profile. In the MARINE trial, 229 patients dosed with AMR101 demonstrated a safety profile comparable to placebo. There were no treatment-related serious adverse events in the MARINE study.

In addition to the MARINE and ANCHOR trials, we completed a 28-day pharmacokinetic study in healthy volunteers, and commenced a 26-week study to evaluate the toxicity of AMR101 in transgenic mice. In addition, we need to complete pharmacokinetic drug-drug interaction studies in healthy subjects to evaluate the effect of AMR101 on certain other common prescription drugs. We expect to complete all of these studies prior to submitting an NDA for AMR101 in the third quarter of 2011.

### ***New Lipid Compounds Preclinical Program***

Amarin is 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 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 pharmaceutically active ingredient of AMR101, to encapsulate, bottle and package AMR101 and to maintain inventory of AMR101. Our existing Japan-based supplier has produced all of the active pharmaceutical ingredients for AMR101 for Amarin's clinical trials and they have Drug Master Files, or DMFs, which contain information on the processes and facilities used in drug manufacture and storage on file for qualified production of this active ingredient for use in the United States and European Union. Key aspects of this specification include pharmaceutical grade compound at a level of purity of at least 96% EPA and containing no DHA. The main raw material that constitutes ethyl-EPA is a naturally occurring substance which is sourced from fish oil. We are aware that certain other manufacturers have the ability to produce ethyl-EPA to a similar level of purity, and we are in discussions with certain of these suppliers in order to broaden our supply chain beyond a single source. We expect to add additional suppliers during 2011.

In November 2010, Amarin entered into a new Supply Agreement for the supply of ethyl-EPA with its existing Japan-based supplier. This agreement supersedes the previously disclosed supply agreement, including all financial obligations therein, entered into between Amarin and the supplier in February 2009. The new agreement requires several financial obligations as follows: (1) a non-refundable upfront payment of \$0.5 million, which was paid upon execution of the agreement, (2) a milestone payment of \$0.5 million payable on the first marketing approval of AMR101 in the United States, and (3) minimum purchase obligations that vary based on pre-NDA submission, 6 month after submission, within 6 months after first marketing approval. Under the agreement, the supplier is responsible for any capital costs required to meet the volume demand of Amarin. If the supplier has expanded its manufacturing capacity in accordance with the agreement, the supplier 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 the supplier for the costs incurred to expand their facility less any profits paid to the supplier for the purchase of ethyl-EPA by Amarin under the agreement, but in any event, not to exceed \$5.0 million. Other termination conditions exist, as defined under the contract, including material breach of contract committed by either party. 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 plan to secure additional supply sources and rely on third parties to manufacture commercial quantities of any products we successfully develop. Among the conditions for FDA approval of a pharmaceutical product is

## **Table of Contents**

the requirement that the manufacturer's quality control and manufacturing procedures conform to current Good Manufacturing Practice (cGMP), which must be followed at all times. The FDA typically inspects manufacturing facilities 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. There can be no assurance that additional suppliers will fully-fund the capital costs of our engagement.

### **Our Marketing Partners**

We currently have minimal marketing, sales or 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. With respect to AMR101 for cardiovascular indications, we plan to consider partnership opportunities with larger pharmaceutical companies for the launch, marketing and sale of AMR101. We are in active discussions with various pharmaceutical companies regarding their potential partnering with us for the launch, marketing and sale of AMR101. In parallel, we are developing plans which would allow us to launch, market and sell AMR101 in the United States on our own in the event that an appropriate partnership agreement does not materialize. In February 2011, we announced the appointment of Paul Huff as Chief Commercial Officer, responsible for planning the potential commercialization of AMR101, either on our own or via a partner. In connection with Mr. Huff's appointment, we plan to create a U.S. sales and marketing office in New Jersey.

### **Historical Product Development Programs**

On October 16, 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

## **Table of Contents**

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 have 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. To date, we have been unsuccessful in partnering EN101.

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

Previously we were engaged in the pre-clinical development of AMR103, a novel delivery form of levodopa. 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 industry is 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.

Other pharmaceutical products, including Lovaza/Omacor, which is marketed in the United States by GlaxoSmithKline, have already received FDA approval to treat hypertriglyceridemia. GlaxoSmithKline has substantially greater resources than we do. We expect GlaxoSmithKline would use these resources to compete against us.

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 50-60% EPA and 15-25% DHA) which is being developed by Omthera Pharmaceuticals and expected to initiate Phase III clinical trials in 2011.

In addition, AMR101 will also face competition from dietary supplement companies marketing naturally occurring Omega-3 fatty acids as nutritional supplements.

See Item 1A Risk Factors Even if our products are approved we may not be able to compete effectively against our competitors pharmaceutical products and Risk Factors 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, may be subject to non-Rx competition and consumer substitution.

## **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 I, Phase II and Phase III clinical trials. In Phase I, 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 II 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 III 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 U.S., 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 U.S., 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 I studies typically require less data than larger Phase III 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. We are currently preparing our NDA for submission to the FDA during the third quarter of 2011. 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, we will be required to have substantially enrolled subjects in a medical outcomes study at the time of our NDA submission. We are in the process of defining the clinical trial design for the outcome study. We do not anticipate initiating the outcome study until after the ANCHOR trial is complete. The results of this outcomes study are not required for approval of the indication studied in the ANCHOR trial; the only requirement is that the outcome study is substantially underway.

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 several years 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 U.S. 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 U.S., 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 U.S., 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 I 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 gran

## **Table of Contents**

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

### **Centralized Procedure**

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

### **Decentralized Procedure**

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

## **Table of Contents**

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.

### ***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 U.S., 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.

### **Patents and Proprietary Technology**

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/

## **Table of Contents**

uses and combinations with other drugs. Amarin is prosecuting nine patent families 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 additional patents will be issued for AMR101 or any other or 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 have patents covering our various compounds and their uses. These include filed and granted composition and use patents for the method of treating a number of central nervous system and cardiovascular disorders with highly pure forms of EPA. We currently have no patents that directly apply to the use of AMR101 for hypertriglyceridemia, hyperlipidemia or cardiovascular therapy in the United States or Europe. We are currently prosecuting a number of patent applications in this area, but these applications have not yet resulted in issued patents for AMR101 formulation or its use in treating hypertriglyceridemia, hyperlipidemia or cardiovascular disease, and we cannot be certain whether patents will issue or what commercial value any patents that do issue would have for us. 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 will 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 in the U.S., 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 We are dependent on patents, proprietary rights and confidentiality, and Risk Factors Potential technological changes in our field of business create considerable uncertainty .

### **Patent Term Restoration and Marketing Exclusivity**

Depending upon the timing, duration and specifics of FDA approval of the use of AMR101, 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. In the future, we intend to apply for

## **Table of Contents**

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.

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. A drug is a new chemical entity 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 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.

We intend to pursue both patent extensions and exclusivity as described above, although there can be no assurance that we will be successful.

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.

## **Employees**

At December 31, 2010, we had 16 full-time employees employed in general and administrative and research and development functions. We believe our relations with our employees are good.

## **Organizational Structure**

At December 31, 2010, 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%                                                          |
| Amarin Finance Limited                 | Bermuda                                         | 100%                                                          |

## **Table of Contents**

As of the date of this annual report, 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, Ester Neurosciences Limited or Amarin Finance Limited.

Our principal research and development facility and certain of our executive offices are located at 12 Roosevelt Avenue, 3<sup>rd</sup> Floor, Mystic, CT 06355, USA. Our telephone number in the United States is (860) 572-4979 and 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.

## **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.

## **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, 2010, 2009 and 2008, we reported losses of approximately \$249.6 million, \$30.6 million and \$18.5 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, stockholders' (deficit) equity and working capital. We expect our research and development expenses to significantly increase in connection with our ongoing Phase III clinical trials for AMR101 and 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,

## **Table of Contents**

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 Evaluation Agency, which we refer to as the EMEA, 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 revenues to attain profitability. In addition, our ability to generate profits after any FDA or EMEA 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 our product candidates.

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 revenues depends on obtaining regulatory approvals for our products.***

In order to successfully commercialize a product, we or our potential partners will be 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 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. We are now completing Phase III clinical trials for AMR101 and therefore, our research and development expenses associated with these trials will decrease in 2011, however, if we elect to conduct an outcomes study, our clinical trial costs could increase substantially from current levels. 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.

## **Table of Contents**

### ***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.

### ***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. On December 31, 2010, we had a cash balance of approximately \$31.4 million. In January 2011, we completed an equity offering from which we received approximately \$98.7 million in net proceeds. Based upon current business activities and existing cash resources, we forecast having sufficient cash to enable us to file an NDA requesting approval to market and sell AMR101 and to prepare for the commercialization of, but potentially not to commercialize, AMR101. Our future capital requirements will depend on many factors, including the:

progress of pre-clinical development and laboratory testing and clinical trials, including outcome study costs;

time and costs involved in obtaining regulatory approvals;

number of product candidates we pursue;

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 entering into strategic collaboration with others relating to the commercialization of our product candidates.

Our ability to execute our business strategy and sustain our infrastructure at our currently planned levels will be impacted by whether or not we have sufficient funds. Depending on market conditions and our ability to maintain financial stability, we may not have access to additional funds on reasonable terms or at all. Any inability to obtain additional funds when needed would have a material adverse effect on our business and on our ability to operate on an ongoing basis.

### ***The continued negative economic conditions would likely negatively impact Amarin's ability to obtain financing on acceptable terms.***

While we expect to seek additional funding through public or private financings, we may not be able to obtain financing on acceptable terms, or at all. In addition, the terms of any financings may be dilutive to, or otherwise adversely affect, holders of our outstanding securities. 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.

## **Table of Contents**

***Raising additional capital may cause dilution to our existing stockholders, 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 stockholder.

As of December 31, 2010, there were warrants outstanding for the purchase of up to 34,024,132 American Depositary Shares, or ADSs, each representing one of our ordinary shares, with a weighted average exercise price of \$1.50 per share. We may issue additional warrants to purchase ADSs or ordinary shares in connection with any future financing we may conduct. Further, as of December 31, 2010 we also had outstanding stock options to purchase 10,027,584 ADSs at an average exercise price of \$2.69 per share. The exercise of any of these options or warrants will further dilute your ownership interest.

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.

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

***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;

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;



## **Table of Contents**

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 the active ingredient in AMR101 may not result in the same success 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 III clinical trials for the treatment of Huntington's disease were negative, as a result of which we revised our clinical strategy and shifted our focus of AMR101 towards 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, such as a contraindication or a "black box" warning that the drug carries significant risks of serious or life-threatening adverse effects or other requirements. 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 manufacturer 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.

***Although our two Phase 3 clinical trials are the subject of SPAs with FDA, there can be no assurance that AMR101 will be approved by FDA, even if the results from these clinical trials are positive.***

The MARINE trial was conducted under a Special Protocol Assessment, or SPA, with the U.S. Food and Drug Administration, or FDA. The ANCHOR trial is currently being conducted under a separate SPA. An SPA is an evaluation by the FDA of a protocol with the goal of reaching an agreement that the Phase III 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. Although we are not aware of any such issue, 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 FDA does not consider either of the SPAs to be binding, the agency could assert that additional studies or data are required to support a regulatory submission.

***If approved, our products will be subject to extensive post-approval government regulation.***

Once a product is approved, 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 potentially applicable federal and local laws in the United States and

## **Table of Contents**

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. Sales, marketing, and scientific/educational grant programs must also comply with the U.S. Medicare-Medicaid Anti-Fraud and Abuse Act, as amended, the U.S. False Claims Act, as amended and similar state laws. Pricing and rebate programs must comply with the U.S. Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990, as amended. If products are made available to authorized users of the U.S. Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to U.S. federal and state consumer protection and unfair competition laws. Similar requirements exist in all 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 reimbursement under applicable third party payment and insurance programs.

***We may be dependent upon the success of a limited range of products.***

If development efforts for our products are not successful for any indications or if they are not approved by the FDA, or if adequate demand for our products 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 range of products we will be able to commercialize may be limited. This could restrict our ability to respond to adverse business conditions. If we are not successful in developing any future product or products, or if there is not adequate demand for any such products or the market for such product develops less rapidly than we anticipate, we may not have the ability to shift our resources to the development of alternative products. As a result, the limited range of products we intend to develop could constrain our ability to generate revenues and achieve profitability.

***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.

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, which currently markets Lovaza, a prescription-only omega-3 fatty acid indicated for patients with very high triglycerides, and Abbott

---

## **Table of Contents**

Laboratories, which currently markets Tricor and Trilipix for the treatment of very high triglycerides and mixed dyslipidemia. In addition, we may compete with universities and other institutions involved in the development of technologies and products that may compete with ours. Many of our competitors will likely have greater resources than we do, including financial, product development, marketing, personnel and other resources. Our projected revenue streams for our product candidates, if approved, could be significantly eroded if a competing product obtains marketing approval, particularly if this approval is obtained before the approval of our product candidate.

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.

***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, may be subject to non-prescription competition and consumer substitution.***

Our current lead product candidate, AMR101, is a prescription-only omega-3 fatty acid. 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.

***In order to commercialize any future product that is approved for marketing, we may need to find a collaborative partner to help with marketing and sales.***

Our strategy for commercializing currently anticipates that we will enter into collaborative arrangements with one or more pharmaceutical companies that have product development resources and expertise, established distribution systems and direct sales forces to successfully market our products. If so, we will be reliant on one or more of these strategic partners to generate revenue on our behalf. In the event that we are not successful in finding a suitable partner, we may choose to commercialize AMR101 ourselves. This would require that we build a substantial commercialization infrastructure in order to compete with larger companies with established marketing and sales capabilities.

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 and generate product revenue.

## **Table of Contents**

For example, in October 2009, we announced our heightened strategic and operating focus on cardiovascular disease and our cessation of research and development of product candidates to treat central nervous system disorders. Subsequent to October 2009, we did not receive any acceptable offers to acquire, out-license or otherwise continue the development of any of these product candidates to treat central nervous system disorders.

### ***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 may become subject to product liability claims as a result of our prior sales and marketing activities related to Permax.***

Amarin was responsible for the sales and marketing of Permax® (pergolide mesylate), as an adjunctive treatment for Parkinson's disease, from May 2001 until February 2004. On May 17, 2001, Amarin acquired the U.S. sales and marketing rights to Permax from Elan Corporation, or Elan. An affiliate of Elan had previously obtained the licensing rights to Permax from Eli Lilly and Company in 1993. Eli Lilly originally obtained approval for Permax on December 30, 1988, and has been responsible for the manufacture and supply of Permax since that date. On February 25, 2004, Amarin sold its U.S. subsidiary, Amarin Pharmaceuticals, Inc., including the rights to Permax, to Valeant.

On March 29, 2007, the FDA announced that the manufacturers of pergolide drug products would voluntarily remove these drug products, including Permax, from the market because of the risk of serious damage to patients' heart valves. Further information about the removal of Permax and other pergolide drug products is available on the FDA's website.

Six cases alleging claims related to cardiac valvulopathy and Permax were filed in April 2008 in the United States and currently remain pending. Eli Lilly, Valeant, Amarin Pharmaceuticals (sold to Valeant in 2004 as described above) and unidentified parties are named as defendants in these cases and are defending against the claims and allegations. Based on our review of the online docket reports for these cases, all six appear to be in some stage of settlement, although it's not clear which, if any, have been dismissed or remain pending. To date, Amarin has not been named as a defendant or served with the complaints from these cases.

## **Table of Contents**

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

*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 these 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 that we do not control does not relieve us of these responsibilities and requirements. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be delayed in obtaining regulatory approvals for our product candidates and may be delayed in our efforts to successfully commercialize our product candidates for targeted diseases.

*Our supply of products for clinical trials and ultimately for commercial supply is dependent upon relationships with manufacturers and key suppliers.*

We have no in-house manufacturing capacity and, to the extent we are successful in completing the development of our product candidates and/or acquiring or developing other marketable products in the future, we will be obliged to rely on contract manufacturers. We cannot assure you that we will successfully manufacture any product we may develop, either independently or under manufacturing arrangements, if any, with 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. Manufacturers, and in certain situations their suppliers, are required to comply with current NDA commitments and good manufacturing practices requirements enforced by the FDA, and similar requirements of other countries. The failure by a manufacturer to comply with these requirements could affect its ability to provide us with product.

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 this single supplier were unable to supply us with adequate supply of ethyl-EPA it could have a material adverse affect on our ability to commercialize AMR101.

In the past and currently, we purchase all supplies of the bulk compound (ethyl-EPA), which constitutes the only pharmaceutically active ingredient of AMR101, from a single supplier with a single manufacturing facility located in Japan. While we have contractual freedom to source this ingredient elsewhere, our agreement with our current supplier includes minimum purchase obligations. Moreover, there is no guarantee we will either be successful in identifying alternative supplier(s) or that these manufacturers will be qualified to manufacture the product to our specifications or that such future supplier(s) will have the manufacturing capacity to meet future requirements. All such suppliers are subject to regulatory approval. We cannot assure you that any alternative supplier will have the necessary capacity to meet our requirements or that we can contract with any such 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.

## **Table of Contents**

***We do not currently have the capability to undertake marketing or sales of any potential products.***

We have invested very little in marketing or product sales resources. We cannot assure you that we will be able to acquire such resources. We cannot assure you that we will successfully market any product we may develop, either independently or under marketing arrangements, if any, with other companies. To the extent that we enter into contractual relationships with other companies to market our products, if any, the success of such products may depend on the success of securing and maintaining such contractual relationships and the efforts of those other companies (and any subcontractors they engage).

***We have limited personnel to oversee outsourced contract manufacturing, clinical testing and the regulatory approval process.***

It is likely that we will also need to hire additional personnel skilled in the manufacturing, clinical testing and regulatory compliance process if we develop additional product candidates with commercial potential. We do not currently have the capability to conduct clinical testing in-house and do not currently have plans to develop such a capability. We outsource our clinical testing to contract research organizations. We currently have a limited number of employees and certain other outside consultants who oversee the contract research organizations involved in clinical testing of our compounds.

***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 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. Congress has passed America's Affordable Health Choices Act of 2009 and is considering a number of proposals that are intended to reduce or limit the growth of health care costs and which could significantly transform the market for pharmaceuticals products. 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. In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, also called the Medicare Modernization Act, or MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce costs. These cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

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 reimbursement from Medicare and private payors. Our products may not

## **Table of Contents**

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 the MMA and additional prescription drug coverage legislation, by the possible effect of this legislation on amounts that private insurers will pay 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 six 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 clinical study that compares the cost-effectiveness of our product candidates to other available therapies. Such pharmacoeconomic studies can be costly and the results uncertain. Our business could be harmed if reimbursement of our products is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels.

### **Risks Related to Our Intellectual Property**

#### ***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 U.S. or Europe. We are currently prosecuting a number of patent applications in this area, but these applications have not yet resulted in issued patents for AMR101 formulation or its use in treating hypertriglyceridemia, hyperlipidemia or cardiovascular disease, and we cannot be certain whether patents will issue or what commercial value any patents that do issue would have for us.

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 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 our competitors from breaching these agreements or third parties from independently developing or learning of our trade secrets.

## **Table of Contents**

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

***If we do not obtain protection under the Hatch-Waxman Amendments and similar foreign legislation to extend our patents and to obtain market exclusivity for our product candidates, our business may be materially harmed.***

We believe that the AMR101 compound is a new chemical entity in the United States and may be eligible for market exclusivity under the Food Drug and Cosmetic Act, or FDCA, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments. A drug can be classified as a new chemical entity if the FDA has not previously approved any other new drug containing the same active agent. Under sections 505(c)(3)(E)(ii) and 505(j)(5)(F)(ii) of the FDCA, as amended by the Hatch-Waxman Amendments, a new chemical entity that is granted regulatory approval may, in the absence of patent protections, be eligible for five years of marketing exclusivity in the United States following regulatory approval. 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. However, there is no assurance that our compounds will be considered to be new chemical entities for these purposes or be entitled to the period of marketing exclusivity. 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 the manufacturers of generic alternatives. Further, even if our compounds are considered to be new chemical entities and we are able to gain five years of 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 complete a full NDA with a complete 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**

***We have lost our foreign private issuer status, which will result in significant additional costs and expenses.***

Until January 1, 2011, we were a foreign private issuer, as such term is defined in Rule 405 under the U.S. Securities Act of 1933, as amended. As such, we were exempt from certain provisions applicable to U.S. public companies including:

the rules under the Securities Exchange Act of 1934, as amended, or Exchange Act, requiring the filing with the SEC of quarterly reports on Form 10-Q and current reports on Form 8-K;

the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act;

the provisions of Regulation FD aimed at preventing issuers from making selective disclosures of material information; and

## **Table of Contents**

the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and establishing insider liability for profits realized from any short-swing trading transaction (a purchase and sale, or sale and purchase, of the issuer's equity securities within less than six months).

We conducted the test for whether or not we were able to remain a foreign private issuer on June 30, 2010 and we determined that we would lose our status as a foreign private issuer effective as of January 1, 2011.

The regulatory and compliance costs to us under U.S. securities laws as a U.S. domestic issuer will be significantly more than costs we incur as a foreign private issuer. In addition to having to make the above described filings with the U.S. Securities and Exchange Commission, which are more detailed than forms typically filed by a foreign private issuer, we lost our ability to rely upon exemptions from certain corporate governance requirements and we are now required to prepare our financial statements in accordance with U.S. generally accepted accounting principles.

***We will incur significant, increased costs as a result of previously applicable, as well as of newly applicable, 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, commencing in fiscal 2010 and continuing in subsequent years, 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. 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 or the existing material weakness may not be fully remediated. 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 existence of the identified material weakness or 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 our stock 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 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.

## **Table of Contents**

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

Although we are incorporated in England and Wales, we have sought to conduct our affairs in such a way so as to be resident in Ireland for tax purposes. In general, 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. 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 this will be the case. 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.

### **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, 2011 we had 124,360,252 common shares outstanding. As of January 31, 2011 there were 124,011,453 shares held as ADSs and 348,799 held as common shares (which are not held in the form of ADSs). We issued 66.4 million ADSs and warrants to purchase an additional 33.2 million ADSs in our October 2009 private placement. 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, particularly 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 announcement of new products or technologies;

innovation by us or our competitors;

developments or disputes concerning any future patent or proprietary rights;

actual or potential medical results relating to our products or our competitors' products;

interim failures or setbacks in product development;

regulatory developments in the United States, the European Union or other countries;

currency exchange rate fluctuations; and

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

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

As of March 7, 2011 our executive officers, directors and affiliated investment funds collectively control approximately 28% of our outstanding ADSs, excluding any ADSs that such persons may have the right to

## **Table of Contents**

acquire upon exercise of outstanding options or warrants. As a result, these stockholders, if they act together, will be able to influence our management and affairs and all matters requiring stockholder 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, Fountain Healthcare Partners 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. Amarin has agreed to nominate one (1) designee of investment funds affiliated with each of Orbimed Advisors LLC, Sofinnova Ventures and Fountain Healthcare Partners to its Board of Directors for so long as such funds beneficially own at least fifty percent (50%) of the ADSs it purchased in the October 2009 private placement. Dr. Carl L. Gordon, Dr. James I. Healy and Dr. Manus Rogan were respectively designated by these investment funds pursuant to this arrangement. Investment funds affiliated with Orbimed Advisors LLC, Sofinnova Ventures and Fountain Healthcare Partners also have the right to designate two (2) additional independent directors for Amarin to nominate to its Board of Directors for so long as these funds collectively own at least twenty-five percent (25%) of Amarin's outstanding voting securities. In addition, Amarin has 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 Amarin's 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 stockholders may desire and might negatively affect the market price of our common stock.

***Actual or potential sales of our stock 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 will continue to adopt pre-arranged stock trading plans to sell a portion of our common stock. Generally, stock sales under such plans by members of our senior management team and directors require public filings. Actual or potential sales of our stock by such persons could cause our stock price to fall or prevent it from increasing for numerous reasons. For example, a substantial amount of our common stock becoming available (or being perceived to become available) for sale in the public market could cause the market price of our common stock to fall or prevent it from increasing. Also, actual or potential sales by such persons could be viewed negatively by other investors.

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

Our ADSs are currently trading above \$1.00; however, during periods of 2010, 2009 and 2008, they were trading beneath \$1.00 per share, including during an extended period from October 6, 2008 to April 7, 2009. If Amarin's closing bid price is less than \$1.00 for 30 consecutive trading days, Amarin will receive a NASDAQ staff deficiency letter indicating that we are not in compliance with the minimum bid price requirement for continued listing. Such a letter would trigger an automatic 180 calendar day period within which the company could regain compliance. Compliance is regained at any time during this period if the Amarin closing bid price is \$1.00 per share or more for a minimum of 10 consecutive trading days. If compliance cannot be demonstrated by the end of the 180 days, Amarin will be afforded an additional 180 calendar day compliance period if NASDAQ determines at that time that we meet the remaining NASDAQ Capital Market initial listing criteria in Rule 5215(b), except for the bid price requirement. If Amarin was not eligible for an additional compliance period, NASDAQ would provide written notification that our securities will be delisted. At that time, Amarin could appeal NASDAQ's determination to delist its securities to a Listing Qualifications Panel.

## **Table of Contents**

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

We are incorporated under English law. The rights of holders of common 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 stockholders in typical U.S. corporations. The principal differences include the following:

Under English law, each stockholder present at a meeting has only one vote unless demand is made for a vote on a poll, in which each holder gets one vote per share owned. Under U.S. law, each stockholder 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, each stockholder generally has preemptive rights to subscribe on a proportionate basis to any issuance of shares. Under U.S. law, stockholders generally do not have preemptive rights unless specifically granted in the certificate of incorporation or otherwise.

Under English law, certain matters require the approval of 75% of the stockholders, including amendments to the Memorandum and 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 stockholder approval is required to amend the certificate of incorporation or to approve other significant transactions.

Under English law, a bidder seeking to acquire us would need to make a tender offer for 90% of our outstanding common shares/ADSs. If this 90% threshold is not achieved in the offer, under English law, the bidder cannot complete a second step merger to obtain 100% control of us. Accordingly, tender of 90% of our outstanding common shares/ADSs will be a condition in a tender offer to acquire us, not 50% as is more common in tender offers for corporations organized under Delaware law.

Under English law, stockholders may be required to disclose information regarding their equity interests 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 the transfer of the shares, as well as restrictions on dividends and other payments. Comparable provisions generally do not exist under U.S. law.

The quorum requirement for a stockholders' meeting is a minimum of two persons present in person or by proxy. Under U.S. law, a majority of the shares eligible to vote must generally be present (in person or by proxy) at a stockholders' 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. stockholders may not be able to enforce civil liabilities against us.***

A number of our directors and 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. Amarin Finance Limited is an exempted company limited by shares organized under the laws of Bermuda. We have been advised by our Bermuda attorneys that uncertainty exists as to whether courts in Bermuda will enforce judgments obtained in other jurisdictions (including the United States) against us or our directors or officers under the securities laws of those jurisdictions or entertain actions in Bermuda against us or our directors or officers under the securities laws of other jurisdictions.



## **Table of Contents**

***U.S. Holders of our ADSs could be subject to material adverse tax consequences if we are considered a PFIC for U.S. federal income tax purposes.***

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.

While we cannot provide any assurance that we are, are not, or will or will not be, a PFIC for the fiscal year ended December 31, 2010 or for future periods, given the status of development for AMR101 and the most recent available information regarding our 2010 financial position and results of operations, we believe it prudent to assume that we may be classified as a PFIC for the fiscal year ended December 31, 2010 and may also be so classified in future years.

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.

***U.S. Holders of our ADSs 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 stockholder 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% stockholder may also be taxable at ordinary income tax rates on any gain realized on a sale of common 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 our common shares or ADSs are urged to consult their own tax advisors regarding the possible application of the CFC rules to them in their particular circumstances.

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

None.

### **Item 2. *Properties***

The following table lists the location, use and ownership interest of our principal properties as of December 31, 2010:

| <b>Location</b>                        | <b>Use</b> | <b>Ownership</b>  | <b>Size (sq. ft.)</b> |
|----------------------------------------|------------|-------------------|-----------------------|
| Dublin, Ireland                        | Offices    | Leased and sublet | 3,251                 |
| Mystic, Connecticut, USA               | Offices    | Leased            | 4,075                 |
| Ely, Cambridgeshire, UK (Gemini House) |            |                   |                       |
| Ground Floor                           | Offices    | Leased and sublet | 7,135                 |
| First Floor                            | Offices    | Assigned          | 2,975                 |

On November 1, 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 expire on October 31, 2011.

## **Table of Contents**

In January 2007 we leased 3,251 square feet of office space in Dublin, Ireland. This lease expires in December 2026, but may be terminated on January 22, 2012 with twelve months' written notice. On October 7, 2010, we gave notice of our intent to terminate the lease agreement, effective as of January 2012, for the lease of office space on the first floor of the building located at Block 3, The Oval, Shelbourne Road, Dublin 4. We were a guarantor of this lease agreement. In connection with the termination of this lease agreement, we will pay a sum equivalent to six months' rent, rates, service fees and insurance premiums and may also be liable for customary dilapidation charges. In June 2010, we sublet a portion of this office and this sublease may be cancelled upon 30 days' written notice.

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

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

### **Item 3.      *Legal Proceedings***

Amarin was responsible for the sales and marketing of Permax® (pergolide mesylate), as an adjunctive treatment for Parkinson's disease, from May 2001 until February 2004. On May 17, 2001, Amarin acquired the U.S. sales and marketing rights to Permax from Elan. An affiliate of Elan had previously obtained the licensing rights to Permax from Eli Lilly and Company in 1993. Eli Lilly originally obtained approval for Permax on December 30, 1988 and has been responsible for the manufacture and supply of Permax since that date. On February 25, 2004, Amarin sold its U.S. subsidiary, Amarin Pharmaceuticals, Inc., including the rights to Permax, to Valeant Pharmaceuticals International.

On March 29, 2007, the FDA announced that the manufacturers of pergolide drug products would voluntarily remove these drug products, including Permax, from the market because of the risk of serious damage to patients' heart valves. Further information about the removal of Permax and other pergolide drug products is available on the FDA's website.

Six cases alleging claims related to cardiac valvulopathy and Permax were filed in April 2008 in the United States and currently remain pending. Eli Lilly, Valeant, Amarin Pharmaceuticals (sold to Valeant in 2004 as described above) and unidentified parties are named as defendants in these cases and are defending against the claims and allegations. Based on our review of the online docket reports for these cases, all six appear to be in some stage of settlement, although it's not clear which, if any, have been dismissed or remain pending. To date, Amarin has not been named as defendant or served with the complaints from these cases.

### ***Other***

We are not a party to any other 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.      *Removed and Reserved***

**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 Capital Market.

|                     | Common Stock Price |         |             |         |
|---------------------|--------------------|---------|-------------|---------|
|                     | Fiscal 2010        |         | Fiscal 2009 |         |
|                     | High               | Low     | High        | Low     |
| First Quarter       | \$ 1.60            | \$ 0.93 | \$ 0.80     | \$ 0.46 |
| Second Quarter      | \$ 2.95            | \$ 1.46 | \$ 2.25     | \$ 0.62 |
| Third Quarter       | \$ 3.23            | \$ 2.02 | \$ 1.60     | \$ 1.01 |
| Fourth Quarter      | \$ 8.64            | \$ 2.43 | \$ 1.85     | \$ 1.01 |
| <b>Shareholders</b> |                    |         |             |         |

As of March 1, 2011, there were approximately 593 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**

*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 Corporation plc'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, 2005 and its relative performance is tracked through December 31, 2010.

| Company/Market/Peer Company | 12/31/2005 | 12/31/2006 | 12/31/2007 | 12/31/2008 | 12/31/2009 | 12/31/2010 |
|-----------------------------|------------|------------|------------|------------|------------|------------|
| Amarin Corporation PLC      | \$ 100.00  | \$ 190.00  | \$ 21.67   | \$ 5.92    | \$ 11.92   | \$ 68.34   |
| NASDAQ Composite Index      | \$ 100.00  | \$ 110.25  | \$ 121.88  | \$ 73.10   | \$ 106.22  | \$ 125.36  |
| NASDAQ Biotechnology Index  | \$ 100.00  | \$ 101.07  | \$ 105.76  | \$ 92.75   | \$ 107.55  | \$ 123.96  |

**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 ADS beneficially owned by you will not generally be subject to UK inheritance tax on your death or on a gift made by you during your lifetime, provided that any applicable United States federal gift or estate tax liability is paid, except where the 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.

### **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.

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

The selected financial data set forth below as of December 31, 2010 and 2009 and for each of the years ended 2010, 2009 and 2008 have been derived from the audited consolidated financial statements of the Company, included elsewhere in this Annual Report on Form 10-K. The selected financial data set forth below as of December 31, 2008, 2007 and 2006 and for the years ended December 31, 2007 and 2006 are 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.

|                                                                 | 2010         | Years Ended December 31,                 |                    |             | 2006        |
|-----------------------------------------------------------------|--------------|------------------------------------------|--------------------|-------------|-------------|
|                                                                 |              | 2009                                     | 2008               | 2007        |             |
|                                                                 |              | (In thousands, except per share amounts) |                    |             |             |
| Consolidated Statements of Operations Data                      |              |                                          |                    |             |             |
| Revenues                                                        | \$           | \$                                       | \$                 | \$          | \$          |
| OPERATING EXPENSES:                                             |              |                                          |                    |             |             |
| Research and development                                        | 28,014       | 20,892                                   | 7,899              | 10,349      | 14,661      |
| General and administrative (1)                                  | 17,087       | 13,152                                   | 19,622             | 18,093      | 12,719      |
| Purchased in-process research & development                     |              |                                          |                    | 19,916      |             |
| Total operating expenses                                        | 45,101       | 34,044                                   | 27,521             | 48,358      | 27,380      |
| Operating loss                                                  | (45,101)     | (34,044)                                 | (27,521)           | (48,358)    | (27,380)    |
| (Loss) gain on change in fair value of derivative liability (2) | (205,153)    | 5,137                                    | 9,289              | 397         | (2,818)     |
| Interest expense                                                | (19)         | (2,832)                                  | (836)              | (180)       | (2)         |
| Interest income                                                 | 53           | 199                                      | 431                | 1,252       | 1,344       |
| Other income (expense), net                                     | 130          | 33                                       | (900)              | 205         | 36          |
| Loss from continuing operations before taxes                    | (250,090)    | (31,507)                                 | (19,537)           | (46,684)    | (28,820)    |
| Benefit from (provision for) income taxes                       | 501          | 901                                      | 1,048              | 837         | 799         |
| Net loss applicable to common stockholders                      | \$ (249,589) | \$ (30,606)                              | \$ (18,489)        | \$ (45,847) | \$ (28,021) |
| (Loss) income per basic and diluted share:                      | \$ (2.49)    | \$ (0.72)                                | \$ (0.84)          | \$ (4.69)   | \$ (3.40)   |
| Weighted average shares:                                        |              |                                          |                    |             |             |
| Basic and diluted                                               | 100,239      | 42,424                                   | 22,086             | 9,784       | 8,231       |
|                                                                 | 2010         | 2009                                     | As of December 31, |             | 2006        |
|                                                                 |              |                                          | 2008               |             |             |
|                                                                 |              |                                          | (in thousands)     |             |             |
| Consolidated Balance Sheet Data:                                |              |                                          |                    |             |             |
| Cash, cash equivalents                                          | \$ 31,442    | \$ 52,258                                | \$ 14,239          | \$ 18,303   | \$ 36,802   |
| Total assets                                                    | 35,367       | 55,444                                   | 17,135             | 22,507      | 39,923      |
| Long-term obligations                                           | 230,157      | 42,090                                   | 1,591              | 7,714       | 110         |
| Stockholders' (deficit) equity                                  | (202,367)    | 6,597                                    | 8,416              | 4,563       | 28,932      |

- (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 employees 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 intend, estimate, anticipate, believe, plan or expect and similar expressions are included to identify forward-looking statements. 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 clinical-stage biopharmaceutical company focused on developing improved treatments for cardiovascular disease. We are currently focusing our efforts on AMR101, a prescription-grade omega-3 fatty acid, comprising not less than 96% ultra pure icosapent ethyl (ethyl-EPA).

On October 16, 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, a significant portion of our board of directors and executive management were changed, 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 November 2010, we reported positive top-line results from the MARINE trial, the first of our two planned Phase 3 clinical trials of AMR101. In the MARINE trial, AMR101 was investigated as a treatment for very high triglycerides ( $\geq 500$  mg/dL). AMR101 is presently being investigated in a second Phase 3 clinical trial, the ANCHOR trial, for the treatment of patients with high triglycerides ( $\geq 200$  and  $< 500$  mg/dL) who are also receiving statin therapy. 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. Patients with this level of triglycerides are characterized as having very high triglyceride levels, as outlined in the NCEP Guidelines. 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. Additionally, we observed in the trial a safety profile for AMR101 similar to placebo.

The ANCHOR trial is 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 patients with high triglycerides ( $\geq 200$  and  $< 500$  mg/dL) who are on 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 primary endpoint in the trial is the percentage change in triglyceride level from baseline compared to placebo after 12 weeks of treatment. No prescription omega-3 based drug, such as AMR101, is currently approved in the U.S. for treating high triglyceride levels in statin-treated patients who have mixed dyslipidemia. In December 2010, we announced that we completed patient enrollment and randomization with 702 patients enrolled and randomized to the 2 gram, 4 gram and placebo arms of the trial. We expect to announce top-line results from the ANCHOR trial in the second quarter of 2011.

## **Table of Contents**

The MARINE trial was conducted under a SPA with the FDA. The ANCHOR trial is currently being conducted under a separate SPA. An SPA is an evaluation by the FDA of a protocol with the goal of reaching an agreement that the Phase III 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. Although we are not aware of any such issue, 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 FDA does not consider either of the SPAs to be binding, the agency could assert that additional studies or data are required to support a regulatory submission.

We expect to submit a New Drug Application, or NDA, to the FDA in the third quarter of 2011 requesting approval to market and sell AMR101 in the United States. Our strategy is to seek FDA approval for AMR101 based on the results of the MARINE and ANCHOR trials while considering additional trials to further expand the indication of use potential for AMR101. We are currently preparing our NDA for AMR101 based on the MARINE trial results. Depending on the timing of the NDA and the results of the ANCHOR trial, we may elect to add the ANCHOR trial results to the NDA we are preparing. If the ANCHOR results are added to the NDA, the NDA will seek approval for the indication studied in the MARINE trial with the ANCHOR results either as a separate indication for use or referenced in the label as data supporting the safe use of AMR101 in the treatment of high triglyceride levels in statin-treated patients who have mixed dyslipidemia. In order to obtain a separate indication for AMR101 based on the ANCHOR trial results, the FDA requires that we have a clinical outcomes study substantially underway at the time of the NDA filing. The results of an outcomes study are not required for FDA approval of the broader indication and an outcomes study is not required for the indication being studied in the MARINE trial. Opportunities to market and sell AMR101 outside the United States are currently under evaluation.

In January 2011 we completed an equity offering from which we received approximately \$98.7 million in net proceeds. Together with our cash balance of \$31.4 million at December 31, 2010, we believe that we have sufficient financial resources to enable us to file the NDA and prepare for the commercialization of AMR 101, regardless of the NDA submission strategy we choose.

### ***Clinical Trial Status***

#### **The MARINE Trial**

Patient enrollment in this trial began in December 2009, enrollment and randomization was completed in August 2010 at 229 patients. On November 29, 2010, we reported top-line data for the MARINE trial, where AMR101 was shown to effectively lower triglyceride levels in patients with very high triglycerides (>500 mg/dL) without significantly increasing LDL-C. The MARINE trial results also included favorable findings with respect to significant reductions in total cholesterol, non-HDL-C, Apo B (Apolipoprotein B), and Lp-PLA2 levels, together with a safety profile for AMR101 comparable to placebo. The MARINE trial was conducted in a population representative of millions of people with very high triglyceride levels, which is estimated to include approximately 4.0 million people in the United States.

The study's primary endpoint, the percent change in triglyceride, or TG, levels from baseline to week 12 compared to placebo, was met for both the 4 gram and 2 gram dose groups. The MARINE study was required to meet a stringent level of statistical significance of 1% ( $p < 0.01$ ), as agreed in our SPA with the FDA. Twenty-five percent of patients in this trial were on background statin therapy. The patient group treated with 4 grams of AMR101 showed a significant median TG decrease of 33% ( $p < 0.0001$ ) compared to placebo, and the patient group treated with 2 grams of AMR101 showed a significant median TG decrease of 20% ( $p = 0.0051$ ) compared to placebo. 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 TG > 750 mg/dL, representing 39% of all patients, the effect of AMR101 in reducing TG 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 TG levels in this subgroup were 1052 mg/dL, 902 mg/dL and 948 mg/dL for placebo, 4 gram and 2 gram groups, respectively. In addition, the subgroup of patients on background statin therapy had much greater median reductions in TG, which were also statistically significant, than those not on statin therapy.

AMR101 did not result in an 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 [ $p=NS$ ]). This is the first and only triglyceride-lowering therapy studied in this population with very high triglyceride levels to show a lack of elevation in LDL-C. In addition, there was a statistically significant decrease in median non-HDL-C (total cholesterol less 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 [ $p < 0.05$ ]).

MARINE trial results also included statistically significant reductions in several important lipid markers, including Apo B, Lp-PLA2 (Lipoprotein-phospholipase A2), VLDL-C and Total Cholesterol. For these achieved endpoints, p-values were  $<0.01$  for most and  $<0.05$  for all. Apo B (Apolipoprotein B) is a sensitive index of residual cardiovascular risk and is generally considered to be a better predictor 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. 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. We plan to provide more details of these results at scientific meetings in 2011.

Patients enrolled in the MARINE trial were given the option to continue on with AMR101 treatment for a period of up to 40-weeks after their last dose in the pivotal trial. The results from this 40-week open label extension period are not part of the MARINE trial clinical endpoints.

The MARINE trial was conducted under a SPA with the FDA. An SPA is an evaluation by the FDA of a protocol with the goal of reaching an agreement that the Phase III 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 trial 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. However, there can be no assurance that this will be the case. If FDA does not consider the SPA to be binding, the agency could assert that additional studies or data are required to support a regulatory submission.

### **The ANCHOR Trial**

The ANCHOR trial is a multi-center, placebo-controlled, randomized, double-blind, 12-week study to evaluate the efficacy and safety of 2 grams and 4 grams of AMR101 in patients with high triglyceride levels of  $\geq 200$  mg/dL and  $<500$  mg/dL who are on stable statin therapy. Patients in this trial are classified as having high triglyceride levels with mixed dyslipidemia. The primary endpoint in the trial is the percent change in triglyceride level from baseline to week 12 compared to placebo. An important secondary endpoint in the ANCHOR trial, necessary in order for us to achieve the broad indication sought from this trial, is to show that the addition of AMR101 to statin therapy does not increase LDL-cholesterol (LDL-C or bad cholesterol) compared to placebo in this population.

Patient enrollment in this trial began in early 2010. On December 16, 2010, we announced that we completed patient enrollment and randomization with 702 patients enrolled and randomized to the 2 gram, 4 gram and placebo arms of the trial. We expect that the 702 patients randomized will be sufficient to demonstrate statistical significance in accordance with the trial protocol. Prior to randomization into the 12-week treatment period, all

## **Table of Contents**

patients underwent a six-to-eight week washout period of lipid altering drugs, as well as diet and lifestyle stabilization. We expect to announce top-line results from the ANCHOR trial in the second quarter of 2011.

If the results from the ANCHOR trial are positive, we intend to use these results as the basis for broadening the label for AMR101 beyond treatment for very high triglycerides to include treatment for elevated triglycerides in patients with mixed dyslipidemia on background statin therapy. This should enable the treatment of the majority of patients clinically indicated for hypertriglyceridemic therapy, as outlined by the NCEP Guidelines. In order to seek approval of this potentially expanded indication, we will be required to have substantially enrolled subjects in a medical outcomes study at the time of our NDA submission. We are in the process of defining the clinical trial design for the outcome study. We do not anticipate initiating the outcome study until after the ANCHOR trial is complete. The results of this outcomes study are not required for approval of the indication studied in the ANCHOR trial; the only requirement is that the outcome study is substantially underway.

The ANCHOR trial is being conducted under an SPA with the FDA and all of the clinical sites in the trial are located in the United States.

## **Critical Accounting Policies and Significant Judgments and Estimates**

Our discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements and notes, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expenses. On an ongoing basis, we evaluate our estimates and judgments, including those related to derivative financial liabilities. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. A summary of our significant accounting policies is contained in Note 2 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K. We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our consolidated financial statements.

*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.

## **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.

**Table of Contents****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, 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).

We expect research and development expenses associated with the MARINE and ANCHOR studies to decrease during 2011 as those trials near completion. However, if we elect to conduct an outcomes study, which decision will follow upon review of the ANCHOR results and finalization of an outcome study design, the anticipated decline in research and development could be substantially offset by costs associated with the outcomes study.

**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 employees 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 Mystic, CT.

We expect general and administrative costs in 2011 to begin to increase as we prepare for the commercialization of AMR101, including costs for market research, sales force preparation and inventory management.

*(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 the Company's common stock. 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

**Table of Contents**

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.

*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.

**Comparison of Fiscal Years Ended December 31, 2009 versus December 31, 2008**

*Revenue.* We recorded no revenue in 2009 or 2008.

*Research and Development Expense.* Research and development expense for the year ended December 31, 2009 was \$20.9 million, versus \$7.9 million in the prior year, an increase of \$13.0 million. Research and development expenses for the years ended December 31, 2009 and 2008 are summarized in the table below:

|                                                                  | 2009      | 2008     |
|------------------------------------------------------------------|-----------|----------|
| Research and development expenses (1)                            | \$ 18,509 | \$ 9,088 |
| Non-cash stock based compensation expense (2)                    | 1,481     | 1,299    |
| Non-cash change in fair value of Ester share based liability (3) | 902       | (2,488)  |
|                                                                  | \$ 20,892 | \$ 7,899 |

- (1) Research and development expense, excluding non cash charges, for the year ended December 31, 2009 was \$18.5 million, versus \$9.1 million in the prior year period, an increase of \$9.4 million. This increase in research and development expense was primarily due to higher costs in 2009 for our new AMR101 cardiovascular program, which included costs associated with our two planned Phase III clinical trials, increases in Mystic, CT-based staffing to support these cardiovascular trials and clinical trial start-up costs incurred with Medpace.
- (2) Stock based compensation expense included within research and development was \$1.5 million and \$1.3 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. Non-cash change in fair value of Ester share based liability for the year ended December 31, 2008 reflects the change in the fair value between December 2007 and December 2008. See further discussion in Note 8 of the Notes to the Consolidated Financial Statements.

*General and Administrative Expense.* General and administrative expense for the year ended December 31, 2009 was \$13.2 million, versus \$19.6 million in the prior year, a decrease of \$6.4 million, or 32.7%. General and administrative expenses for the years ended December 31, 2009 and 2008 are summarized in the table below:

|                                                   | 2009      | 2008      |
|---------------------------------------------------|-----------|-----------|
| General and administrative expenses (1)           | \$ 8,593  | \$ 15,796 |
| Non-cash warrant related compensation expense (2) | 1,040     |           |
| Non-cash stock based compensation expense (3)     | 1,378     | 2,955     |
| Restructuring, severance and lease exit costs (4) | 2,141     | 871       |
|                                                   | \$ 13,152 | \$ 19,622 |

- (1) General and administrative expense, excluding restructuring, severance and non-cash compensation charges for stock compensation and warrants, for the year ended December 31, 2009 was \$8.6 million, versus



## **Table of Contents**

- \$15.8 million in the prior year, a decrease of \$7.2 million, or 45.6%. The decrease was primarily due to reorganization and cost rationalization programs implemented during 2008.
- (2) Warrant related compensation expense for the year ended December 31, 2009 of \$1.0 million reflects a non-cash expense for the fair value of the warrants issued in October 2009 to three former employees of Amarin.
  - (3) General and administrative expenses also includes stock compensation expense of \$1.4 million related to option awards for the year ended December 31, 2009, versus \$3.0 million in the prior year.
  - (4) Restructuring, severance and lease exit costs for the period ended December 31, 2009 includes a charge of \$2.1 million for severance and other reorganization costs associated with office consolidation and the relocation of certain operations to Mystic, CT. Restructuring, severance and lease exit costs for the period ended December 31, 2008 includes a charge of \$0.9 million reflecting accrued costs for leased office space no longer used.
- (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, 2009 was income of \$5.1 million, versus income of \$9.3 million in the prior year. (Loss) gain on change in fair value of derivative liability for the year ended December 31, 2009 is primarily related to the fair value of the warrants issued in conjunction with the October 2009 private placement. In October 2009 the Company issued approximately 36.1 million warrants at an exercise price of \$1.50 and recognized \$48.3 million for the fair value of the warrant derivative liability. As these warrants have been classified as a liability, they are revalued 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 \$41.5 million and the Company recognized a \$6.6 million gain on change in fair value of derivative liability related to these warrants for year ended December 31, 2009. (Loss) gain on change in fair value of derivative liability for the year ended December 31, 2009 also included changes in fair value for three other derivative liabilities, the total net gain on changes in fair value for derivative liabilities was \$5.1 million. See further discussion of the derivative liability in Note 2 and Note 7 of the Notes to the Consolidated Financial Statements.

For the year ended December 31, 2008 we recognized a \$9.3 million gain on change in fair value of a derivative liability associated with the fair value changes of two derivative liabilities. A gain on change in fair value of a derivative liability of \$1.6 million was recorded in conjunction with a decrease in fair value of a derivative associated with a variable pricing feature of warrants issued in December 2007. In addition, we recognized a \$7.7 million gain on change in fair value of derivative liabilities for a decrease in the fair value of a derivative liability associated with a financing participation option granted in conjunction with the May 2008 financing.

*Interest Income (Expense), net.* Interest income includes interest earned on cash balances. Interest expense for the year ended December 31, 2009 was \$2.8 million versus \$0.8 million in the prior year period. The increase 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. The bridge loans were repaid in conjunction with our October 2009 private placement.

*Other Income (Expense), net.* Other income includes gains and losses on foreign exchange transactions. Other income for the year ended December 31, 2009 included \$0.7 million from the sale of intellectual property. Other expense for the year ended December 31, 2008 was due primarily to foreign exchange losses.

## **Liquidity and Capital Resources**

Our sources of liquidity as of December 31, 2010 include cash and cash equivalents of \$31.4 million. In addition, in January 2011 we completed an equity offering from which we received approximately \$98.7 million in net proceeds. Our projected uses of cash include the completion of our two Phase III clinical trials for AMR101, the submission of an NDA, commercial preparation 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):

**Table of Contents**

|                                                   | Years Ended December 31, |           |           |
|---------------------------------------------------|--------------------------|-----------|-----------|
|                                                   | 2010                     | 2009      | 2008      |
| Cash (used in) provided by continuing operations: |                          |           |           |
| Operating activities                              | \$ (33.9)                | \$ (28.4) | \$ (30.1) |
| Investing activities                              |                          | 0.6       | (0.3)     |
| Financing activities                              | 13.1                     | 65.8      | 26.3      |
| (Decrease) increase in cash and cash equivalents  | \$ (20.8)                | \$ 38.0   | \$ (4.1)  |

We had no debt obligations at December 31, 2010.

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 2011 financing, will be sufficient to fund our projected operations for the next twelve months which contemplates not only working capital and general corporate needs but also, including the filing of an NDA and commercial preparations for 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. If we elect to commercialize AMR101 ourselves, rather than through a partner, or decide to commence an outcome study, we will need additional funds to complete such activities. The sale of any equity or debt securities may result in additional dilution to our stockholders, and we cannot be certain that additional financing will be available in amounts or on terms acceptable to us, if at all.

**Contractual Obligations**

The following table summarizes our contractual obligations at December 31, 2010 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   | 2011   | 2012<br>to 2013 | 2014<br>to 2015 | After 2015 |
|------------------------------------|---------|--------|-----------------|-----------------|------------|
| Contractual Obligations:           |         |        |                 |                 |            |
| Purchase obligations (1)           | \$ 13.4 | \$ 0.8 | \$ 12.6         | \$              | \$         |
| Operating lease obligations        | 0.6     | 0.4    | 0.2             |                 |            |
| Total contractual cash obligations | \$ 14.0 | \$ 1.2 | \$ 12.8         | \$              | \$         |

- (1) Represents minimum purchase obligations under a supplier agreement with a Japan-based supplier. 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

## **Table of Contents**

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 do not enter into financial instruments for trading or speculative purposes.

In addition to the obligations in the table above, we have approximately \$0.5 million of gross liability for uncertain tax positions that have been recorded as liabilities at December 31, 2010. We are not able to reasonably estimate in which future periods these amounts will ultimately be settled.

The above table does not reflect our contract with Medpace for the conduct of our two registration trials for AMR101. We anticipate paying an additional \$9.0 million to Medpace in 2011 prior to the completion of this contract, of which approximately \$3.0 was included in accounts payable and accrued liabilities at December 31, 2010.

We may incur some capital costs from time-to-time to support our office facilities. In 2011 we expect to rent office space in New Jersey to establish our U.S. sales and marketing headquarters.

During 2010, we amended our contract with a third-party manufacturer and we anticipate incurring certain costs associated with the qualification of product produced by this manufacturer. In an effort to further expand production capacity at this manufacturer or through the addition of supplemental manufacturers, we may make capital commitments to support their expansion, particularly if such commitments further reduce the cost to us of the manufactured product.

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 of 1% royalty on net sales up to £100 million (\$162.0 million); 0.5% for net sales between £100 million (\$162.0 million) and £500 million; and 0.25% for sales in excess of £500 million (\$810.0 million). In addition, upon receipt of marketing approval in the United States and/or Europe for the first indication for AMR101 (or 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 (\$12.2 million) for each of the two potential market approvals (i.e. £15.0 million maximum, or \$24.3 million). In addition, upon receipt of a marketing approval in the United States or Europe for any other product using Amarin Neuroscience intellectual property or for a different indication of a previously approved product, we must make an aggregate stock or cash payment (at the sole option of each of the sellers) of £5.0 million (\$8.1 million) for each of the two potential market approvals (i.e. £10.0 million maximum, or \$16.2 million). We were previously subject to a potential 7% royalty payable to Scarista Limited. In November 2010 we reached agreement with Scarista in which we returned certain central nervous system-related intellectual property rights to Scarista and in return the potential royalty obligation was terminated. No provision has been made for these contingencies at December 31, 2010.

## **Off-Balance Sheet Arrangements**

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

## **Shelf Registration Statement**

We have on file with the SEC a universal shelf registration statement on Form F-3 (Registration No. 333-170505), which provides for the offer, from time to time, of common shares, preferred shares, or senior or subordinated debt securities up to an aggregate availability of approximately \$150 million, or the equivalent denominated in foreign currencies. The SEC declared the shelf registration statement effective on November 23, 2010. In connection with our public offering in January 2011, we issued and sold 13.8 million American

## **Table of Contents**

Depository Shares, or ADSs, each representing one share of our common stock. The price per each ADS in the offering was \$7.60, which resulted in gross proceeds of \$104.9 million and estimated net proceeds of \$98.7 million.

We believe that having an effective shelf registration statement is prudent for providing us with financial flexibility. From time to time, including but not limited to after the filing of this Annual Report on Form 10-K, we may file a new shelf registration statement to increase our potential access to capital. The addition of these securities, if issued, into the market may be dilutive to existing stockholders and 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.

*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, including our contract with our Medpace, 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, 2010, the fair value of our cash and cash equivalents maturing in one year or less was \$31.4 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, 2010, 2009 and 2008 there was no outstanding debt.

We record as a liability the fair value of warrants to purchase 31.0 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 market price of our common stock (\$9.02 based on the \$8.20 market price of our stock at December 31, 2010) on which the December 31, 2010 valuation was based, the value would have increased by \$24.3 million. Such increase would have been reflected as additional loss on revaluation of the warrant liability in our statement of operations.

### **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.

## **Table of Contents**

### **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 and Exchange Act of 1934 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, 2010, 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 Securities and Exchange Act of 1934). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer have concluded based upon the evaluation described above that, as of December 31, 2010, our disclosure controls and procedures were not effective at the reasonable assurance level, due to the material weakness in our internal control over financial reporting described below.

Notwithstanding the identified material weakness, management believes the consolidated financial statements included in this Annual Report on Form 10-K fairly present in all material respects our financial condition, results of operations and cash flows at and for the periods presented in accordance with U.S. GAAP.

#### **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 Securities Exchange Act of 1934, 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.

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2010 based on the framework in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and



## **Table of Contents**

related COSO guidance. Based on our evaluation under this framework, our management identified a material weakness in internal control over financial reporting as of December 31, 2010. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. Because of the continued existence of a previously identified material weakness, as further described below, our management concluded that our internal control over financial reporting was not effective as of December 31, 2010.

As previously disclosed in our Annual Report on Form 20-F filed on June 25, 2010 for the year ended December 31, 2009, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, 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.

Our assessment of the effectiveness of our internal control over financial reporting as of December 31, 2010 has been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report, which is set forth below.

### **Changes in Internal Control over Financial Reporting**

During 2010, including the quarter ended December 31, 2010, there have not been any changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15(d)-15(f) promulgated under the Securities Exchange Act of 1934, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting, other than as described below.

### **Remediation Efforts**

In response to the material weakness described above, management, with the input, oversight, and support of the Audit Committee, identified and took the following steps beginning during the second half of 2010 and which continued into 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. In addition, as a result of the relocation of the accounting functions from Dublin, Ireland to our Mystic, CT offices during 2010, we hired new accounting personnel, implemented new controls over financial reporting, implemented new accounting software, and use the assistance of outside professionals as warranted to ensure that data and reports can be relied upon for the purpose of accurately and timely recording transactions in accordance with U.S. GAAP.

## **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, 2010, 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 accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

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

Because of the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of the internal control over financial reporting to future periods are subject to the risk that the controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. The following material weakness has been identified and included in management's assessment:

The Company did not maintain effective 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.

## **Table of Contents**

This material weakness was considered in determining the nature, timing, and extent of audit tests applied in our audit of the consolidated financial statements as of and for the year ended December 31, 2010, of the Company and this report does not affect our report on such financial statements.

In our opinion, because of the effect of the material weakness identified above on the achievement of the objectives of the control criteria, the Company has not maintained effective internal control over financial reporting as of December 31, 2010, 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, 2010 of the Company and our report dated March 16, 2011 expressed an unqualified opinion on those financial statements.

/s/ DELOITTE & TOUCHE LLP

Boston, Massachusetts

March 16, 2011

### **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**

Certain information required by Part III of Form 10-K is omitted from this report because we expect to file a definitive proxy statement for our 2011 Annual General Meeting of Shareholders within 120 days after the end of the fiscal year covered by this report, and the information included in such definitive proxy statement is incorporated herein by reference to the extent provided below.

#### **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 2011 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 12 Roosevelt Avenue, 3<sup>rd</sup> Floor, Mystic, Connecticut 06355, 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 2011 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 2011 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 2011 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 2011 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 Deposit Agreement, dated as of March 29, 1993, among the Company, Citibank, N.A., as Depositary, and all holders from time to time of American Depositary Receipts issued thereunder                                | Registration Statement on Form F-1, File No. 33-58160                                                         | February 11, 1993  |
| 4.2            | Amendment No. 1 to Deposit Agreement, dated as of October 8, 1998, among the Company, Citibank, N.A., as Depositary, and all holders from time to time of the American Depositary Receipts issued thereunder                | Registration Statement on Post-Effective Amendment No. 1 to Form F-6, File No. 333-5946, as Exhibit (a)(ii)   | September 26, 2002 |
| 4.3            | Amendment No. 2 to Deposit Agreement, dated as of September 25, 2002 among the Company, Citibank, N.A., as Depositary, and all holders from time to time of the American Depositary Receipts issued thereunder              | Registration Statement on Post-Effective Amendment No. 2 to Form F-6, File No. 333-147660, as Exhibit (a)(ii) | November 28, 2007  |
| 4.4            | Letter Agreement supplementing the Deposit Agreement, dated as of March 29, 2006, among the Company, Citibank, N.A., as Depositary, and all holders from time to time of the American Depositary Receipts issued thereunder | Registration Statement on Form F-6, File No. 333-147660, as Exhibit (b)(iii)                                  | November 28, 2007  |
| 4.5            | Letter Agreement supplementing the Deposit Agreement, dated as of April 11, 2006, among the Company, Citibank, N.A., as Depositary, and all holders from time to time of the American Depositary Receipts issued thereunder | Registration Statement on Form F-6, File No. 333-147660, as Exhibit (b)(ii)                                   | November 28, 2007  |

**Table of Contents**

| Exhibit |                                                                                                                                                                                                                               | Incorporated by Reference Herein                                                |                   |
|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|-------------------|
| Number  | Description                                                                                                                                                                                                                   | Form                                                                            | Date              |
| 4.6     | Letter Agreement supplementing the Deposit Agreement, dated as of October 16, 2007, among the Company, Citibank, N.A., as Depositary, and all holders from time to time of the American Depositary Receipts issued thereunder | Registration Statement on Form F-6, File No. 333-147660, as Exhibit (b)(i)      | November 28, 2007 |
| 4.7     | Letter Agreement supplementing the Deposit Agreement, dated as of December 5, 2007, among the Company, Citibank, N.A., as Depositary, and all holders from time to time of the American Depositary Receipts issued thereunder | Registration Statement on Form F-6, File No. 333-171573, as Exhibit (b)(v)      | January 6, 2011   |
| 4.8     | Letter Agreement supplementing the Deposit Agreement, dated as of May 16, 2008, among the Company, Citibank, N.A., as Depositary, and all holders from time to time of the American Depositary Receipts issued thereunder     | Registration Statement on Form F-6, File No. 333-171573, as Exhibit (b)(iv)     | January 6, 2011   |
| 4.9     | Letter Agreement supplementing the Deposit Agreement, dated as of August 5, 2009, among the Company, Citibank, N.A., as Depositary, and all holders from time to time of the American Depositary Receipts issued thereunder   | Registration Statement on Form F-6, File No. 333-171573, as Exhibit (b)(iii)    | January 6, 2011   |
| 4.10    | Letter Agreement supplementing the Deposit Agreement, dated as of October 7, 2009, among the Company, Citibank, N.A., as Depositary, and all holders from time to time of the American Depositary Receipts issued thereunder  | Registration Statement on Form F-6, File No. 333-171573, as Exhibit (b)(ii)     | January 6, 2011   |
| 4.11    | Letter Agreement supplementing the Deposit Agreement, dated as of October 15, 2009, among the Company, Citibank, N.A., as Depositary, and all holders from time to time of the American Depositary Receipts issued thereunder | Registration Statement on Form F-6, File No. 333-171573, as Exhibit (b)(i)      | January 6, 2011   |
| 4.12    | 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    |

**Table of Contents**

| Exhibit |                                                                                                                                                                                           | Incorporated by Reference Herein                                                 |                   |
|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|-------------------|
| Number  | Description                                                                                                                                                                               | Form                                                                             | Date              |
| 4.13    | Form of American Depositary Receipt evidencing ADSs                                                                                                                                       | Registration Statement on Form F-6, File No. 333-171573, as Exhibit (a)(i)       | January 6, 2011   |
| 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    | 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    |
| 10.3    | 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 |
| 10.4    | 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      |
| 10.5    | 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     |
| 10.6    | 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      |
| 10.7    | 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      |
| 10.8    | 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 |

**Table of Contents**

| Exhibit |                                                                                                                                                                                           | Incorporated by Reference Herein                                                   |                   |
|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|-------------------|
| Number  | Description                                                                                                                                                                               | Form                                                                               | Date              |
| 10.9    | 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 |
| 10.10   | 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 |
| 10.11   | 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  |
| 10.12   | 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  |
| 10.13   | 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      |
| 10.14   | 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  |
| 10.15   | 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      |
| 10.16   | 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  |
| 10.17   | 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  |
| 10.18   | 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  |

**Table of Contents**

| Exhibit |                                                                                                                                                                         | Incorporated by Reference Herein                                                  |                   |
|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|-------------------|
| Number  | Description                                                                                                                                                             | Form                                                                              | Date              |
| 10.19   | 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  |
| 10.20   | Letter Agreement dated August 1, 2008 with Paresh Somi                                                                                                                  | Filed herewith                                                                    |                   |
| 10.21   | Amendment No. 1 to Bridge Loan Agreement, dated September 30, 2009, between the Company and the Lenders identified therein                                              | Filed herewith                                                                    |                   |
| 10.22   | Letter of Termination to William Mason dated October 9, 2009                                                                                                            | Registration Statement on Form F-1, File No. 333-163704, as Exhibit 4.98          | December 14, 2009 |
| 10.23   | Letter of Termination to Anthony Russell-Roberts dated October 9, 2009                                                                                                  | Registration Statement on Form F-1, File No. 333-163704, as Exhibit 4.99          | December 14, 2009 |
| 10.24   | Letter of Termination to John Climax dated October 9, 2009                                                                                                              | Registration Statement on Form F-1, File No. 333-163704, as Exhibit 4.100         | December 14, 2009 |
| 10.25   | 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  |
| 10.26   | Letter Agreement dated October 12, 2009 with Dr. Declan Doogan                                                                                                          | Registration Statement on Form F-1, File No. 333-163704, as Exhibit 4.101         | December 14, 2009 |
| 10.27   | Letter Agreement dated October 12, 2009 with Joseph S. Zakrzewski                                                                                                       | Registration Statement on Form F-1, File No. 333-163704, as Exhibit 4.102         | December 14, 2009 |
| 10.28   | 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  |
| 10.29   | 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  |
| 10.30   | 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  |
| 10.31   | 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 |
| 10.32   | Management Rights Deed of Agreement dated October 16, 2009 by and among the Company and Purchasers named therein                                                        | Annual Report on Form 20-F for the year ended December 31, 2009, as Exhibit 4.100 | June 25, 2010     |

**Table of Contents**

| Exhibit |                                                                                                                                                       | Incorporated by Reference Herein                                          |                   |
|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------|-------------------|
| Number  | Description                                                                                                                                           | Form                                                                      | Date              |
| 10.33   | 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 |
| 10.34   | 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 |
| 10.35   | Letter Agreement, dated December 2, 2009, among the Company, Sunninghill Limited, Michael Walsh and Simon Kukes                                       | Filed herewith                                                            |                   |
| 10.36   | 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 |
| 10.37   | Compromise Agreement dated December 10, 2009 with Tom Maher                                                                                           | Report of Foreign Private Issuer filed on Form 6-K, as Exhibit 99.3       | December 14, 2009 |
| 10.38   | Transitional Employment Agreement, dated August 10, 2010, between the Company and Declan Doogan                                                       | Filed herewith                                                            |                   |
| 10.39   | Letter Agreement, dated August 16, 2010, between the Company and Colin Stewart                                                                        | Filed herewith                                                            |                   |
| 10.40   | Supply Agreement, dated November 1, 2010, between Nisshin Pharma Inc. and Amarin Pharmaceuticals Ireland Limited                                      | Filed herewith                                                            |                   |
| 10.41   | Resignation and Release Agreement, dated November 9, 2010, between the Company and Colin Stewart                                                      | Filed herewith                                                            |                   |
| 10.42   | Letter Agreement, dated November 15, 2010, between the Company and John F. Thero                                                                      | Filed herewith                                                            |                   |
| 10.43   | Employment Agreement, effective December 31, 2010, between the Company and Joseph S. Zakrzewski                                                       | Filed herewith                                                            |                   |
| 10.44   | Amarin Corporation plc Management Incentive Compensation Plan                                                                                         | Filed herewith                                                            |                   |
| 10.45   | Consulting Agreement, dated November 10, 2010, between the Company and Joseph S. Zakrzewski                                                           | Filed herewith                                                            |                   |
| 10.46   | Letter Agreement dated March 1, 2010 with Frederick W. Ahlholm                                                                                        | Filed herewith                                                            |                   |
| 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                                                            |                   |

---

**Table of Contents**

| Exhibit |                                                                                                                                                                          | Incorporated by Reference Herein |      |
|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|------|
| Number  | Description                                                                                                                                                              | Form                             | Date |
| 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                   |      |
| 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                   |      |

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: March 16, 2011

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           |
|-------------------------------|--------------------------------------------------------------------|----------------|
|                               | President                                                          | March 16, 2011 |
| /s/ John F. Thero             | (Principal Financial Officer)                                      |                |
| John F. Thero                 |                                                                    |                |
|                               | Chief Executive Officer and Director (Principal Executive Officer) | March 16, 2011 |
| /s/ Joseph Zakrzewski         |                                                                    |                |
| Joseph Zakrzewski             |                                                                    |                |
|                               | Vice President Finance                                             | March 16, 2011 |
| /s/ Frederick W. Ahlholm, CPA | (Principal Accounting Officer)                                     |                |
| Frederick W. Ahlholm, CPA     |                                                                    |                |
|                               | Director                                                           | March 16, 2011 |
| /s/ Joseph Anderson, Ph.D.    |                                                                    |                |
| Joseph Anderson, Ph.D.        |                                                                    |                |
|                               | Director                                                           | March 16, 2011 |
| /s/ Lars Ekman                |                                                                    |                |
| Lars Ekman                    |                                                                    |                |

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

|                              |          |                |
|------------------------------|----------|----------------|
|                              | Director | March 16, 2011 |
| /s/ Carl Gordon, Ph.D, CFA   |          |                |
| Carl Gordon, Ph.D, CFA       |          |                |
|                              | Director | March 16, 2011 |
| /s/ James Healy, M.D., Ph.D. |          |                |
| James Healy, M.D., Ph.D.     |          |                |
|                              | Director | March 16, 2011 |
| /s/ Kristine Peterson        |          |                |
| Kristine Peterson            |          |                |
|                              | Director | March 16, 2011 |
| /s/ Manus Rogan              |          |                |
| Manus Rogan                  |          |                |
|                              | Director | March 16, 2011 |
| /s/ Jan van Heek             |          |                |
| Jan van Heek                 |          |                |

**Table of Contents**

AMARIN CORPORATION PLC

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

|                                                                     |                    |
|---------------------------------------------------------------------|--------------------|
| <u>Report of Independent Registered Public Accounting Firm</u>      | <b>Page</b><br>F-1 |
| Financial Statements:                                               |                    |
| <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                |
| Financial Statement Schedules:                                      |                    |

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

**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, 2010 and 2009, 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, 2010. 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, 2010 and 2009, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2010, 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, 2010, 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 March 16, 2011 expressed an adverse opinion on the Company's internal control over financial reporting because of a material weakness.

/s/ DELOITTE & TOUCHE LLP

Boston, Massachusetts

March 16, 2011

**Table of Contents**

## AMARIN CORPORATION PLC

**CONSOLIDATED BALANCE SHEETS**

|                                                                                                                                                                                       | December 31,                                       |           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------|-----------|
|                                                                                                                                                                                       | 2010                                               | 2009      |
|                                                                                                                                                                                       | (in thousands, except share and per share amounts) |           |
| ASSETS                                                                                                                                                                                |                                                    |           |
| Current Assets:                                                                                                                                                                       |                                                    |           |
| Cash and cash equivalents                                                                                                                                                             | \$ 31,442                                          | \$ 52,258 |
| Deferred tax asset                                                                                                                                                                    | 608                                                | 10        |
| Other current assets                                                                                                                                                                  | 1,063                                              | 1,975     |
| Total current assets                                                                                                                                                                  | 33,113                                             | 54,243    |
| Property, plant and equipment, net                                                                                                                                                    | 88                                                 | 128       |
| Deferred tax asset                                                                                                                                                                    | 2,166                                              | 1,073     |
| TOTAL ASSETS                                                                                                                                                                          | \$ 35,367                                          | \$ 55,444 |
| LIABILITIES AND STOCKHOLDERS (DEFICIT) EQUITY                                                                                                                                         |                                                    |           |
| Current Liabilities:                                                                                                                                                                  |                                                    |           |
| Accounts payable                                                                                                                                                                      | \$ 4,449                                           | \$ 3,507  |
| Accrued expenses and other liabilities                                                                                                                                                | 3,128                                              | 3,250     |
| Total current liabilities                                                                                                                                                             | 7,577                                              | 6,757     |
| Long-Term Liabilities:                                                                                                                                                                |                                                    |           |
| Warrant derivative liability                                                                                                                                                          | 230,069                                            | 41,520    |
| Lease obligations and other long-term liabilities                                                                                                                                     | 88                                                 | 570       |
| Total liabilities                                                                                                                                                                     | 237,734                                            | 48,847    |
| Commitments and contingencies (Note 9)                                                                                                                                                |                                                    |           |
| Stockholders (Deficit) Equity:                                                                                                                                                        |                                                    |           |
| Common stock, £0.50 par value, unlimited authorized; 106,856,731 issued, 106,836,652 outstanding at December 31, 2010; 98,801,982 issued, 98,781,903 outstanding at December 31, 2009 | 90,465                                             | 84,219    |
| Additional paid-in capital                                                                                                                                                            | 206,718                                            | 172,339   |
| Treasury stock; 20,079 shares at December 31, 2010 and 2009                                                                                                                           | (217)                                              | (217)     |
| Accumulated deficit                                                                                                                                                                   | (499,333)                                          | (249,744) |
| Total stockholders (deficit) equity                                                                                                                                                   | (202,367)                                          | 6,597     |
| TOTAL LIABILITIES AND STOCKHOLDERS (DEFICIT) EQUITY                                                                                                                                   | \$ 35,367                                          | \$ 55,444 |

See the notes to the consolidated financial statements.

**Table of Contents****AMARIN CORPORATION PLC****CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**

|                                                             | <b>Years Ended December 31,</b>                           |             |             |
|-------------------------------------------------------------|-----------------------------------------------------------|-------------|-------------|
|                                                             | <b>2010</b>                                               | <b>2009</b> | <b>2008</b> |
|                                                             | <b>(In thousands, except share and per share amounts)</b> |             |             |
| Revenues                                                    | \$                                                        | \$          | \$          |
| Operating Expenses:                                         |                                                           |             |             |
| Research and development                                    | 28,014                                                    | 20,892      | 7,899       |
| General and administrative                                  | 17,087                                                    | 13,152      | 19,622      |
| Total operating expenses                                    | 45,101                                                    | 34,044      | 27,521      |
| Operating loss                                              | (45,101)                                                  | (34,044)    | (27,521)    |
| (Loss) gain on change in fair value of derivative liability | (205,153)                                                 | 5,137       | 9,289       |
| Interest expense                                            | (19)                                                      | (2,832)     | (836)       |
| Interest income                                             | 53                                                        | 199         | 431         |
| Other income (expense), net                                 | 130                                                       | 33          | (900)       |
| Loss from operations before taxes                           | (250,090)                                                 | (31,507)    | (19,537)    |
| Benefit from income taxes                                   | 501                                                       | 901         | 1,048       |
| Net and comprehensive loss                                  | \$ (249,589)                                              | \$ (30,606) | \$ (18,489) |
| Loss per basic and diluted share:                           | \$ (2.49)                                                 | \$ (0.72)   | \$ (0.84)   |
| Weighted average shares:                                    |                                                           |             |             |
| Basic and diluted                                           | 100,239                                                   | 42,424      | 22,086      |

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, 2010, 2009 AND 2008**

(in thousands, except share data)

|                                                                                             |                    |                  |                                  |                   |                        | Total                               |
|---------------------------------------------------------------------------------------------|--------------------|------------------|----------------------------------|-------------------|------------------------|-------------------------------------|
|                                                                                             | Common<br>Shares   | Common<br>Stock  | Additional<br>Paid-in<br>Capital | Treasury<br>Stock | Accumulated<br>Deficit | Shareholders<br>(Deficit)<br>Equity |
| <b>At January 1, 2008</b>                                                                   | <b>13,905,745</b>  | <b>\$ 12,942</b> | <b>\$ 192,487</b>                | <b>\$ (217)</b>   | <b>\$ (200,649)</b>    | <b>\$ 4,563</b>                     |
| Shares issued under Proseed agreement                                                       | 97,500             | 118              | 232                              |                   |                        | 350                                 |
| Shares issued in May private placement                                                      | 13,043,479         | 12,604           | 13,352                           |                   |                        | 25,956                              |
| Fair value of May participation rights                                                      |                    |                  | (8,218)                          |                   |                        | (8,218)                             |
| Stock based compensation                                                                    |                    |                  | 4,254                            |                   |                        | 4,254                               |
| Loss and comprehensive loss                                                                 |                    |                  |                                  |                   | (18,489)               | (18,489)                            |
| <b>At December 31, 2008</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>                 |

See the notes to the consolidated financial statements.

**Table of Contents**

## AMARIN CORPORATION PLC

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

|                                                                         | Years Ended December 31, |             |             |
|-------------------------------------------------------------------------|--------------------------|-------------|-------------|
|                                                                         | 2010                     | 2009        | 2008        |
|                                                                         | (in thousands)           |             |             |
| <b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>                            |                          |             |             |
| Net loss                                                                | \$ (249,589)             | \$ (30,606) | \$ (18,489) |
| Adjustments to reconcile loss to net cash used in operating activities: |                          |             |             |
| Depreciation and amortization                                           | 63                       | 583         | 251         |
| Gain on sale of intellectual property                                   |                          | (700)       |             |
| Stock-based compensation                                                | 5,207                    | 2,859       | 4,254       |
| Stock-based compensation Ester                                          |                          | 902         | (2,488)     |
| Stock-based compensation warrants                                       | 5,713                    | 1,040       |             |
| Excess tax benefit from stock-based awards                              | (543)                    |             |             |
| Non-cash interest                                                       |                          | 2,803       |             |
| Loss (gain) on changes in fair value of derivative liability            | 205,153                  | (5,137)     | (9,289)     |
| Deferred income taxes                                                   | (1,691)                  | (689)       | (394)       |
| Change in lease liability                                               | (583)                    | (290)       | 851         |
| Shares issued for services                                              | 12                       |             |             |
| Changes in assets and liabilities:                                      |                          |             |             |
| Other current assets                                                    | 912                      | (68)        | 1,533       |
| Other non-current assets                                                |                          |             | 169         |
| Accounts payable and other current liabilities                          | 1,476                    | 897         | (4,438)     |
| Other long-term liabilities                                             |                          |             | (2,067)     |
| Net cash used in operating activities                                   | (33,870)                 | (28,406)    | (30,107)    |
| <b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>                            |                          |             |             |
| Purchases of equipment                                                  | (23)                     | (116)       | (251)       |
| Sale of lorazepam                                                       |                          | 700         |             |
| Net cash (used in) provided by investing activities                     | (23)                     | 584         | (251)       |
| <b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>                            |                          |             |             |
| Proceeds from issuance of common stock, net of transaction costs        |                          | 62,253      | 26,306      |
| Proceeds from exercise of stock options, net of transaction costs       | 3,642                    |             |             |
| Proceeds from exercise of warrants, net of transaction costs            | 8,904                    |             |             |
| Proceeds on issuance of convertible debt                                |                          | 5,600       |             |
| Repayment of convertible debt                                           |                          | (2,000)     |             |
| Excess tax benefit from stock-based awards                              | 543                      |             |             |
| Repayment of finance leases                                             | (12)                     | (12)        | (12)        |
| Net cash provided by financing activities                               | 13,077                   | 65,841      | 26,294      |
| NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS                    | (20,816)                 | 38,019      | (4,064)     |
| CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD                          | 52,258                   | 14,239      | 18,303      |
| CASH AND CASH EQUIVALENTS, END OF PERIOD                                | \$ 31,442                | \$ 52,258   | \$ 14,239   |
| <b>Supplemental disclosure of cash flow information:</b>                |                          |             |             |
| Cash paid during the year for:                                          |                          |             |             |
| Interest                                                                | \$ 2                     | \$ 125      | \$ 6        |

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

|                                                            |    |        |    |        |    |
|------------------------------------------------------------|----|--------|----|--------|----|
| Income taxes                                               | \$ | 230    | \$ |        | \$ |
| Supplemental disclosure of non-cash items:                 |    |        |    |        |    |
| Reclass of warrant liability to additional paid-in capital | \$ | 22,317 | \$ | 5,328  | \$ |
| 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 consolidated financial statements.

F-5

**Table of Contents**

**AMARIN CORPORATION PLC**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(1) Nature of Business, Basis of Presentation and Subsequent Event**

**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 Capital 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, 2010 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 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.

## **Table of Contents**

At December 31, 2010, the Company had cash and cash equivalents of \$31.4 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.

In January 2011, the Company completed an offering of 13.8 million American Depositary Shares (ADSs), with each ADS representing one share of the Company's common stock. The shares were sold at a price of \$7.60 per share, and resulted in net proceeds of \$98.7 million.

The Company believes its cash, including the net proceeds from the January 2011 financing, will be sufficient to fund its projected operations for the next twelve months which contemplates not only working capital and general corporate needs but also the filing of a New Drug Application (NDA) for and 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. If the Company elects to commercialize AMR101 themselves, rather than through a partner, or decides to commence an outcome study, they will need additional funds to complete such activities.

## **(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.

## **Table of Contents**

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.

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.

---

**Table of Contents**

**Loss per Share**

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

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

**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.

**Table of Contents**

The following table presents information about the Company's liability as of December 31, 2010 and 2009 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, 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     |

| <i>In thousands</i>          |              | <b>December 31, 2009</b> |                |                |
|------------------------------|--------------|--------------------------|----------------|----------------|
|                              | <b>Total</b> | <b>Level 1</b>           | <b>Level 2</b> | <b>Level 3</b> |
| <b>Liability:</b>            |              |                          |                |                |
| Warrant derivative liability | \$ 41,520    | \$                       | \$             | \$ 41,520      |

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.

As of December 31, 2009, the fair value of the warrant derivative liability was determined to be \$41.5 million applying the following assumptions: (i) risk-free rate of 2.69%, (ii) remaining term of 4.8 years, (iii) no dividend yield (iv) volatility of 116%, and (v) the stock price on the date of measurement. The decrease in the fair value of the warrant derivative liability of \$6.8 million was recognized as a \$6.6 million gain on change in fair value of derivative liability and \$0.2 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 period ended December 31, 2009.

**Table of Contents**

At December 31, 2010, the fair value of the warrant derivative liability was determined to be \$230.1 million using the Black-Scholes option valuation model 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. The change in the fair value of the warrant derivative liabilities is as follows (in thousands):

|                                                                                               | October<br>2009<br>Warrants | June and<br>July 2009<br>Warrants | May 2008<br>Participation<br>Rights | December<br>2007<br>Warrants | Totals            |
|-----------------------------------------------------------------------------------------------|-----------------------------|-----------------------------------|-------------------------------------|------------------------------|-------------------|
| <b>Balance at December 31, 2007</b>                                                           | <b>\$</b>                   | <b>\$</b>                         | <b>\$</b>                           | <b>\$ 2,108</b>              | <b>\$ 2,108</b>   |
| Initial measurement, May 2008 participation option                                            |                             |                                   | 8,218                               |                              | 8,218             |
| (Gain) loss on change in fair value of derivative liability                                   |                             |                                   | (7,714)                             | (1,575)                      | (9,289)           |
| Transfer to equity                                                                            |                             |                                   |                                     |                              |                   |
| <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) expense 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>  |
| (Gain) loss on change in fair value of derivative liability                                   | 205,153                     |                                   |                                     |                              | 205,153           |
| Compensation (income) 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> |

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 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:

**Table of Contents**

(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, 2010, 2009 and 2008, 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:

|                                                 | 2010<br>(in thousands) | 2009            |
|-------------------------------------------------|------------------------|-----------------|
| Research and development credits receivable (1) | \$ 351                 | \$ 1,117        |
| Prepaid expenses and other                      | 712                    | 858             |
|                                                 | <b>\$ 1,063</b>        | <b>\$ 1,975</b> |

- (1) Represents refunds receivable in the U.K. for research and development expenditures incurred in 2009 and 2008 at Amarin Neuroscience Ltd (ANL). No recovery has been recorded for fiscal year 2010 since the expenditures at ANL during the year ended December 31, 2010 were negligible.

**(4) Property Plant & Equipment**

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

|                                                 | 2010<br>(in thousands) | 2009          |
|-------------------------------------------------|------------------------|---------------|
| Leasehold improvements                          | \$ 14                  | \$ 4          |
| Computer equipment and software                 | 163                    | 148           |
| Furniture and fixtures                          | 26                     | 28            |
|                                                 | 203                    | 180           |
| Less: accumulated depreciation and amortization | (115)                  | (52)          |
|                                                 | <b>\$ 88</b>           | <b>\$ 128</b> |

Depreciation expense for the years ended December 31, 2010, December 31, 2009, and December 31, 2008 was \$0.1 million, \$0.6 million, and \$0.3 million, respectively.

**(5) Ester Asset Purchase**

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

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

F-12

**Table of Contents**

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, 2010 and 2009:

|                                      | 2010            | 2009            |
|--------------------------------------|-----------------|-----------------|
|                                      | (in thousands)  |                 |
| Payroll and payroll-related expenses | \$ 1,631        | \$ 1,210        |
| Research and development expenses    | 340             | 400             |
| Income taxes payable                 | 585             | 173             |
| All other                            | 572             | 1,467           |
|                                      | <b>\$ 3,128</b> | <b>\$ 3,250</b> |

**(7) Warrants and Derivative Liability**

The Company has 34,024,132 warrants to purchase common shares outstanding at December 31, 2010 at a weighted-average exercise price of \$1.50, as summarized in the following table:

| Issue Date | Amount            | Exercise Price | Expiration Date |
|------------|-------------------|----------------|-----------------|
| 1/26/2006  | 29,400            | \$ 30.60       | 1/26/2011       |
| 4/27/07    | 17,500            | 17.90          | 1/17/2014       |
| 6/1/07     | 61,559            | 7.20           | 5/31/12         |
| 11/29/07   | 1,000             | 3.60           | 11/28/12        |
| 12/5/07    | 657,341           | 1.17           | 12/3/12         |
| 6/4/09     | 55,555            | 1.00           | 6/3/14          |
| 7/31/09    | 736,108           | 1.00           | 7/30/14         |
| 7/31/09    | 1,666,666         | 1.00           | 7/30/14         |
| 10/16/09   | 29,994,998        | 1.50           | 10/15/14        |
| 10/16/09   | 804,005           | 1.50           | 10/15/14        |
|            | <b>34,024,132</b> | <b>\$ 1.50</b> |                 |



## **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 issued 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 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 executives. 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.

### **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.

## **Table of Contents**

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.

### **May 2008 Private Placement**

On May 13, 2008, the Company completed a private placement of 13,043,479 common shares to institutional investors and certain current and former directors for \$26.3 million in net proceeds. Under the terms of the agreement, these investors had the option to participate in a further financing dependent upon the Company achieving certain business milestones. The amount subscribed was split between an equity component and an option to subscribe for an additional amount of up to \$30.0 million. On May 13, 2008 the initial fair value of this derivative liability was calculated to be approximately \$8.2 million using a Monte Carlo option pricing model, and recorded as a reduction to additional paid-in capital. Due to the variable nature of this option, the Company classified the option as a derivative liability, which is remeasured at each reporting date with changes in fair value recognized in the statement of operations which contractually would expire at the date of the next financing. At December 31, 2008, the fair value of this option was recalculated to be \$0.5 million and the Company recognized a \$7.7 million gain on change in fair value of derivative liability for the period ended December 31, 2008.

In October 2009, in conjunction with the \$70.0 million private placement, and per agreement with investors, this participation option was cancelled. As a result of the cancellation of the option, the Company recognized a gain on change in fair value of derivative liability of \$0.5 million.

### **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

**Table of Contents**

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 on the Company's balance sheet within equity at December 31, 2010 and 2009.

**(8) Debt**

As of December 31, 2010 and 2009, 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, 2010, there were no asserted claims against the Company which in the opinion of management, would have a material adverse 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, 2010 are as follows (in thousands):

| Year Ending December 31, | Operating | Capital |
|--------------------------|-----------|---------|
| 2011                     | \$ 452    | \$ 8    |
| 2012                     | 64        |         |
| 2013                     | 36        |         |
| 2014                     | 32        |         |
| Total                    | \$ 584    | 8       |

Less: amount representing interest

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

|                             |    |
|-----------------------------|----|
| Total principal obligations | 8  |
| Less: current portion       | 8  |
| Long-term capital lease     | \$ |

F-16

## **Table of Contents**

On November 1, 2008 the Company entered into a three year operating lease for office space in Mystic, CT expiring on October 31, 2011. The lease includes an option for Amarin to renew for three years. Total rent expense during the years ended 2010, 2009 and 2008 was approximately \$0.3 million, \$0.3 million, and \$1.0 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, 2010 and 2009 were \$0.1 million and \$0.7 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:

An agreement in respect of certain patents and other intellectual property rights relating to a formulation of the compound Apomorphine, no longer in development;

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 of: (A) in all fiscal years pre-NDA submission - 1.08 metric tons each fiscal year (B) within 6 months after submission in the United States of an NDA for the first Marketing Approval of the drug substance - 20 metric tons and (C) within 6 months after the first Marketing Approval in the United States - 50 metric tons; 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 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 and (ii) a \$0.2 million payment if the drug is tested in an efficacy study; and

In connection with commercialization of AMR101, prior to the end of 2012 we are required to pay potential royalties of 1% on net sales up to £100 million (\$162.0 million at December 31, 2010); 0.5% for net sales between £100 million (\$162.0 million) and £500 million (\$810.0 million); and 0.25% for sales in excess of £500 million. In addition, 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), Amarin must make an aggregate stock or cash payment (at the sole option of each of the sellers) of £7.5 million (\$12.2 million) for each of the two potential marketing approvals (i.e. £15.0 million maximum, or \$24.3 million). 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 £5.0 million (\$8.1 million) for each of the two potential market approvals (i.e. £10.0 million maximum, or \$16.2 million).

The Company has no provision for any of these obligations since the amounts are either not probable or estimable as of December 31, 2010.

**Table of Contents****(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 net proceeds of \$98.7 million. After the offering there were 120,636,652 shares of common stock outstanding.

During the year ended December 31, 2010, the Company issued 1,706,016 shares as a result of the exercise of stock options, resulting in net proceeds of \$3.6 million. In addition the Company issued 6,344,136 shares as a result of the exercise of warrants, resulting in net proceeds of \$8.9 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 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, 2010, 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 \$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, 2010, 2009 and 2008:

|                                  | 2010           | 2009   | 2008 |
|----------------------------------|----------------|--------|------|
|                                  | (In thousands) |        |      |
| Beginning uncertain tax benefits | \$ 304         | \$ 48  | \$   |
| Current year increases           | 254            | 256    | 48   |
| Current year decreases           |                |        |      |
| Ending uncertain tax benefits    | \$ 558         | \$ 304 | \$48 |

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, 2010:

| Jurisdiction   | Tax Years |
|----------------|-----------|
| United States  | 2007-2010 |
| Ireland        | 2005-2010 |
| United Kingdom | 2009-2010 |



**Table of Contents**

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

|               | 2010         | 2009<br>(In thousands) | 2008        |
|---------------|--------------|------------------------|-------------|
| United States | \$ 1,987     | \$ 162                 | \$ (773)    |
| Foreign       | (252,077)    | (31,669)               | (18,764)    |
|               | \$ (250,090) | \$ (31,507)            | \$ (19,537) |

The benefit from income taxes shown in the accompanying consolidated statements of operations consists of the following for fiscal 2010, 2009 and 2008:

|                               | 2010       | 2009<br>(In thousands) | 2008       |
|-------------------------------|------------|------------------------|------------|
| Current:                      |            |                        |            |
| Federal                       | \$ 1,068   | \$ 121                 | \$ 15      |
| State                         | 122        | 32                     | 5          |
| Foreign                       |            | (365)                  | (674)      |
| Total Current                 | \$ 1,190   | \$ (212)               | \$ (654)   |
| Deferred:                     |            |                        |            |
| Federal                       | (1,604)    | (353)                  | (252)      |
| State                         | (87)       | (336)                  | (142)      |
| Foreign                       | (6,035)    | (3,540)                | 23,539     |
| Change in valuation allowance | 6,035      | 3,540                  | (23,539)   |
| Total Deferred                | \$ (1,691) | \$ (689)               | \$ (394)   |
|                               | \$ (501)   | \$ (901)               | \$ (1,048) |

The 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 2010, 2009 and 2008:

|                                       | 2010        | 2009<br>(In thousands) | 2008       |
|---------------------------------------|-------------|------------------------|------------|
| Benefits from taxes at statutory rate | \$ (62,523) | \$ (7,877)             | \$ (4,884) |
| Rate differential                     | 3,871       | 1,945                  | 109        |
| Research credits                      | (1,014)     | (897)                  | (767)      |
| Irish migration                       |             |                        | 24,086     |
| Change in rate                        |             |                        | 2,864      |
| Change in valuation reserves          | 6,035       | 3,540                  | (23,539)   |
| Permanent & other                     | 17          | 3,433                  | 1,066      |
| Warrant derivative liabilities        | 52,761      | (1,406)                |            |
| Other                                 | 352         | 361                    | 17         |
|                                       | \$ (501)    | \$ (901)               | \$ (1,048) |

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

The tax residency of Amarin Corporation plc migrated from the 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, 2010, 2009 and 2008, the Company's corporate tax rate was 25% as Amarin Corporation plc is subject to the 25% tax rate in Ireland.

F-19

**Table of Contents**

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

|                                        | 2010           | 2009      |
|----------------------------------------|----------------|-----------|
|                                        | (In thousands) |           |
| Deferred tax assets:                   |                |           |
| Net operating losses                   | \$ 27,171      | \$ 21,705 |
| Stock based compensation               | 2,997          | 1,777     |
| Depreciation                           | 132            | 150       |
| Tax credits                            | 30             | 265       |
| Other reserves and accrued liabilities | 422            | 78        |
| Net deferred tax asset                 | 30,752         | 23,975    |
| Less: valuation allowance              | (27,978)       | (22,892)  |
|                                        | \$ 2,774       | \$ 1,083  |

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 foreign 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 foreign net operating loss carryforwards of \$133.8 million, which begin to expire in 2011. In addition, the Company has available U.S. Federal tax credit carryforwards of \$0.01 million and state tax credit carryforwards of \$0.4 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 \$9.9 million are not likely to be realized in the future.

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

The Amarin Corporation plc 2002 Stock Option Plan (2002 Plan) as amended, effective January 1, 2002, provides for a maximum of 14.0 million common shares to be issued to eligible persons. The 2002 Plan is administered by the remuneration committee of our Board of Directors and expires on January 1, 2012. Under the terms of the 2002 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.

**Table of Contents**

The following table summarizes stock option activity for the year ended December 31, 2010:

|                                                 | Number of<br>Shares | Weighted<br>Average<br>Exercise<br>Price<br>(in thousands, except for per share amounts) | Weighted<br>Average<br>Remaining<br>Contractual<br>Term | Aggregate<br>Intrinsic<br>Value |
|-------------------------------------------------|---------------------|------------------------------------------------------------------------------------------|---------------------------------------------------------|---------------------------------|
| Outstanding January 1, 2010                     | 7,764               | \$ 2.69                                                                                  |                                                         |                                 |
| Granted                                         | 7,870               | 2.68                                                                                     |                                                         |                                 |
| Cancelled/Expired                               | (3,900)             | 2.91                                                                                     |                                                         |                                 |
| Exercised                                       | (1,706)             | 2.16                                                                                     |                                                         |                                 |
| Outstanding, December 31, 2010                  | 10,028              | \$ 2.69                                                                                  | 8.51 years                                              | \$ 59,515                       |
| Exercisable, December 31, 2010                  | 3,286               | \$ 3.94                                                                                  | 6.97 years                                              | \$ 18,257                       |
| Vested and Expected to Vest, December 31, 2010  | 9,526               | \$ 2.69                                                                                  | 8.51 years                                              | \$ 56,539                       |
| Available for future grant at December 31, 2010 | 2,262               |                                                                                          |                                                         |                                 |

The weighted average fair value of the stock options granted during the year ended December 31, 2010, 2009 and 2008 was \$2.21, \$1.12, and \$2.22, respectively.

During the year ended December 31, 2010, the Company received cash of \$3.7 million from the exercise of options. The intrinsic value of options exercised during fiscal 2010 was \$10.3 million. As of December 31, 2010 and 2009, there was \$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 2.9 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 years 2009 or 2008. The following table presents the stock-based compensation expense related to option awards for the period ended December 31:

|                                  | 2010     | 2009<br>(in thousands) | 2008     |
|----------------------------------|----------|------------------------|----------|
| Research and development         | \$ 1,534 | \$ 1,481               | \$ 1,299 |
| General and administrative       | 3,673    | 1,378                  | 2,955    |
| Stock based compensation expense | \$ 5,207 | \$ 2,859               | \$ 4,254 |

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.



**Table of Contents**

For 2010, 2009 and 2008, the Company used the following assumptions to estimate the fair value of share-based payment awards:

|                              | 2010        | 2009        | 2008        |
|------------------------------|-------------|-------------|-------------|
| Risk free interest rate      | 1.5% - 3.1% | 2.5% - 3.0% | 3.1% - 3.4% |
| Expected dividend yield      | 0.00%       | 0.00%       | 0.00%       |
| Expected option life (years) | 5.75 - 6.25 | 5.75 - 6.25 | 5.0 - 6.0   |
| Expected volatility          | 105% - 110% | 105% - 110% | 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, 2010, 2009 and 2008 amounted to \$21,000, \$306,000 and \$548,000, respectively.

**(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 Mr. Joe 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 is also 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 \$230.1 million warrant derivative liability at December 31, 2010, the fair value of the warrants held by the current and former directors of the Company and their related investment funds amounted to \$134.5 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®). Mr. Shane Cooke, chief financial officer of Elan is related to Mr. Alan Cooke, former president of Amarin. Under the terms of the agreement, we paid \$0.2 million to Elan during the year ended December 31, 2008. 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.

Icon

At December 31, 2009 Poplar Ltd, a company controlled by Dr. Climax, a non-executive Director of the Company until October 2009, owned approximately 5.5% of Icon plc. Under a 2005 agreement with Amarin, Icon Clinical Research Ltd (a company wholly owned by Icon plc) performed trial management services for

**Table of Contents**

Amarin's studies on AMR101 for Huntington's disease. For the years ended December 31, 2010, 2009 and 2008 Amarin incurred costs of \$-0-, \$0.3 million and \$0.4 million, respectively, under this agreement. The Company's former Chairman and Chief Executive Officer, Mr. Thomas Lynch served as an outside director of Icon during the period of the agreement with Icon.

**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.

**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, 2010      |                |                |                |
|---------------------------------------|------------------------------------------|----------------|----------------|----------------|
|                                       | 1st<br>Quarter                           | 2nd<br>Quarter | 3rd<br>Quarter | 4th<br>Quarter |
|                                       | (In thousands, except per share amounts) |                |                |                |
| Revenue                               | \$                                       | \$             | \$             | \$             |
| Net loss                              | (9,211)                                  | (41,357)       | (11,209)       | (187,812)      |
| Net loss per basic and diluted share: | \$ (0.09)                                | \$ (0.42)      | \$ (0.11)      | \$ (1.82)      |

|                                       | Fiscal year ended December 31, 2009      |                |                |                |
|---------------------------------------|------------------------------------------|----------------|----------------|----------------|
|                                       | 1st<br>Quarter                           | 2nd<br>Quarter | 3rd<br>Quarter | 4th<br>Quarter |
|                                       | (In thousands, except per share amounts) |                |                |                |
| Revenue                               | \$                                       | \$             | \$             | \$             |
| Net loss(1)                           | (8,048)                                  | (8,522)        | (7,948)        | (6,088)        |
| Net loss per basic and diluted share: | \$ (0.30)                                | \$ (0.32)      | \$ (0.29)      | \$ (0.07)      |

- (1) 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.

F-23