AMARIN CORP PLC\UK
Form 20-F
May 19, 2008

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
Form 20-F

o REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR 12(g)
OF THE SECURITIES EXCHANGE ACT OF 1934

OR

þ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2007

OR

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934
FOR THE TRANSITION PERIOD FROM TO

OR

o SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934
DATE OF EVENT REQUIRING THIS SHELL COMPANY REPORT

Commission file number 0-21392
AMARIN CORPORATION PLC
(Exact Name of Registrant as Specified in Its Charter)
England and Wales
(Jurisdiction of Incorporation or Organization)
First Floor, Block 3, The Oval
Shelbourne Road, Ballsbridge
Dublin 4, Ireland
(Address of Principal Executive Offices)

SECURITIES REGISTERED OR TO BE REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT:

| Title of Each Class | Name of Each Exchange on Which Registered |
|---|---|
| None | None |

SECURITIES REGISTERED OR TO BE REGISTERED PURSUANT TO SECTION 12(g) OF THE ACT:
American Depositary Shares, each representing one Ordinary Share
Ordinary Shares, 5 pence par value per share
(Title of Class)

SECURITIES FOR WHICH THERE IS A REPORTING OBLIGATION PURSUANT TO SECTION 15(d) OF THE ACT:
None.

Indicate the number of outstanding shares of each of the issuer’s classes of capital or common stock as of the close of the period covered by the annual report.

139,057,370 Ordinary Shares, 5 pence par value per share

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

YES o NO þ

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.

YES o NO þ

Note — Checking the box above will not relieve any registrant required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 from their obligations under those Sections.

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 þ NO o

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

Large accelerated filer o Accelerated filer o Non-accelerated filer þ

Indicate by check mark which financial statement item the registrant has elected to follow.

ITEM 17 o ITEM 18 þ

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

YES o NO þ

TABLE OF CONTENTS

## INTRODUCTION

This report comprises the annual report to shareholders of Amarin Corporation plc (NASDAQCM: AMRN) and its annual report on Form 20-F in accordance with the requirements of the United States Securities and Exchange Commission, or SEC, for the year ended December 31, 2007.

As used in this annual report, unless the context otherwise indicates, the terms "Group", "Amarin", "we", "us" and "our" refer Amarin Corporation plc and its wholly owned subsidiary companies. Laxdale Limited, a company which we acquired in October 2004 and is now known as Amarin Neuroscience Limited, may be referred to herein as "Amarin Neuroscience" or "Laxdale." Ester Neurosciences Limited, a company which we acquired in December 2007 may be referred to herein as "Ester Neurosciences" or "Ester".

Also, as used in this annual report, unless the context otherwise indicates, the term "Ordinary Shares" refers to our Ordinary Shares, par value 5 pence per share, and the term "Preference Shares" refers to our authorized preference shares, par value 5 pence per share. As of December 31, 2007, there were no Preference Shares outstanding. Unless otherwise specified, all shares and share related information (such as per share information and share price information) in this annual report have been adjusted to give effect, retroactively, to our one-for-ten Ordinary Share consolidation effective on July 17, 2002 whereby ten ordinary shares of 10p each became one Ordinary Share of £1.00 each and to the subsequent sub-division and conversion of each issued and outstanding Ordinary Share of £1.00 each on June 21, 2004 into one ordinary share of 5 pence and one deferred share of 95 pence (and the subsequent purchase by the Company and cancellation of all such deferred shares) and each of the authorized but unissued Ordinary Shares of £1 each in the capital of the Company into 20 ordinary shares of 5 pence each.

In addition, as used in this annual report, the term "Debentures" refers to our 8% Convertible Debentures due 2010 which were issued on December 6, 2007 in connection with the financing of our acquisition of Ester.

On January 18, 2008, our Ordinary Shares were consolidated on a one-for-ten basis whereby ten Ordinary Shares of 5p each became one Ordinary Share of 50p. Unless otherwise specified, all shares and share related information (such as per share information and share price information) in this annual report have not been adjusted to give effect to this one-for-ten Ordinary Share consolidation.

On May 14, 2008, we announced a private placement of Ordinary Shares for up to $60.0 million. The first tranche from new investors of $28.0 million closed on May 19, 2008. See Item 8B "Significant changes" for further information.

In this annual report, references to "pounds sterling," "£" or "GBP£" are to U.K. currency, references to "U.S. Dollars", "$" "US$" are to U.S. currency, references to "euro" or "€" are to Euro currency and references to "New Israeli Shekel", "NIS "shekel" are to Israeli currency.

This annual report contains trademarks, tradenames or registered marks owned by Amarin or by other entities, including:

- Permax®, which during the fiscal year covered by this report was registered in Eli Lilly and Company or its affiliates, which we may refer to in this annual report as "Lilly".

- Nanocrystal®, which during the fiscal year covered by this report was registered in Elan Corporation plc or its affiliates, which we may refer to in this annual report as "Elan".

3

## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This annual report contains forward-looking statements about our financial condition, results of operations, business prospects and products in research and involve substantial risks and uncertainties. You can identify these statements by the fact that they use words such as “will”, “anticipate”, “estimate”, “project”, “forecast”, “intend”, “plan”, “believe” a words and terms of similar meaning in connection with any discussion of future operating or financial performance or events. Among the factors that could cause actual results to differ materially from those described or projected herein are the following;

- The success of our research and development activities;

- Decisions by regulatory authorities regarding whether and when to approve our drug applications, as well as their decisions regarding labeling and other matters that could affect the commercial potential of our products;

- The speed with which regulatory authorizations, pricing approvals and product launches may be achieved;

- The success with which developed products may be commercialized;

- Competitive developments affecting our products under development;

- The effect of possible domestic and foreign legislation or regulatory action affecting, among other things, pharmaceutical pricing and reimbursement, including under Medicaid and Medicare in the United States, and involuntary approval of prescription medicines for over-the-counter use;

- Claims and concerns that may arise regarding the safety or efficacy of our product candidates;

- Governmental laws and regulations affecting our operations, including those affecting taxation;

- Our ability to maintain sufficient cash and other liquid resources to meet operating requirements and debt service requirements; general changes in International Financial Reporting Standards (“IFRS”) as adopted by the European Union (“E.U.”) and as issued by the International Accounting Standards Board (“IASB”);

- Patent positions can be highly uncertain and patent disputes are not unusual. An adverse result in a patent dispute can hamper commercialization of products or negatively impact sales of future products or result in injunctive relief and payment of financial remedies;

- Uncertainties of the U.S. Food and Drug Administration ("FDA") approval process and the regulatory approval processes in other countries, including, without limitation, delays in approval of new products;

- Difficulties in product development. Pharmaceutical product development is highly uncertain. Products that appear promising in development may fail to reach market for numerous reasons. They may be found to be ineffective or to have harmful side effects in clinical or pre-clinical testing, they may fail to receive the necessary regulatory approvals, they may turn out not to be economically feasible because of manufacturing costs or other factors or they may be precluded from commercialization by the proprietary rights of others; and

- Growth in costs and expenses; and the impact of acquisitions, divestitures and other unusual items.

4

PART I

Item 1 Identity of Directors, Senior Management and Advisers

Not applicable.

Item 2 Offer Statistics and Expected Timetable

Not applicable.

Item 3 Key Information

A. Selected Financial Data

General

The following table presents selected historical consolidated financial data. The selected historical consolidated financial data as of December 31, 2007 and 2006 and for each of the years ended December 31, 2007 and 2006 have been derived from our audited consolidated financial statements beginning on page F-1 of this annual report, prepared in accordance with International Financial Reporting Standards ("IFRS") as adopted by the E.U. and as issued by the International Accounting Standards Board ("IASB"), which have been audited by PricewaterhouseCoopers, an independent registered public accountant firm, for the years ended December 31, 2007 and 2006.

The selected historical consolidated financial data as of December 31, 2005, 2004 and 2003 and for the years then ended has been derived from our audited historical financial statements prepared in accordance with generally accepted accounting principles in the United Kingdom ("U.K. GAAP") which are not included in these financial statements.

Unless otherwise specified, all references in this annual report to "fiscal year" or "year" of Amarin refer to a twelve-month financial period ended December 31. We prepare our consolidated financial statements in accordance with IFRS as adopted by the E.U. and as issued by the IASB.

We adopted IFRS for the first time for our financial year ended December 31, 2007. Our audited Consolidated Financial Statements as of and for the year ended December 31, 2006 were originally prepared in accordance with U.K. GAAP. As part of our adoption of IFRS, we have restated our Consolidated Financial Statements in accordance with IFRS for comparative purposes.

During 2002 our Ordinary Shares were consolidated on a ten-for-one basis. Concurrently, we amended the terms of our American Depositary Shares, or ADSs, to provide that each ADS would represent one Ordinary Share. Previously each ADS had represented ten ordinary shares of 10p each. The new conversion ratio has been reflected in all years in the weighted average share numbers shown in the consolidated statement of operations data below. In June 2004 we converted each of our £1 Ordinary Shares into one Ordinary Share of 5 pence and one deferred share of 95 pence (with such deferred shares having been subsequently cancelled). This share conversion in 2004 did not affect the ratio as between our Ordinary Shares and our ADSs but is recorded below in the year 2004.

On January 18, 2008 our Ordinary Shares were consolidated on a one-for-ten basis whereby ten Ordinary Shares of 5p each became one Ordinary Share of 50p each.

On May 14, 2008, we announced a private placement of Ordinary Shares for up to $60.0 million. The first tranche from new investors of $28.0 million closed on May 19, 2008. See Item 8B “Significant changes” for further information.

Selected Consolidated Financial Data — IFRS

| | 2006 | 2007 |
|---|---|---|
| | (In U.S. $, thousands except per share data and number of shares information) | |
| Statement of Operations Data — IFRS | | |
| Net sales revenues | 500 | — |
| Total loss from operations | (28,068) | (40,733) |
| Net loss | (26,751) | (38,197) |
| Net loss per Ordinary Share (basic – post share split**) | (3.25) | (3.90) |
| Net loss per Ordinary Share (basic – pre share split**) | (0.33) | (0.39) |
| Net loss per Ordinary Share (diluted – post share split**) | (3.25) | (3.90) |
| Net loss per Ordinary Share (diluted – pre share split**) | (0.33) | (0.39) |
| Consolidated balance sheet data - amounts in accordance with IFRS | | |
| Working capital assets | 28,710 | 6,316 |
| Total assets | 49,559 | 42,254 |
| Long term obligations | (110) | (2,693) |
| Capital stock (ordinary shares) | 7,990 | 12,942 |
| Total shareholders' equity | 38,568 | 24,149 |
| Number of ordinary shares in issue (thousands – post share split**) | 9,068 | 13,906 |
| Number of ordinary shares in issue (thousands – pre share split**) | 90,684 | 139,057 |
| Denomination of each ordinary share (post share split**) | £0.50 | £0.50 |
| Denomination of each ordinary share (pre share split**) | £0.05 | £0.05 |

Selected Consolidated Financial Data — U.K. GAAP

| | Years Ended December 31 | | |
|---|---|---|---|
| | 2003 | 2004* as restated | 2005* as restated |
| | (In U.S. $, thousands except per share data and number of shares information) | | |
| Statement of Operations Data — U.K. GAAP | | | |
| Net sales revenues | 7,365 | 1,017 | 500 |
| Total loss from operations | (38,821) | (11,875) | (20,748) |
| Loss from continuing operations | (6,200) | (10,608) | (20,748) |
| Net (loss)/income | (19,224) | 3,229 | (20,547) |
| Loss from continuing operations per Ordinary Share (basic – post share split**) | (3.63) | (4.71) | (4.45) |
| Loss from continuing operations per Ordinary Share (basic – pre share split**) | (0.36) | (0.47) | (0.45) |
| Net (loss)/income per Ordinary Share (basic – post share split**) | (11.25) | 1.43 | (4.41) |
| Net (loss)/income per Ordinary Share (basic – pre share split**) | (1.13) | 0.14 | (0.44) |
| Net (loss)/income per Ordinary Share (diluted – post share split**) | (11.25) | 1.43 | (4.41) |
| Net (loss)/income per Ordinary Share (diluted – pre share split**) | (1.13) | 0.14 | (0.44) |

| | | | |
|---|---|---|---|
| Consolidated balance sheet data - amounts in accordance with U.K. GAAP | | | |
| Working capital (liabilities)/assets | (39,128) | 8,651 | 28,673 |
| Total assets | 47,377 | 23,721 | 46,760 |
| Long term obligations | — | (2,687) | (180) |
| Capital stock (ordinary shares) | 29,088 | 3,206 | 6,778 |
| Total shareholders' (deficit)/equity | (6,348) | 16,693 | 38,580 |
| Number of ordinary shares in issue (thousands – post share split**) | 1,794 | 3,763 | 7,755 |
| Number of ordinary shares in issue (thousands – pre share split**) | 17,940 | 37,632 | 77,549 |
| Denomination of each ordinary share (post share split**) | £10.00 | £0.50 | £0.50 |
| Denomination of each ordinary share (pre share split**) | £1.00 | £0.05 | £0.05 |

For previously reported 2006 financial information prepared under U.K. GAAP please see our 2006 20-F filed with the SEC on March 5, 2007.

* As restated for the non-cash compensation expense due to the adoption of U.K. GAAP, Financial Reporting Standard 20 "Share-based payments".

** On January 18, 2008, our Ordinary Shares were consolidated on a one-for-ten basis whereby ten Ordinary Shares of 5p each became one Ordinary Share of 50p. Post-split shares and share information above has been adjusted to reflect this share consolidation.

Exchange Rates

We changed our functional currency on January 1, 2003 from pounds sterling to U.S. Dollars to reflect the fact that the majority of our transactions, assets and liabilities were denominated in that currency. Consequently, all data provided in this annual report is in U.S. Dollars from 2003.

As some of our assets, liabilities and transactions are denominated in pounds sterling, euro and shekel, the rate of exchange between pounds sterling and the U.S. Dollar, between euro and U.S. Dollar and between shekel and U.S. Dollar, which is determined by supply and demand in the foreign exchange markets and affected by numerous factors, continues to impact our financial results. Fluctuations in the exchange rates between the U.S. Dollar and pounds sterling, between U.S. Dollar and euro and between the U.S. Dollar and shekel may affect any earnings or losses reported by us and the book value of our shareholders' equity as expressed in U.S. Dollars, and consequently may affect the market price for our ADSs.

The following table sets forth, for the periods indicated, the average of the noon buying rate on the last day of each month during the relevant period as announced by the Federal Reserve Bank of New York for pounds sterling expressed in U.S. Dollars per pound sterling:

| Fiscal Period | Average Noon Buying Rate (U.S. Dollars/pound sterling) |
|---|---|
| 12 months ended December 31, 2003 | 1.6450 |
| 12 months ended December 31, 2004 | 1.8356 |
| 12 months ended December 31, 2005 | 1.8204 |
| 12 months ended December 31, 2006 | 1.8434 |
| 12 months ended December 31, 2007 | 2.0073 |

The following table sets forth, for each of the last six months, the high and low noon buying rate during each month as announced by the Federal Reserve Bank of New York for pounds sterling expressed in U.S. Dollars per pound sterling:

| Month | High Noon Buying Rate (U.S. Dollars/pound sterling) | Low Noon Buying Rate (U.S. Dollars/pound sterling) |
|---|---|---|
| November 2007 | 2.1104 | 2.0478 |
| December 2007 | 2.0658 | 1.9774 |
| January 2008 | 1.9895 | 1.9515 |
| February 2008 | 1.9923 | 1.9405 |
| March 2008 | 2.0311 | 1.9823 |
| April 2008 | 1.9994 | 1.9627 |

The noon buying rate as of May 15, 2008 was 1.9488 U.S. Dollars per pound sterling.

B. Capitalization And Indebtedness

Not applicable.

C. Reasons For The Offer And Use Of Proceeds

Not applicable.

D. Risk Factors

## RISK FACTORS

You should carefully consider the risks and the information about our business described below, together with all the other information included in this annual report. You should not interpret the order in which these considerations are presented as an indication of their relative importance to you. The risks and uncertainties described below are not the only ones that we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may also adversely affect our business. If any of the following risks and uncertainties develops into actual events, our business, financial condition and results of operations could be materially and adversely affected. In such an instance, the trading price of our ADSs and Ordinary Shares could decline.

We have a history of losses, and we may not be able to attain profitability in the foreseeable future.

We have not been profitable in four of the last five fiscal years. For the fiscal years ended December 31, 2003, 2004 and 2005, we reported (losses)/profits under U.K. GAAP of approximately $(19.2) million, $3.2 million and $(20.5) million respectively. For the fiscal years ended December 31, 2006 and 2007, we reported losses under IFRS of approximately $26.8 million and $38.2 million respectively. Unless and until marketing approval is obtained from either the U.S. Food and Drug Administration, which we refer to as the FDA, or European Medicines Evaluation Agency, which we refer to as the EMEA, for any of our products, or we are otherwise able to acquire rights to products 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 in future periods to enable us to attain profitability.

We acquired Amarin Neuroscience (formerly Laxdale Limited) on October 8, 2004 and Ester Neurosciences Limited on December 5, 2007. We continue to have limited operations, assets and financial resources. We currently have no marketable products or other source of revenues other than the Multicell out-licensing contract described herein. All of our current products are in the development stage. The development of pharmaceutical products is a capital intensive business. Therefore, we expect to incur expenses without corresponding revenues at least until we are able to obtain regulatory approval and sell our future products in significant quantities. This may result in net operating losses until we can generate an acceptable level of revenues, which we may not be able to attain. Further, even if we do achieve operating revenues, there can be no assurance that such revenues will be sufficient to fund continuing operations. Therefore, we cannot predict with certainty whether we will ever be able to achieve profitability.

In addition to advancing our existing development pipeline, we may also acquire rights to additional products. However, we may not be successful in doing so. We may need to raise additional capital before we can acquire any products. There is also a risk that any of our development stage products we may acquire will not be approved by the FDA or regulatory authorities in other countries on a timely basis or at all. The inability to obtain such approvals would adversely affect our ability to generate revenues.

The likelihood of success of our business plan must be considered in light of the problems, expenses, difficulties, complications and delays frequently encountered in connection with developing and expanding early stage businesses and the regulatory and competitive environment in which we operate.

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

As a consequence of divestitures in 2003 and 2004 and our acquisition of Amarin Neuroscience in October 2004 and Ester Neurosciences Limited in December 2007, our historical financial results do not form an accurate basis upon which investors should base an assessment of our business and prospects. We are now focused on the research, development and commercialization of novel drugs for the central nervous system and cardiovascular disease. Accordingly, our historical financial results reflect a substantially different business from that currently being conducted.

Our indebtedness under our 8% Convertible Debentures due 2010 could adversely affect our financial condition and our ability to respond to changes in our business.

As described in our Report of Foreign Issuer furnished to the SEC on December 12, 2007, on December 4, 2007, we issued $2.75 million aggregate principal amount of our 8% Convertible Debentures due 2010 to finance, in part, our acquisition of Ester Neurosciences Limited, a private pharmaceutical development company based in Israel. We have debt service obligations under our Debentures. These debt obligations could have significant negative consequences, including, but not limited to:

- increasing our vulnerability to general adverse economic and industry conditions;
- limiting our ability to obtain additional financing in the future for working capital, capital expenditures, acquisitions or other business purposes;
- limiting our flexibility to plan for, or react to, changes in our business and the industry in which we compete;
- placing us at a possible disadvantage to competitors with fewer debt obligations and competitors that have better access to capital resources; and
- requiring us to dedicate a substantial portion of our cash flow from operations to payments on our indebtedness, thereby reducing the availability of our cash flow to fund working capital expenditures, research and development efforts and other general corporate purposes.

We may incur additional indebtedness.

The indenture governing the Debentures does not prohibit us from incurring substantial additional indebtedness in the future. Any such additional indebtedness that is permitted to be secured would be effectively senior to the Debentures to the extent of the assets securing such indebtedness. As described under the heading “Description of Debentures — Additional Covenant — Limitation on Incurrence of Subsidiary Indebtedness” in our prospectus supplement filed with the SEC on December 5, 2007, the Debentures limit the ability of our subsidiaries to incur indebtedness. However, because they are not guaranteed by our subsidiaries (or any other third party), the Debentures are structurally subordinated to the indebtedness and other liabilities that our subsidiaries are permitted to incur. In addition, the indenture does not contain any restrictive covenants limiting our ability to pay dividends, make any payments on junior or other indebtedness or otherwise limit our financial condition.

We may have to issue additional equity, leading to shareholder dilution.

We are committed to issue equity to the former shareholders of Amarin Neuroscience upon the successful achievement of specified milestones for the AMR101 development program (subject to such shareholders’ right to choose cash payment in lieu of equity). Pursuant to the Amarin Neuroscience share purchase agreement, further success-related milestones will be payable as follows:

Upon receipt of marketing approval in the United States and Europe for the first indication of any product containing Amarin Neuroscience intellectual property as secured in the 2004 Laxdale acquisition, we must make an aggregate stock or cash payment (at the sole option of each of the sellers) of GBP£7.5 million for each of the two potential market approvals (i.e., GBP£15.0 million maximum). In addition, upon receipt of a marketing approval in the United States and Europe for any other product using Amarin Neuroscience intellectual property as secured in the 2004 Laxdale acquisition 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 GBP£5.0 million for each of the two potential market approvals (i.e., GBP£10.0 million maximum). The exchange rate as of May 15, 2008 was approximately $1.9488 per GBP£.

As described under the heading “Unaudited Pro Forma Financial Information” in our Report of Foreign Issuers on Form 6-K filed with the SEC on December 5, 2007, if the Monarsen Phase IIa in Myasthenia Gravis (“MG”) clinical study meets its study objectives, we are committed to pay $5 million, at Amarin’s option, in equity or cash, to the former shareholders of Ester Neurosciences Limited. In addition, upon successful completion of the Monarsen Phase II MG development program with adequate efficacy and safety data that fully supports the commencement of a Phase III clinical study in the U.S., we are committed to pay $6 million, at Amarin's option, in equity or cash, to the former shareholders of Ester Neurosciences Limited.

In December 2007, we issued $2.75 million in aggregate principal amount of three-year convertible Debentures. The Debentures may be converted into 5.7 million ADSs commencing four months after the date of closing at a conversion price of $0.48 per ADS. If, at any time prior to December 6, 2009, the Company issues Ordinary Shares, securities convertible into ADSs or Ordinary Shares, warrants to purchase ADSs or Ordinary Shares or options to purchase any of the aforementioned convertible debentures at a price that is less than, or converts at a price that is less than, $3.66 ("Down-round Price"), then the conversion price shall be adjusted to equal 130% of the Down-round Price.

In addition, the Debenture holders received five-year warrants to purchase 2.3 million ADSs at an exercise price of $0.48. If, at any time prior to December 6, 2009, the Company issues Ordinary Shares, securities convertible into ADSs or Ordinary Shares, warrants to purchase ADSs or Ordinary Shares or options to purchase any of the aforementioned warrants at a price that is less than, or converts at a price that is less than, $3.66 ("Down-round Price"), then the exercise price shall be adjusted to equal 130% of the Down-round Price.

The convertible Debentures will be required to be repaid from the proceeds of, and the holders of the convertible Debentures will have the right to participate in, future financings of the Company, with certain exceptions.

Taking account for the one-for-ten consolidation of our Ordinary Shares on January 18, 2008, as at May 16, 2008 we had 2,052,473 warrants outstanding with a weighted average exercise price of $8.70 per share. As at May 16, 2008, we also had outstanding employee options to purchase 1,475,481 Ordinary Shares at an average exercise price of $13.23 per share.

Additionally, in pursuing our growth strategy we will either need to issue new equity as consideration for the acquisition of products, or to otherwise raise additional capital, in which case equity, debt convertible into equity or debt instruments may be issued. The creation of new shares may lead to dilution of the value of the shares held by our current shareholder base.

We have granted the initial purchasers of the Debentures the right to participate in certain of our future financings, which may restrict our ability to raise capital.

So long as the initial purchaser of a Debenture is the registered holder of the Debenture, such initial purchaser shall have a right, subject to certain exceptions, to participate in future equity or debt financings by us for cash on terms equal to those of other investors in such future financings. This right is not transferable upon the sale of the Debentures by initial purchasers. This financing participation right may restrict our ability to raise capital through equity financing in the future as it may, among other things, make potential investors less likely to enter into negotiations with us.

If we cannot find additional capital resources, we will have difficulty in operating as a going concern and growing our business.

At December 31, 2007, we had a cash balance of approximately $18.3 million. On May 14, 2008, we announced a private placement of Ordinary Shares for up to $60.0 million. The first tranche from new investors of $28.0 million closed on May 19, 2008. Based upon current business activities, we forecast having sufficient cash to fund operations for at least the next 12 months from May 19, 2008. We may also require further funds in the future to implement our long-term growth strategy of acquiring additional development stage and/or marketable products, recruiting clinical, regulatory and sales and marketing personnel, and growing our business. Our ability to execute our business strategy and sustain our infrastructure at our current level 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.

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

On April 24, 2007, we reported top-line results from our two Phase III clinical trials of AMR101 to treat Huntington's disease. Study data showed no statistically significant difference in either study between AMR101 and placebo with regard to the primary and secondary endpoints at 6-months of treatment. The adverse clinical trial data on AMR101 for Huntington's disease could materially affect our ability to develop the product for Huntington's disease and for other therapeutic indications. 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 are not generated, our business will be materially and adversely affected. Although we intend to bring additional products forward from our research and development efforts, even if we are successful in doing so, 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.

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

In order to successfully commercialize a product, we will be required to conduct all tests and clinical trials needed in order to meet regulatory requirements, to obtain applicable regulatory approvals, and to prosecute patent applications. 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. Additionally, the terms of any approvals may not have the scope or breadth needed for us to commercialize products successfully.

We may not be successful in developing or marketing future products if we cannot meet extensive regulatory requirements of the FDA and other regulatory agencies for quality, safety and efficacy.

Our long-term strategy involves the development of products we may acquire from third parties. The success of these efforts is dependent in part upon the ability of the Group, its contractors, and its products to meet and to continue to meet regulatory requirements in the jurisdictions where we ultimately intend to sell such products. 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 may be delayed by many factors, including:

- 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 trials;
- the lack of effectiveness during clinical trials;
- unforeseen safety issues;
- delay, suspension, or termination of a trial by the institutional review board responsible for overseeing the study at a particular study site; and
- government or regulatory delays or “clinical holds” requiring suspension or termination of a trial.

Even if we obtain positive results from early stage pre-clinical or clinical trials, we may not achieve the same success in future trials. Clinical trials that we conduct may not provide sufficient safety and effectiveness data to obtain the requisite regulatory approvals for product candidates. The failure of clinical trials to demonstrate safety and

effectiveness 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.

Any approvals that are obtained may be limited in scope, or may be accompanied by burdensome post-approval study or other requirements. This 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. Additionally, even after approval, a marketed drug and its manufacturer are subject to continual review. 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.

After approval, our products will be subject to extensive government regulation.

Once a product is approved, numerous post-approval requirements apply. Among other things, the holder of an approved NDA or other license 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.

Advertising and promotional materials must comply with FDA rules in addition to other potentially applicable federal and local laws in the United States and in other countries. In the United States, the distribution of product samples to physicians must comply with the requirements of the U.S. Prescription Drug Marketing Act. Manufacturing facilities remain subject to FDA inspection and must continue to adhere to the FDA's current good manufacturing practice requirements. Application holders must obtain FDA approval for product and manufacturing changes, depending on the nature of the change. 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 comply with FDA and other requirements, new information regarding the safety or effectiveness of a product could lead the FDA to modify or withdraw a product approval. Adverse regulatory action, whether pre- or post-approval, can potentially lead to product liability claims and increase our product liability exposure. We must also compete against other products in qualifying for reimbursement under applicable third party payment and insurance programs.

Our future products may not be able to compete effectively against those of our competitors.

Competition in the pharmaceutical industry is intense and is expected to increase. If we are successful in completing the development of any of our products, we may face competition to the extent other pharmaceutical companies are able to develop products for the treatment of similar indications. Potential competitors in this market may include companies with greater resources and name recognition than us. 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 may include large, well-established pharmaceutical companies, specialty pharmaceutical sales and marketing companies, and specialized neurology companies. 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 us, including financial, product development, marketing, personnel and other resources. Should a competing product obtain marketing approval prior to any of our products, this would significantly erode the projected revenue streams for our product.

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 subscriptions 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 supply of future products could be 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 products and/or acquiring or developing other marketable products in the future, we will be obliged to rely on contract manufacturers to produce our products. We may not be able to enter into manufacturing arrangements on terms that are favorable to us. Moreover, if any future manufacturers should cease doing business with us or experience delays, shortages of supply or excessive demands on their capacity, we may not be able to obtain adequate quantities of product in a timely manner, or at all. Manufacturers 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 future manufacturer to comply with these requirements could affect its ability to provide us with product. Any manufacturing problem 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.

We may not be able to grow our business unless we can acquire and market or in-license new products.

We are pursuing a strategy of product acquisitions and in-licensing in order to supplement our own research and development activity. For example, in December 2007, we acquired the entire issued share capital of Ester Neurosciences Limited whose lead product, EN101, is currently in Phase IIa clinical development to treat myasthenia gravis, a debilitating neuromuscular disease; in March 2007, we acquired the global rights to a novel, nasal lorazepam formulation for the out-patient treatment of emergency seizures in epilepsy patients, specifically status epilepticus and acute repetitive seizures; and in May 2006, we acquired the global rights to a novel formulation of apomorphine for the treatment of “off” episodes in patients with advanced Parkinson’s disease. Our success in this regard will be dependent on our ability to identify other companies that are willing to sell or license product lines to us. We will be competing for these products with other parties, many of whom have substantially greater financial, marketing and sales resources than we do. Even if suitable products are available, depending on competitive conditions we may not be able to acquire rights to additional products on acceptable terms, or at all. Our inability to acquire additional products or successfully introduce new products could have a material adverse effect on our business.

In order to commercialize our future products, we will need to establish a sales and marketing capability.

At present, we do not have any sales or marketing capability since all of our products are currently in the development stage. However, if we are successful in obtaining regulatory approval for any product for any indication, we may directly commercialize this product for that indication in the U.S. market. Similarly, to the extent we execute our long-term strategy of expanding our portfolio by developing or acquiring additional marketable products, we intend to directly sell our neurology products in the United States. In order to market new products, we will need to add marketing and sales personnel who have expertise in the pharmaceuticals business. We must also develop the

necessary supporting distribution channels. Although we believe we can build the required infrastructure, we may not be successful in doing so if we cannot attract personnel or generate sufficient capital to fund these efforts. Failure to establish a sales force and distribution network in the U.S. would have a material adverse effect on our ability to grow our business.

The planned expansion of our business may strain our resources.

Our strategy for growth includes potential acquisitions of new products for development and the introduction of these products to the market. Since we currently operate with limited resources, the addition of such new products could require a significant expansion of our operations, including the recruitment, hiring and training of additional personnel, particularly those with a clinical or regulatory background. Any failure to recruit necessary personnel could have a material adverse effect on our business. Additionally, the expansion of our operations and work force could create a strain on our financial and management resources and it may require us to add management personnel.

We may incur potential liabilities relating to discontinued operations or products.

In October 2003, we sold Gacell Holdings AB, the Swedish holding company of Amarin Development AB, which we refer to as ADAB, our Swedish drug development subsidiary, to Watson Pharmaceuticals, Inc. In February 2004, we sold our U.S. subsidiary, Amarin Pharmaceuticals Inc., and certain assets, to Valeant. In connection with these transactions, we provided a number of representations and warranties to Watson and Valeant regarding the respective businesses sold to them, and other matters, and we undertook to indemnify Watson and Valeant under certain circumstances for breaches of such representations and warranties. We are not aware of any circumstances which could reasonably be expected to give rise to an indemnification obligation under our agreements with either Watson or Valeant. However, we cannot predict whether matters may arise in the future which were not known to us and which, under the terms of the relevant agreements, could give rise to a claim against us.

We will be 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 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.

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.

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.

The loss of any key management or qualified personnel could disrupt 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 are subject to continuing potential product liability.

Although we disposed of the majority of our former products during 2003 and 2004, we 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. The potential for liability exists despite the fact that our former subsidiary, Amarin Pharmaceuticals Inc. conducted all sales and marketing activities with respect to such products. Although we have not retained any liabilities of Amarin Pharmaceuticals Inc. in this regard, as the prior holder of ownership rights to such former products, third parties could seek to assert potential claims against us. Since we distributed and sold our products to a wide number of end users, the risk of such claims could be material.

We do not at present carry product liability insurance to cover any such risks. If we were to seek insurance coverage, we may not be able to maintain product liability coverage on acceptable terms if our claims experience results in high rates, or if product liability insurance otherwise becomes costlier or unavailable because of general economic, market or industry conditions. If we add significant products to our portfolio, we will require product liability coverage and may not be able to secure such coverage at reasonable rates or at all.

Product liability claims could also be brought 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. Amarin does not carry product liability insurance to cover clinical trials.

Amarin was responsible for the sales and marketing of Permax 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.

In late 2002, Eli Lilly, as the holder of the NDA for Permax, received a recommendation from the U.S. Food and Drug Administration (“FDA”) to consider making a change to the package insert for Permax based upon the very rare observation of cardiac valvulopathy in patients taking Permax. While Permax has not been definitely proven as the cause of this condition, similar reports have been notified in patients taking other ergot- derived pharmaceutical products, of which Permax is an example. In early 2003, Eli Lilly amended the package insert for Permax to reflect the risk of cardiac valvulopathy in patients taking Permax and also sent a letter to a number of doctors in the United States describing this potential risk. Causation has not been established, but is thought to be consistent with other fibrotic side effects observed in Permax.

On March 29, 2007, the FDA announced that the manufacturers of pergolide drug products will voluntarily remove these drug products, including Permax, from the market. Further information about the removal of Permax and other pergolide drug products is available on the FDA’s website.

During 2007, one lawsuit alleging claims related to cardiac valvulopathy and Permax was pending in the United States and currently remains pending. Eli Lilly, Elan, Valeant, Amarin Pharmaceuticals Inc., Athena Neurosciences, Inc., and Amarin are named as defendants in this lawsuit, and are defending against the claims and allegations. The case is currently in discovery. In addition, a lawsuit alleging claims related to cardiac valvulopathy and Permax was filed in March 2008 and is currently pending in the United States. Eli Lilly, Elan, Valeant, and Amarin are named as defendants in this lawsuit. Amarin has not been formally served with the complaint from this lawsuit.

Two other claims related to cardiac valvulopathy and Permax and one claim related to compulsive gambling and Permax are or were being threatened against Eli Lilly, Elan, and/or Valeant, and could possibly implicate Amarin.

The group has reviewed the position and having taken external legal advice considers the potential risk of significant liability arising for Amarin from these legal actions to be remote. No provision is booked in the accounts at December 31, 2007.

The price of our ADSs and Ordinary 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. Our ADSs may

also be subject to volatility as a result of their limited trading market. At December 31, 2007 we had 132,712,369 ADSs representing Ordinary Shares outstanding and 6,345,001 Ordinary Shares outstanding (which are not held in the form of ADSs). Taking account for the one-for-ten consolidation of our Ordinary Shares on January 18, 2008 we currently have 25,339,642 ADSs representing Ordinary Shares outstanding and 837,509 Ordinary Shares outstanding (which are not held in the for of ADSs). There is a risk that there may not be sufficient liquidity in the market to accommodate significant increases in selling activity or the sale of a large block of our securities. Our ADSs have historically had limited trading volume, which may also result in volatility. During the twelve-month period ending December 31, 2007, the average daily trading volume for our ADSs was 1,161,203 ADSs.

If our public float and the level of trading remain at limited levels over the long term, this could result in volatility and increase the risk that the market price of our ADSs and Ordinary Shares may 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.

The issuances of ADSs and Ordinary Shares upon the conversion or exercise of our securities will dilute the ownership interest of existing stockholders, including stockholders who had previously exercised their warrants.

The issuances of ADSs and Ordinary Shares in connection with the conversion of our Debentures and exercise of our warrants will dilute the ownership interest of existing stockholders. Any sales in the public market of the ADSs and Ordinary Shares issuable upon such conversion or exercise could adversely affect prevailing market prices of our ADSs and Ordinary Shares.

Future sales of our ADSs and/or Ordinary Shares in the public market could lower the market price for our ADSs and/or Ordinary Shares.

In the future, we may sell additional ADSs and/or Ordinary Shares to raise capital or pursuant to contractual obligations. See "— We may have to issue additional equity, leading to shareholder dilution." We cannot predict the size of future issuances or sales of our ADSs and/or Ordinary Shares to raise capital or the effect, if any, that they may have on the market price for our ADSs and/or Ordinary Shares. The issuances and sales of substantial amounts of ADSs and/or Ordinary Shares, or the perception that such issuances and sales may occur, could adversely affect the market price of our ADSs and/or Ordinary Shares.

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

There is a risk that we will be classified as a passive foreign investment company, or "PFIC", for U.S. federal income tax purposes. Our status as a PFIC could result in a reduction in the after-tax return to U.S. Holders of our Ordinary Shares or ADSs and may cause a reduction in the value of such shares. We will be classified as a PFIC for any taxable year in which (i) 75% or more of our gross income is passive income or (ii) at least 50% of the average value of all our assets produce or are held for the production of passive income. For this purpose, passive income includes interest, gains from the sale of stock, and royalties that are not derived in the active conduct of a trade or business. Because we receive interest and may receive royalties, there is a risk that we will be considered a PFIC

under the income test described above. In addition, because of our cash position and our ownership of patents, there is a risk that we will be considered a PFIC under the asset test described above. While we believe that the PFIC rules were not intended to apply to companies such as us that focus on research, development and commercialization of drugs, no assurance can be given that the U.S. Internal Revenue Service or a U.S. court would determine that, based on the composition of our income and assets, we are not a PFIC currently or in the future. If we were classified as a PFIC, U.S. Holders of our Ordinary Shares or ADSs could be subject to greater U.S. income tax liability than might otherwise apply, imposition of U.S. income tax in advance of when tax would otherwise apply, and detailed tax filing requirements that would not otherwise apply. The PFIC rules are complex and a U.S. Holder of our Ordinary Shares or ADSs is urged to consult its own tax advisors regarding the possible application of the PFIC rules to it in its particular circumstances.

U.S. Holders of our Ordinary Shares or ADSs may be subject to U.S. income taxation at ordinary income tax rates on undistributed earnings and profits.

Given our current ownership, we expect that we will be a controlled foreign corporation, ("CFC") for the taxable year 2008 and we may be classified as a CFC in future taxable years. If we are classified as a CFC for U.S. federal income tax purposes, any shareholder that is a U.S. person that owns directly, indirectly or by attribution, 10% or more of the voting power of our outstanding shares may be subject to current U.S. income taxation at ordinary income tax rates on all or a portion of the Company's undistributed earnings and profits attributable to "subpart F income." Such 10% shareholder may also be taxable at ordinary income tax rates on any gain realized on a sale of Ordinary Shares or ADSs to the extent of the Company's current and accumulated earnings and profits attributable to such shares. The CFC rules are complex and U.S. Holders of our Ordinary shares or ADSs are urged to consult their own tax advisors regarding the possible application of the CFC rules to them in their particular circumstances.

The recent adverse clinical trial data on AMR101 for Huntington's disease could materially affect our ability to develop AMR101 for other therapeutic indications.

On April 24, 2007, we reported top-line results from our two Phase III clinical trials of AMR101 to treat Huntington's disease ("HD"). We had conducted two Phase III double-blind, placebo-controlled studies in which HD patients were randomized to receive either placebo or 2 grams (1 gram twice daily) of AMR101 daily for six months. Study data showed no statistically significant difference in either study between AMR101 and placebo with regard to the primary and secondary endpoints at 6-months of treatment. These findings were inconsistent with earlier clinical trial data that showed statistical significance in a subset of HD patients with a CAG repeat length of less than or equal to 44. This adverse clinical trial data on AMR101 for Huntington's disease could materially affect our ability to develop AMR101 for other therapeutic indications.

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

We are incorporated under English law and our Ordinary Shares were admitted to trading on the AIM market of the London Stock Exchange and the IEX market of the Irish Stock Exchange on July 17, 2006. The rights of holders of Ordinary Shares and, therefore, certain of the rights of holders of ADSs, are governed by English law, including the provisions of the Companies Act 1985 (as amended) that remain in force and the Companies Act 2006 (together the "Companies Acts"), and by our memorandum and articles of association and the Group is subject to the rules of AIM and IEX. These rights differ in certain respects from the rights of shareholders in typical U.S. corporations. The principal differences include the following:

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

- Under English law, each shareholder generally has pre-emptive rights to subscribe on a proportionate basis to any issuance of shares. Under U.S. law, shareholders generally do not have pre-emptive rights unless specifically granted in the certificate of incorporation or otherwise.

- Under English law, certain matters require the approval of 75% of the shareholders, 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 shareholder approval is required to amend the certificate of incorporation or to approve other significant transactions. Under the rules of AIM and IEX, certain transactions require the approval of 50% of the shareholders, including disposals resulting in a fundamental change of business and reverse takeovers. In addition, certain transactions with a party related to the Group for the purposes of the AIM rules requires that the Group consult with its nominated adviser as to whether the transaction is fair and reasonable as far as shareholders are concerned.

- Under English law, shareholders 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.

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The quorum requirements for a shareholders' 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 shareholders' meeting in order to constitute a quorum. The minimum number of shares required for a quorum can be reduced pursuant to a provision in a company's certificate of incorporation or bylaws, but typically not below one-third of the shares entitled to vote at the meeting.

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

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

Foreign currency fluctuations may affect our future financial results or cause us to incur losses.

We prepare our financial statements in U.S. Dollars. Since our strategy involves the development of products for the U.S. market, a significant part of our clinical trial expenditures are denominated in U.S. Dollars and we anticipate that the majority of our future revenues will be denominated in U.S. Dollars. However, a significant portion of our costs are denominated in pounds sterling, euro and shekel as a result of our being engaged in activities in the United Kingdom, the European Union and Israel. As a consequence, the results reported in our financial statements are potentially subject to the impact of currency fluctuations between the U.S. Dollar on the one hand, and pounds sterling, euro or shekel on the other hand. We are focused on development activities and do not anticipate generating on-going revenues in the short-term. Accordingly, we do not engage in significant currency hedging activities in order to limit the risk of exchange rate fluctuations. However, if we should commence commercializing any products in the United States, changes in the relation of the U.S. Dollar to the pound sterling, euro and/or the shekel may affect our revenues and operating margins. In general, we could incur losses if the U.S. Dollar should become devalued relative to pounds sterling, euro and/or the shekel.

We do not currently have the capability to undertake manufacturing of any potential products.

We have not invested in manufacturing and have no manufacturing experience. 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. To the extent that we enter into contractual relationships with other companies to manufacture our products, if any, the success of those products may depend on the success of securing and maintaining contractual relationships with third party manufacturers (and any sub-contractors they engage).

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

We have not invested 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 the efforts of those other companies (and any sub-contractors they engage).

We have limited personnel to oversee out-sourced clinical testing and the regulatory approval process.

It is likely that we will also need to hire additional personnel skilled in the 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 out-source 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.

We cannot assure you that our limited oversight of the contract research organizations will suffice to avoid significant problems with the protocols and conduct of the clinical trials.

We depend on contract research organizations to conduct our pre-clinical and our clinical testing. We have engaged and intend to continue to engage third party contract research organizations and other third parties to help us develop our drug candidates. Although we have designed the clinical trials for drug candidates, the contract research organizations will be conducting all of our clinical trials. As a result, many important aspects of our drug development programs have been and will continue to be outside of our direct control. In addition, the contract research organizations may not perform all of their obligations under arrangements with us. If the contract research organizations do not perform clinical trials in a satisfactory manner or breach their obligations to us, the development and commercialization of any drug candidate may be delayed or precluded. We cannot control the amount and timing of resources these contract research organizations devote to our programs or product candidates. The failure of any of these contract research organizations to comply with any governmental regulations would substantially harm our development and marketing efforts and delay or prevent regulatory approval of our drug candidates. If we are unable to rely on clinical data collected by others, we could be required to repeat, extend the duration of, or increase the size of our clinical trials and this could significantly delay commercialization and require significantly greater expenditures.

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.

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 neurological and cardiovascular disorders. We cannot assure you that unforeseen problems will not develop with these technologies or applications or that commercially feasible products will ultimately be developed by us.

Third-party reimbursement and health care cost containment initiatives and treatment guidelines may constrain our future revenues.

Our ability to market successfully our existing and future new products will depend in part on the level of reimbursement that government health administration authorities, private health coverage insurers and other organizations provide for the cost of our products and related treatments. Countries in which our products are sold through reimbursement schemes under national health insurance programs frequently require that manufacturers and sellers of pharmaceutical products obtain governmental approval of initial prices and any subsequent price increases. In certain countries, including the United States, government-funded and private medical care plans can exert significant indirect pressure on prices. We may not be able to sell our products profitably if adequate prices are not approved or reimbursement is unavailable or limited in scope. Increasingly, third-party payers attempt to contain health care costs in ways that are likely to impact our development of products including:

- failing to approve or challenging the prices charged for health care products;
- introducing reimportation schemes from lower priced jurisdictions;
- limiting both coverage and the amount of reimbursement for new therapeutic products;
- denying or limiting coverage for products that are approved by the regulatory agencies but are considered to be experimental or investigational by third-party payers;
- refusing to provide coverage when an approved product is used in a way that has not received regulatory marketing approval; and
- refusing to provide coverage when an approved product is not appraised favorably by the National Institute for Clinical Excellence in the U.K., or similar agencies in other countries.

19

We are undergoing significant organizational change. Failure to manage disruption to the business or the loss of key personnel could have an adverse effect on our business.

We are making significant changes to both our management structure and the locations from which we operate. As a result of this, in the short term, morale may be lowered and key employees may decide to leave, or may be distracted from their usual role. This could result in delays in development projects, failure to achieve managerial targets or other disruption to the business which could have material adverse affects on our business and results of operations.

Item 4 Information on the Company

A. History and Development of the Company

Amarin Corporation plc (formerly Ethical Holdings plc) is a public limited company with its primary stock market listing in the U.S. on the NASDAQ Capital Market and secondary listings in the U.K. and Ireland on AIM and IEX, respectively. 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.

Our registered office is located at 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 and our telephone number is +353-1-6699010. The directors are responsible for the maintenance and integrity of our website, www.amarincorp.com. Our principal research and development facilities are located in Oxford, England.

In the period from late 2003 through 2004, we executed a comprehensive restructuring of our operations. In 2003, we disposed of our drug delivery business to Watson. In 2004, we sold our U.S. sales and marketing subsidiary and the majority of our U.S. operations to Valeant and acquired the entire issued share capital of Laxdale, a research and development based neuroscience company, with particular expertise in lipid science.

During 2007, we initiated a cardiovascular development program, leveraging our proprietary expertise and intellectual property in lipid science to target billion dollar market opportunities such as dyslipidemia. We also focused on expanding and strengthening our research and development management team. In April 2007, we appointed Dr. Declan Doogan to the newly-created position of Head of Research and Development. Dr. Doogan was previously Senior Vice President and Head of Worldwide Development at Pfizer Global Research and Development. Since joining Amarin, Dr. Doogan has been instrumental in transforming our research and development organization and streamlining development activities from translational research through clinical operations. Other recent additions to our management team include Dr. Keith Wood, a thirty year industry veteran as Head of Research and Development Operations and Stuart Sedlack (formerly Global Head of Negotiations for a business unit of Novartis Pharma AG) as Executive Vice President, Corporate Development.

In 2006 and 2007 we expanded our CNS pipeline through the acquisition of a global license to a novel sublingual apomorphine for patients with advanced Parkinson's disease, a novel nasal formulation of lorazepam for the out-patient treatment of emergency seizures in epilepsy patients and the addition of EN101 for myasthenia gravis via the acquisition of Ester Neurosciences Limited.

With respect to our Huntington's disease program, in late 2007 we met with the FDA following the completion of a comprehensive analysis of the 12-month data from the U.S. Phase III trial of AMR101 in HD showing a statistically significant benefit with AMR101 over longer periods of treatment. The FDA indicated that one additional Phase III trial demonstrating robust results, in conjunction with the confirmatory evidence from the existing clinical data, may be sufficient clinical data to support a New Drug Application. We are also in discussions with EMEA.

On December, 19, 2007, Mr. Thomas Lynch was appointed Chief Executive Officer following the resignation of Mr. Richard Stewart. Mr. Lynch joined us in January 2000 as Chairman of the Board. Between 1993 and 2004, Mr. Lynch was with Elan Corporation plc where he held a number of positions including Chief Financial Officer and Executive Vice Chairman. Also on December 19, 2007, Mr. Alan Cooke was appointed to the position of President and Chief Operating Officer.

In the period from late 2004 to late 2007, we completed a series of financings raising aggregate gross proceeds of approximately $96.7 million, including $18.5 million from our directors and officers.

B. Business Overview

Our Business

We are committed to improving the lives of patients suffering from central nervous system and cardiovascular diseases. Our goal is to be a leader in the research, development and commercialization of novel drugs that address unmet patient needs.

Our recently initiated cardiovascular program capitalizes on the known therapeutic benefits of essential fatty acids in cardiovascular disease. Our CNS development pipeline includes programs in myasthenia gravis, Huntington's disease, Parkinson's disease, epilepsy and memory. We also have two proprietary technology platforms: a lipid-based technology platform for the targeted transport of molecules through the liver and/or to the brain, and a unique mRNA technology based on cholinergic neuromodulation.

The following table summarizes the status of our development pipeline:

AMR101

AMR101 is a semi-synthetic, highly purified (greater than 96%) derivative of (all-cis)-5,8,11,14,17-eicosapentaenoic acid ("ethyl-EPA"). It is a long chain highly unsaturated fatty acid (often written in short as 20:5n-3 or 20: 3).

AMR101 and Derivatives for Cardiovascular Disease

We have initiated a cardiovascular development strategy to capitalize on the known therapeutic benefits of unsaturated fatty acids in cardiovascular disease. We plan to utilize our extensive know-how and experience in lipid science to develop and advance these programs.

We are planning to commence a series of clinical trials with AMR101 (ultra-pure ethyl-EPA) in dyslipidemia, particularly the treatment of high triglycerides and the evaluation of the effect of the co-administration and co-formulation of AMR101 with other cardiovascular medications.

In excess of two million patients in Japan have been prescribed ultra-pure EPA for the treatment of high triglyceride levels (a component of dyslipidemia) since its approval. The safety profile of ultra-pure EPA is very good, especially in comparison to other triglyceride lowering agents such as fibrates, statins and niacin.

We believe that proof of concept with AMR101 in cardiovascular disease can be established relatively quickly and inexpensively as efficacy is measured by well defined biochemical endpoints. This would enable rapid progress of effective compounds into the final stages of development.

In addition, we intend to commence investigation of new compounds from our existing development portfolio for the treatment of dyslipidemia and potentially other cardiovascular related diseases.

AMR101 Clinical Development for HD

HD is inherited as an autosomal dominant disease that gives rise to progressive, selective (localized) neural cell death associated with choreic movements and dementia. On April 24, 2007, we announced top line results from two Phase III studies with AMR101 in HD. Study data showed no statistically significant difference in either study between AMR101 and placebo with regard to the primary and secondary endpoints at 6 months of treatment. These top-line findings were inconsistent with data from an earlier 12-month 135 patient clinical trial.

However, on November 19, 2007, Amarin announced that analysis of a comprehensive review of the 12-month data from the U.S. Phase III study showed a statistically significant difference in TMS-4 between the long term AMR101 group (12-month treatment) and those patients who had switched to AMR101 at 6-months.

In November 2007, we met with the FDA following the completion of the comprehensive review of all clinical data for AMR101 in HD. The FDA indicated that one additional Phase III trial demonstrating robust results, in conjunction with the confirmatory evidence from the existing clinical data, may be sufficient clinical data to support a New Drug Application.

We have also submitted the comprehensive review of all clinical data for AMR101 in HD to EMEA and discussions are ongoing regarding next steps.

EN101

EN101 is an orally available antisense oligonucleotide, specifically targeting the “read-through” or “R” isoform (“AChE-R”) of acetylcholinesterase (“AChE”). The molecule suppresses the production of the AChE-R protein without the negative cholinergic effects currently observed with conventional inhibitors.

Myasthenia gravis, a debilitating neuromuscular disease, is the first target indication for which EN101 is undergoing clinical development. A Phase Ib clinical trial was conducted by Ester in 2002 to assess the safety, efficacy and pharmacokinetics of oral EN101 in MG patients. In 2004, Ester commenced a Phase IIa dose finding study in MG patients. Interim analysis from this study was announced in May 2007. Based on the results of the Phase IIa interim analysis, and the results of the Phase Ib study, EN101 appears to have a more favorable safety and efficacy profile, as well as a more favorable dosing regimen compared to the current standard of care, Mestinon (pyridostigmine).

We plan to complete the Phase IIa study and other non-clinical studies before progressing to a larger clinical study.

Sublingual Apomorphine for Parkinson’s Disease

Our novel sublingual (under the tongue) formulation of Apomorphine aims to achieve rapid absorption directly into the bloodstream after sublingual administration. Apomorphine is a particularly effective for the treatment of “off” episodes in Parkinson’s disease patients. This novel formulation would offer patients a more user friendly alternative to the currently available injectable formulation of Apomorphine and we believe, could result in higher rates of

utilization.

The oral bioavailability of our novel sublingual formulation had initially been demonstrated by us in a proof of concept study in human volunteers, while also showing it to being well tolerated. We subsequently progressed it through further Phase I pharmacokinetic studies and the lead formulation has now been selected for optimization in a final pharmacokinetic study.

Nasal Lorazepam

Our novel, nasal formulation of lorazepam is in development for the out-patient treatment of emergency seizures in epilepsy patients. The only treatment currently approved by the FDA for seizure emergencies in the out-patient setting is a rectal gel formulation of the drug diazepam. Diazepam gel's use is limited by its rectal route of administration.

In early 2008, we announced the successful completion of an initial pre-clinical proof of concept study with the novel formulation. The data generated supports its further development as an out-patient treatment of emergency seizures.

AMR101 for AAMI

Following on from positive preclinical results with AMR101 in memory and cognition, in January 2008 we commenced a Phase IIa trial with AMR101 in Age Associated Memory Impairment ("AAMI"). The trial - randomized, double-blinded, and placebo-controlled - will enrol 96 patient volunteers with AAMI. Three dose strengths of AMR101 (1g, 2g, 4g) will be tested versus placebo using a computer-derived cognitive batch of tests. Initial results from the study are anticipated in the second half of 2008.

Targeted Lipid Transport Technology ("TLT") Platform (previously Combinatorial Lipids)

We have researched and patented how to use different types of chemical linkage to attach a range of bioactive lipids either to other lipids or other drugs. The results are novel single chemical entities with predictable properties, potentially offering substantial and clinically relevant advantages over either compound alone.

This technology has application across a broad range of therapeutic areas including CNS, cardiovascular, gastrointestinal and oncology. AMR103, a novel form of levodopa in pre-clinical development for Parkinson's disease, is our lead candidate utilizing this technology.

Cholinergic Modulation and Inflammation

Ester, which was acquired by us in December 2007, also has a platform messenger RNA ("mRNA") silencing technology based on novel and proprietary discoveries in the field of AChE, developed by Professor Hermona Soreq of the Hebrew University of Jerusalem.

Ester's technology platform exhibits anti-inflammatory effects, including an indirect inhibitory effect on key pro-inflammatory cytokines via modulation of AChE-R, as well as a direct anti-inflammatory effect via modulation of macrophage activity mediated by interaction with the toll-like receptor or TLR signalling pathway.

Our Marketing Partners

AMR101 for HD has been partnered in the major E.U. markets with Scil Biomedical GmbH, Juste S.A.Q.F. and Archimedes Pharma Ltd.

Additionally, we are party to a license agreement dated July 21, 2003 with a marketing partner in Japan to develop, use, offer to sell, sell and distribute products in Japan utilizing certain of our intellectual property in the pharmaceutical fields of HD, depression, schizophrenia, dementia and certain less significant indications (by patient population) including the ataxias, for a period of 10 years from the date of first commercial sale or, if later, until patent protection expires.

In December 2005, Amarin Neuroscience entered into a worldwide exclusive license with Multicell Technologies, Inc. ("Multicell") pursuant to which Amarin Neuroscience licensed the worldwide rights for MCT-125 to Multicell in return for a series of development based milestones and a royalty on net sales. Multicell is obliged to use reasonable good faith efforts to develop and commercialize MCT-125. Multicell is currently planning a Phase IIb trial with MCT-125 in the treatment of fatigue in patients suffering from MS.

The Financial Year

We had no revenues in 2007. Our consolidated revenues in 2006 comprise milestone payments received from Multicell and were derived from the licensing of exclusive, worldwide rights to Multicell for MCT-125 (formerly LAX-202).

For the year ended December 31, 2006, all revenues originated in the United Kingdom. No revenues were generated from licensing, development or contract manufacturing fees.

At present all of our products are in the development stage and we therefore have no products that can be marketed.

Competition

In pursuing our strategy of acquiring marketable and/or development stage neurology products, we expect to compete with other pharmaceutical companies for product and product line acquisitions, and more broadly for the distribution and marketing of pharmaceutical and consumer products. These anticipated competitors include companies which may also seek to acquire branded or development stage pharmaceutical products and product lines from other pharmaceutical companies. Most of our potential competitors will likely possess substantially greater financial, technical, marketing and other resources. In addition, we will compete for supplier manufacturing capacity with other companies, including those whose products are competing with ours. Additionally, our future products may be subject to competition from products with similar qualities. See Item 3 "Key Information — Risk Factors — Our future products may not be able to compete effectively against those of our competitors."

Government Regulation

Any product development activities relative 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 are generated in two distinct development stages: pre-clinical and clinical. 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. Good laboratory practice requirements must be followed in order for the resulting data to be considered valid and reliable. For established molecules this stage can be limited to formulation and manufacturing process development and in vitro studies to support subsequent clinical evaluation.

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. Studies in volunteers are

also undertaken to begin assessing the pharmacokinetics of the drug (e.g. the way in which the body deals with the compound from absorption, to distribution in tissues, to elimination).

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 from a number of different sites, which may be in one country or in several different countries or continents. Such trials are designed to provide the pivotal data necessary to establish the effectiveness of the product for its intended use, and its safety in use, and typically 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.

Prior to the start of human clinical studies of a new drug in the United States or, generally, for submission in support of a U.S. marketing application, an investigational new drug application, or IND, is filed with the FDA. Similar notifications are required in other countries. The amount of data that must be supplied in the IND application depends on the phase of the study. Earlier investigations, such as Phase I studies, typically require less data than the larger and longer-term studies in Phase III. A clinical plan must be submitted to the FDA prior to commencement of a clinical trial. In general, studies may begin in the U.S. without specific approval by the FDA 30-days after submission of the IND. However, the FDA may prevent studies from moving forward, and may suspend or terminate studies once initiated. Regular reporting of study progress and adverse experiences is required. During the testing phases, meetings can be held with the FDA to discuss progress and future requirements for the NDA. Studies are also subject to review by independent institutional review boards responsible for overseeing studies at particular sites and protecting human research study subjects. An independent institutional review board may prevent a study from beginning or suspend or terminate a study once initiated. Studies must also be conducted and monitored in accordance with good clinical practice and other requirements.

Following the completion of clinical trials, the data must be thoroughly analyzed to determine if the clinical trials successfully demonstrate safety and efficacy. If they do the data can be 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. In the US, FDA approval of an NDA must be obtained before marketing a developed product. The NDA must contain proof of safety, purity, potency and efficacy, which entails extensive pre-clinical and clinical testing.

Although the type of testing and studies required by the FDA do not differ significantly from those of other countries, the amount of detail required by the FDA can be more extensive. In addition, it is likely that the FDA will re-analyze the clinical data, which could result in extensive discussions between us and the licensing authority during the review process. The processing of applications by the FDA is extensive and time consuming and may take several years to complete. The FDA's goal generally is to review and make a recommendation for approval of a new drug within ten months, and of a new "priority" drug within six months, although final FDA action on the NDA can take substantially longer, may entail requests for new data and/or data analysis, and may involve review and recommendations by an independent FDA advisory committee. 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 act favorably or quickly in making such reviews and significant difficulties or costs may be encountered by the Group in its efforts to obtain FDA approvals. The FDA may also 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 if compliance with regulatory standards is not maintained or if problems occur following initial marketing.

In the European Union, our future products may also be subject to extensive regulatory requirements. As in the U.S., the marketing of medicinal products has for many years 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.

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

In the European Union, approval of new medicinal products can be obtained through one of three processes. The first such process is known as the mutual recognition procedure. An applicant submits an application in one European Union member state, known as the reference member state. Once the reference member state has granted the marketing authorization, the applicant may choose to submit applications in other concerned member states, requesting them to mutually recognize the marketing authorizations already granted. Under this mutual recognition process, authorities in other concerned member states have 55 days to raise objections, which must then be resolved by discussions among the concerned member states, the reference member state and the app