

AMARIN CORP PLC\UK  
Form 20-F/A  
October 17, 2005

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 20-F/A**

**(Amendment No. 1)**

- o **REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR  
12(g) OF THE SECURITIES EXCHANGE ACT OF 1934**  
OR
- ý **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934  
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2004**  
OR
- o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF  
THE SECURITIES EXCHANGE ACT OF 1934**  
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

FOR THE TRANSITION PERIOD FROM TO

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)

**7 Curzon Street  
London W1J 5HG  
England**

(Address of Principal Executive Offices)

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

	<b>Title of Each Class</b>	<b>Name of Each Exchange On Which Registered</b>
<i>None</i>		<i>None</i>

**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.

**37,632,123 Ordinary Shares, 5 pence par value per share**

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

YES  NO

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

ITEM 17  ITEM 18

### **Explanatory Note**

This Amendment No. 1 (this Amendment) to Amarin Corporation plc's (Amarin) Annual Report on Form 20-F for the fiscal year ended December 31, 2004 (the 2004 Form 20-F) is being filed solely to amend Item 5. The 2004 Form 20-F was originally filed with the U.S. Securities and Exchange Commission (the SEC) on April 1, 2005. This Amendment provides, additional, expanded disclosure in Item 5 regarding in-process research and development costs arising as part of the October 2004 acquisition of Amarin Neuroscience Limited (formerly Laxdale Limited).

This Amendment consists of a cover page, this explanatory note, the complete text of Item 5, as amended, the signature page and the required certifications of the Chief Executive Officer and the Chief Financial Officer of Amarin. Other than the amendments described above, no changes have been made to Item 5 or to any other Items to the Form 20-F as originally filed. This Amendment continues to speak as of the date of the original filing of the Form 20-F and, except as described above, does not purport to amend or update the information contained in the Form 20-F filed on April 1, 2005, or reflect any events that have occurred after the Form 20-F was filed.

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## Item 5 Operating and Financial Review and Prospects

### A. Operating Results

The following discussion of operating results should be read in conjunction with our selected financial information set forth in Item 3 Key Information Selected Financial Data and our consolidated financial statements and notes thereto beginning on page F-1 of this annual report.

#### Comparison of Fiscal Years Ended December 31, 2004 and December 31, 2003

##### Overview

2004 was a significant year for Amarin. The Company is now a neuroscience company focused on the research, development and commercialization of novel drugs for central nervous system disorders. This was achieved through the execution of a series of transactions including the sale of our US sales and marketing operations, the settlement of our outstanding debt obligations and the acquisition of Laxdale, our former research and development partner. In addition, our non-executive chairman, Mr. Thomas Lynch, acquired all of Elan's equity and debt interests in Amarin, thereby becoming Amarin's largest shareholder, with a current equity stake of approximately 20%. In October, we further strengthened our financial position by completing a \$12.775 million private placement of equity.

In 2003 and early 2004, our former US operations were incurring substantial operating losses due to the introduction of generic competition to Permax in December 2002. Also, in early 2004, we were faced with debt of \$31.5 million due on demand to Elan. In the first quarter of 2004, we divested the majority of our U.S. operations through the sale of Amarin Pharmaceuticals Inc. together with our rights to Permax, our primary care portfolio and the development product Zelapar (these divested assets are collectively referred to in this Item 5 Operating and Financial Review and Prospects as API). The purchaser was Valeant Pharmaceutical International, Inc (Valeant) and the upfront proceeds from the sale were \$38 million in cash. This divestiture to Valeant eliminated the substantial operating losses being incurred by API in the U.S and enabled Amarin to simultaneously settle its debt obligations with Elan and retain the U.S sales and marketing rights to Miraxion for Huntington's disease.

Having completed the sale of API and retained the U.S. sales and marketing rights to Miraxion for Huntington's disease, we were still dependent on our research and development partner, Laxdale, to successfully manage the development and regulatory processes for Miraxion. In addition, in the event of Miraxion's approval in the U.S. for Huntington's disease we would have been obliged to pay Laxdale a royalty of 40-45% of net sales.

Thus, in October 2004, we acquired Laxdale, our neuroscience research and development partner and the originator of Miraxion. This represented an important step towards achieving our newly stated goal of becoming a leader in the research, development and commercialization of novel drugs for the treatment of central nervous system (CNS) disorders. In addition to providing us with control of the clinical development and regulatory processes for Miraxion and eliminating the royalty to Laxdale of 40-45%, the acquisition broadened our development pipeline to include North American, E.U. and Japanese rights to Miraxion for all CNS disorders, including Huntington's disease and treatment-unresponsive depression. It also provided Amarin with an extensive portfolio of intellectual property in the area of CNS. For further details on the Laxdale acquisition see Recent Developments Laxdale Acquisition.

On October 1, 2004 Mr. Thomas Lynch, our non-executive chairman, signed an agreement with Elan to purchase the following securities in Amarin from Elan Corporation, plc and its subsidiaries:

4,653,819 Amarin American Depositary Shares representing, at that time, an approximate 25.9% shareholding on an undiluted basis;

Warrants to subscribe for 500,000 Amarin Ordinary Shares at an exercise price of US\$1.90 per share; and

US\$5 million in principal amount of Amarin Secured 8% Loan Note, issued pursuant to a loan note instrument dated February 25, 2004.

The board of Amarin reviewed and approved the transaction after consultation with its advisers. On October 7, 2004 Mr. Lynch agreed to convert \$3 million of the \$5 million loan notes into 2,717,391 ordinary shares with an option to convert the remaining \$2 million at the offering price of any future equity financing. Amarin's total debt was thus reduced to, and is currently at, \$2 million with a maturity in 2009, if not previously converted.

Also, on October 7, 2004, we further strengthened our financial position by completing a private placement of 13,474,945 ordinary shares raising gross proceeds for Amarin of \$12.775 million with a group of new and existing investors and management.

Since the acquisition of Laxdale and the completion of the private placement of equity in October, Amarin has been preparing for the commencement of two phase III trials with Miraxion in Huntington's disease. Substantial progress has been made and the trials are due to begin late in the second quarter of this year, subject to FDA agreement to the clinical trial protocol.

Miraxion is also in phase II clinical development for treatment-unresponsive depression. In the first quarter of 2005, Amarin announced that a program of data analysis was carried out on three phase IIa studies, using Miraxion to treat depression. The analysis identified that Miraxion showed a significant clinical benefit in each of the three studies for those depression patients with melancholic characteristics as defined by using select criteria from DSM IV (Diagnostic and Statistical Manual of Mental Disorders-Fourth Edition). As a result of these encouraging clinical trial results, Amarin intends to further evaluate the clinical benefits of Miraxion in depression and is seeking a development and marketing partner for the U.S. and E.U. markets to accelerate this program. Amarin has already partnered its intellectual property for this indication in the Japanese market.

Amarin reported net income in 2004, including discontinued activities, of \$4.7 million, compared with a net loss of \$19.3 million in 2003 and \$37.2 million in 2002. The operating losses for the years ended December 31, 2004, 2003 and 2002 are analyzed in note 4 to the financial statements between continuing and discontinued activities. Amarin's results for the year ended December 31, 2004 include the results of Laxdale from October 8, 2004, being the closing date of the acquisition, thereby increasing our operating expenses by approximately \$2.2 million (excluding the non recurring payment of \$0.9 million discussed below) during the year ended December 31, 2004 as explained below.

### *Continuing Operations*

#### Revenue

After the disposal of API and the acquisition of Laxdale, our remaining business comprises primarily a corporate head office in London, and a neuroscience research and development subsidiary based in Stirling, Scotland with products in late stage development. Revenues in 2004, 2003 and 2002 entirely relate to our two divested businesses, API and ADAB, and have been classified as discontinued activities. In 2005, Amarin's only revenue, if any, will be from earning up front license fees from partnering its development pipeline, such as a license of Miraxion for depression.

#### Operating Expenses

Total operating expenses for the continuing business were \$9.9 million compared to \$6.2 million in 2003 and \$6.1 million in 2002, an increase of approximately 59.68% and 62.30% respectively, and comprised primarily selling, general and administrative expenses of \$8.3 million and research and development expenditure of \$1.0 million and amortization of product rights of \$0.6 million. The increase was primarily due to the inclusion of Laxdale's operating expenses in the fourth quarter of 2004 of \$2.2 million (comprising research and development expenses of \$1.0 million, selling, general and administration of \$1.1 million and amortization of \$0.1 million), together with the inclusion of the non-recurring

payment of \$0.9 million to Scarista Limited to reduce future royalty rates and the high level of professional fees incurred due to the significant amount of corporate activity during the year.

Amarin is preparing to commence two phase III trials with Miraxion in Huntington's disease late in the second quarter of 2005. Amarin intends to utilize the data from these trials to support an application for marketing approval to the FDA and EMEA. In Europe, prior to its acquisition by Amarin, Laxdale submitted a marketing approval application based upon the initial phase III study to EMEA. Amarin voluntarily withdrew that application and plans to re-submit when data from the two planned phase III trials is available. The conduct of these two phase III trials through 2005 and 2006 will result in our research and development expenditure increasing significantly when compared to levels incurred in previous years.

#### Amortization

Amortization attributable to continuing operations relates to Miraxion and is included in selling, general and administrative expenses. During November 2000, Amarin acquired limited rights to Miraxion as a licensee. On the date of acquiring Laxdale, the intangible fixed asset had a net book value of approximately \$3.6 million. The Laxdale acquisition gave rise to the recognition of a further intangible fixed asset, representing intellectual property rights, relating to Miraxion (formerly known as Lax-101) and other intellectual property valued at \$6.9 million. The useful economic life remaining for the November 2000 intangible fixed asset and the intangible acquired on purchase of Laxdale has been determined as 15.5 years, representing the time to patent expiry. The effect of this is a decrease in the amortization charge for the year of \$79,000 on the intangible fixed asset purchased in November 2000.

#### Foreign exchange

Amarin holds cash in pounds sterling, US dollars and Euro. In 2004, continuing operations gained \$0.4 million arising from holding pounds sterling as the US dollar weakened. Offsetting this gain was a \$0.3 million loss arising on the translation into US dollars of the operating results of our research and development subsidiary, Laxdale, whose functional currency is pounds sterling.

#### *Discontinued Operations*

For the year ended December 31, 2004, the Company earned an operating loss of \$1.2 million on discontinued activities compared with an operating loss of \$32.6 million for 2003 and \$26.5 million in 2002. The operating loss from discontinued activities for 2004 reflects:

the results of Amarin's former U.S. operations that were sold to Valeant in February 2004 as described above;

the research and development costs incurred by Amarin in 2004 relating to the completion of safety studies on Zelapar (the rights to which are owned by Valeant). Following the sale of the majority of Amarin's U.S. operations to Valeant in the first quarter of 2004, Amarin remained responsible for the cost of undertaking safety studies on Zelapar and was liable for up to \$2.5 million of development costs. That obligation has been fulfilled and Amarin will not incur any more costs relating to the development of Zelapar; and

the settlement of an outstanding dispute with Valeant. In September 2004, Amarin reached agreement with Valeant to settle a dispute following the disposal of our US operations and certain product rights. It was agreed that a \$3 million payment (which was contingent upon completion of the Zelapar safety studies) would be reduced to \$2 million and paid to Amarin, unconditionally on November 30, 2004 of which \$1 million was paid to Elan. Amarin also agreed to waive rights to future milestone payments from Valeant of \$3,000,000 (due on successful completion of Zelapar safety studies) and \$5,000,000 (due on approval by the US Food and Drug Administration).



In addition, three exceptional items relating to discontinued activities arose in 2004 as follows:

an exceptional loss of \$3.1 million on disposal of the majority of the U.S. operations and certain products to Valeant;

an exceptional gain of \$0.75 million, representing receipt of the final installments of the sale proceeds from the disposal of Amarin's Swedish drug delivery business to Watson in October 2003; and

an exceptional gain of \$24.6 million on the settlement of debt obligations to Elan.

#### Revenue

Discontinued Revenues in 2004 were \$1.0 million compared with \$7.4 million for 2003, a decline of \$6.4 million or 86% and \$65.4 million in 2002. The decrease was largely due to API only being included in 2004 from January 1 to February 25, being the date of its disposal. API was included for the full years of 2003 and 2002. In addition, discontinued revenues in 2003 and 2002 included the revenues from our Swedish drug delivery business up to October 28, 2003, the date of its disposal.

Also, 2003 revenue reflects exceptional charges, relating to turnover comprising \$10,624,000 relating to product returns and sales deductions. The exceptional charges arose because of the level of in-market inventories coupled with a sharp decline in 2003 demand when compared to 2002 because of generic competition.

In 2004, all of our revenue was attributable to discontinued operations. In 2003, 54% of revenue was attributable to one customer and the next four largest customers accounted for an additional 36% of our revenue.

## Gross Margin

The gross margin for 2004 from discontinued business was a profit of \$0.9 million compared to a loss of \$4.5 million for 2003 and a profit of \$35.3 million in 2002. The 2003 loss was the result of charges of \$4,518,000 in respect of Permax inventory write-offs because of the deterioration in sales following the launch of a generic competitor in December 2002 and inventory losses of \$762,000 on the primary care line of products because of deteriorating sales and high in-market inventories. Offsetting these charges was a \$600,000 reduction in Permax royalty relating to the exceptional reductions in revenues.

Prior to these charges in 2003 (both against revenue and in inventory provisions), the gross margin increased to 89% in 2004 of sales from 60% in 2003, due to the accounting adjustments prior to the conclusion of the disposal of API to Valeant.

## Operating Expenses

In 2004, expenses for discontinued operations include selling, general and administrative expenses of \$1.6 million being costs originated in API prior to disposal, research and development expenses of \$2.5 million representing our obligations to fund Zelapar safety studies as part of the disposal of API to Valeant, and \$2 million of other income associated with the settlement of our dispute with Valeant. Selling, general and administrative expenses from discontinued activities decreased to \$1.6 million in 2004 from \$15.1 million in 2003 and \$18.1 million in 2002. The decrease is primarily due to the disposal of API and ADAB in February 2004 and October 2003 respectively. Research and development expenditure on discontinued operations decreased to \$2.5 million or by 54% in 2004 from \$5.4 million in 2003 and \$6.2 million in 2002. The \$2.5 million in 2004 reflects the costs incurred by Amarin on Zelapar as explained above. Research and development expenses in 2003 and 2002, reflect the research and development costs incurred with respect to our US operations and Swedish drug delivery business prior to their disposal.

## Amortization

Amortization of Permax and the Primary Care Portfolio is included in selling, general and administrative expenses. Amortization expenditure during 2004 was \$nil in 2004, as both were impaired down to their net realized values, at 31 December 2003, using the disposal proceeds values arising from the 25 February 2004 disposal to Valeant. The amortization charge was \$4.9 million in 2003 and \$6.8 million in 2002.

## *Interest and Similar Income and Interest and Similar Expense*

Net interest income for 2004 was \$0.22 million compared to net interest expense of \$0.84 million for 2003 and \$2.0 million in 2002. The 2004 net income comprises interest and similar income of \$0.55 million (compared to \$0.07 million in 2003 and \$0.4 million in 2002), which was earned from cash balances held on deposit and on the loan made to Laxdale prior to its acquisition, and interest expense and similar charges of \$0.33 million (compared to \$0.9 million in 2003 and \$2.4 million in 2002). The interest expense arises on the loan from Elan (which was subsequently assigned to Mr. Thomas Lynch), as explained in more detail below in Liquidity and Capital Resources. The increase in net interest income is primarily due to Amarin having lower interest bearing debt during 2004 compared to 2003 and 2002 and a foreign exchange gain of \$0.4 million arising on cash balances during 2004. Following the reduction of debt in 2002 and 2003, on February 25, 2004, the outstanding principal amount was reduced further to \$5 million. As discussed above, this debt (loan notes) of \$5 million in favor of Elan was purchased by

Mr. Lynch. This reduction was subsequently followed by the conversion of \$3 million of the loan notes into equity, leaving \$2 million of debt outstanding from October 7, 2004 onwards.

***Taxation***

A non-cash deferred tax accounting charge of \$7.5 million on the exceptional gain on the settlement of debt obligations to Elan is included in the tax charge for the year ended December 31, 2004. This offsets a deferred tax credit of an equivalent amount included in the income statement of the fourth quarter of 2003. The tax charge of \$3.5 million in 2002 includes \$2.6 million in relation to corporation tax on a capital gain incurred on the disposal of assets in a discontinued business which took place during the 1999 fiscal year.

***Preference Share Dividend***

During 2003, the last remaining 2,000,000 3% convertible preference shares held by Elan were converted into 2,000,000 ordinary shares and non-equity dividends of \$24,000 were accrued. On conversion, Elan gave up their preferential rights, including rights to an accrued dividend, in exchange for the new ordinary shares allocated. In February 2004, Amarin settled its debt obligations with Elan by the payment of cash and the issue of a \$5 million loan note. As a result, with there being no longer a need to maintain an accrual for a preference dividend in 2004, Amarin released the accrued preference share dividends of \$643,000.

## Comparison of Fiscal Years Ended December 31, 2003 and December 31, 2002

### Overview

In 2003 we saw strong competition to Permax, our leading product at the time, from both other dopamine agonists and generic competition that entered the market in December 2002. In addition, as disclosed in our annual report on Form 20-F for the year ended December 31, 2002, we ended 2002 with high wholesaler inventory levels for all of our US products and experienced low revenues during 2003 as in-market inventory levels at the end of 2003 declined. These factors resulted in significant losses in 2003 and significant net cash outflow.

This deterioration in our trading during 2003 meant that we were unable to generate sufficient cash flows from operations to meet our debt obligations. To address our debt obligations we divested most of our operations through two transactions, one in 2003 and the other shortly after the year-end. The first of these transactions was the sale of Amarin Development AB ( ADAB ) on October 28, 2003. The second was the sale of API on February 25, 2004.

In accordance with UK GAAP, the results of both businesses divested were shown as discontinued for 2004 and for the comparative years ended December 31, 2003 and 2002.

### Revenue

After the disposals of ADAB and API, our remaining business comprised a corporate head office and US rights to Miraxion for Huntington's Disease, which was then owned by Laxdale Limited. Accordingly, our continuing operations did not generate any revenues in 2003 or 2002.

### Operating Expenses

Total operating expenses for the continuing business were \$6.2 million in 2003 compared to \$6.1 million in 2002, an increase of 2%, and comprised selling, general and administrative expenses of \$5,624,000 in 2003 (\$5,554,000 in 2002) and amortization of product rights of \$576,000 in both 2003 and 2002.

### Interest Income and Interest Expense

Net interest expense for 2003 was \$0.8 million compared to \$2.0 million for 2002. The 2003 net charge comprises Interest Income of \$0.1 million (compared to \$0.4 million in 2002), which was entirely earned from cash balances held on deposit, and Interest Expense of \$0.9 million (compared to \$2.4 million in 2002). The Interest Expense for 2003 arose on the \$25 million interest bearing loan from Elan. The 2002 comparative included a provision of \$0.5 million for interest on a capital gains tax liability in relation to the disposal of assets in a discontinued

business in 1999. The reduction in Net Interest Expense is primarily due to lower average interest bearing debt during 2003 compared to 2002 following the January 2003 \$17.5 million partial loan repayment to Elan.

#### Discontinued Operations

As explained above, discontinued operations include the results of API for the whole of 2003 and of ADAB for the period through to its sale on October 28, 2003.

Discontinued Revenues in 2003 were \$7.3 million compared with \$65.4 million for 2002, a decline of \$58.1 million or 89%.

Revenues for 2003 were impacted by a number of factors in addition to underlying trading changes. The key factors were:

Charges for Permax returns and in-market inventory risks as a result of generic competition and high in-market inventory levels of \$9.0 million;

Charges for returns on the Primary Care Portfolio of \$1.6 million; and

The inclusion of ADAB through October 28 2003 compared to the full year 2002 a reduction in Revenue of \$2.2 million.

Taking into account these factors, revenues from discontinued operations declined by \$45.3 million.

For 2003, Permax net revenues were negative \$2.4 million because of the returns charges, and net revenues prior to these charges

were \$6.6 million. This compares to \$41.3 million of Permax revenues in 2002. At the end of 2002, wholesale customers held significant inventories of Permax and with the decline in demand due to competition did not require us to make further sales throughout 2003. In-market inventory levels at the end of 2003 remained high in number of months forward coverage due to the reduction in monthly in-market demand.

In-market total Permax prescriptions fell to 68,815 in the year to December 31, 2003 from 160,469 in the prior year, a decline of 57%. Consistent with the trend seen in 2002, according to external industry data, total prescriptions for the dopamine agonist market in which Permax competes continued to grow and were up 14% to 1.6 million in the year to December 31, 2003. We attribute the decline in prescriptions of Permax to greater sales and marketing resources dedicated to competing dopamine agonists, the introduction of a competitive generic product and labeling safety disadvantages of Permax. At the end of 2003, based on an externally sourced report, wholesalers and similar customers held approximately 7.1 months supply at the end of 2003 (based on December 2003 in-market demand) compared to 5.1 months (based on December 2002 in-market demand) at the end of 2002. Externally sourced inventory information is not readily available and when available is not necessarily accurate or verifiable.

The primary care portfolio generated \$5.0 million of revenue in 2003, compared to \$16.3 million in 2002. The decline was due to an exceptional returns provision for excess inventory at one customer of \$1.6 million (see above) and wholesaler inventory changes. Wholesaler inventory levels had risen during 2002 in response to discounts that we offered. Management believed that the resulting levels of inventory held by wholesalers at the start of 2003 were too high and an inventory reduction program was initiated, including the moderation of previous discounting practices.

The Phrenilin family of products generated revenues of \$2.1 million in 2003, compared to \$6.9 million in 2002. In-market total prescriptions for the Phrenilin family declined 19% in the year ended December 31, 2003 compared to the prior year. According to external industry data, the butalbital market in which Phrenilin competes declined 36% over the same period. Bontril generated revenues of \$3.3 million in 2003 compared to \$5.8 million in 2002 and in market its total prescriptions declined 9% in 2003, again compared to 2002. According to external industry data, total prescriptions of the anti-obesity market in which Bontril competes declined 16% over the same period. Motofen generated revenues of \$0.7 million in 2003 compared to \$1.4 million in 2002 and its total prescriptions were down 10% in the same period. This 10% reduction in prescriptions for Motofen was due to management's decision to reduce marketing expenditure in response to financial constraints.

We had only limited information on in-market inventory levels for our primary care portfolio. Information available for Bontril indicated that wholesalers and similar customers held approximately 8.5 months supply at the end of 2003 (based on December 2003 in-market demand), the same number of months (based on December 2002 in-market demand) as for 2002.

In 2003, 54% of our revenue was attributable to one customer, compared to 23% in 2002, and the next four largest customers accounted for an additional 36% of our revenue, compared to 56% in 2002.

The gross margin for 2003 from discontinued business was a loss of \$4.5 million compared to a profit of \$35.3 million for 2002. The 2003 loss was a result of the charges against revenue explained above plus the charges for inventory provisions of \$5.3 million relating to Permax and Primary Care in-house inventory that was projected to expire prior to its sale, offsetting these charges are \$0.6 million reduction in Permax royalty payments relating to the exceptional reductions in revenues. The 2002 gross margin included a \$4.7 million charge relating to the withdrawal of Phrenilin with Caffeine and Codeine in that year.

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Prior to these charges (both against revenue and in inventory provisions for 2003 and 2002), the gross margin decreased to 60% of sales from to 61% in 2002. The slight decrease is a result of product mix offset by management's decision not to offer similar levels of discounts to customers as were offered in 2002.

Included in the 2003 selling, general and administrative expenses attributable to discontinued operations were impairment charges of \$10.1 million relating to the write down of the intangible assets of Permax (\$9.4 million) and the primary care portfolio (\$0.7 million). This compares to \$38.8 million in 2002 related to Permax (\$38.3 million) and Moraxen (\$0.5 million). The 2003 impairment charges were made to reflect the actual net realizable value under the Valeant sale post year-end. The 2002 Permax impairment charge arose as a result of the launch of a generic form of Permax in the last quarter of 2002.

Included in total operating expenses for 2003 was \$0.1 million in royalties and distribution fees to Elan for sales of Permax, as compared to \$1.4 million in royalties and distribution fees to Elan for Permax sales in 2002.

As disclosed in our Annual Report on Form 20-F for the year ended December 31, 2002, in January 2003 we agreed a reduction in our deferred consideration obligations to Elan relating to our purchase of Permax. This resulted in a gain of \$7.5 million that was reflected as a credit in operating expenses attributable to discontinued operations.

The 2002 results included a \$0.5 million provision for the closure of the New Jersey facility, which took place during 2002 and a gain of \$1.1 million on the release of a provision related to transdermal contracts that were sold in 1999 and as to which potential liabilities were no longer anticipated to crystallize.

Amortization of Permax and the Primary Care Portfolio which were included in selling, general and administrative expenses attributable to discontinued operations, decreased to \$4.9 million in 2003 from \$6.8 million in 2002. The reduction in amortization charge in 2003 arose because of the impairment to the Permax intangible asset carrying value at the end of 2002.

Included in the selling, general and administrative expenses in 2002 was a foreign exchange gain of \$8.1 million (no gain or loss in 2003). The exchange gain resulted from translating dollar denominated balance sheet amounts into pounds sterling at the prevailing exchange rates. As of January 1, 2003 we changed our functional currency from pounds sterling to US dollars, which eliminated the effect of foreign exchange rates on US dollar amounts from that date forward. Our foreign currency net investments were not hedged by currency borrowings or other hedging instruments.

Research and development expenditure on discontinued operations decreased 12% in 2003 to \$5.4 million. This decrease was largely driven by the inclusion of ADAB only for approximately 10 months in 2003 compared to 12 months for 2002.

A gain of \$13.1 million arose on the sale of ADAB to Watson in 2003 and was disclosed in disposal of operations and was attributable to discontinued operations.

## **Taxation**

In 2003, a deferred tax asset of \$7.5 million was recognized on the excess of tax book values compared to accounting carrying values for Permax. A deferred tax asset on part of the timing differences was recognized to the extent that it was realized in 2004 to shelter a gain arising on the settlement of Elan debt obligations. Establishing this deferred tax asset gave rise to a tax credit of \$7.5 million in 2003, being the substantial portion of the 2003 tax credit of \$7.4 million. Included in the 2002 tax on profit on ordinary activities of \$3.5 million is a provision of \$2.6 million in relation to corporate tax on a capital gain incurred on the disposal of assets in a discontinued business which took place during the 1999 fiscal year.

## **Critical Accounting Policies**

Our significant accounting policies are described in Note 2 to the consolidated financial statements beginning on page F-1 of this annual report. As discussed above we disposed of ADAB in October 2003 and certain product lines and API in February 2004. This facilitated the settlement of our debt obligations owed to Elan. Following our acquisition of Laxdale, the Company is now a neuroscience company focused on the research, development and commercialization of novel drugs for central nervous system disorders. As such, our key asset is our research and development pipeline and the related intellectual property portfolio, which is classified under intangible assets. Our main source of funds until such time as the products under development receive regulatory approval for marketing will be from equity based financings and license fees (upfront and milestone fees) from partnering our drug



development pipeline. As such we consider our most critical accounting policies to be those relating to intangible assets and specifically the treatment of research and development expenditure, together with our accounting policy relating to revenue recognition and specifically the treatment of upfront fees and milestones. Both critical accounting policies are considered customary within research and development companies in the pharmaceuticals industry.

#### Intangible Assets

Under UK GAAP intangible fixed assets are recognized when they meet the definitions set out in accounting standards. FRS 7 Fair values in acquisition accounting refers to separability (where items can be disposed of separately from the company as a whole) and control (e.g. via custody or legal/contractual rights). FRS 10 Goodwill and intangible assets refers to reliable measurement. We have applied these standards to the acquisition of Amarin Neuroscience Limited (see note 3 to this Form 20-F annual report) such that the value of the intangible fixed asset recognized, as supported by risk adjusted discounted cashflow analysis, is capped to ensure negative goodwill does not arise.

UK GAAP requires that we periodically evaluate acquired assets for potential impairment indicators. Our judgments regarding the existence of impairment indicators are based on legal factors, market conditions, operational performance and expected cash flows from the assets. Since indications of impairments can result from events outside of our control, it can be difficult to predict when an impairment loss may occur. However, should an impairment occur, we would be required to write down the carrying value of the affected asset to its recoverable amount and to recognize a corresponding charge to the income statement. Any such impairment may

have a material adverse impact on our financial condition and results of operations.

When we acquire a development product, as required under UK GAAP, amounts paid are capitalized and amortized over the estimated life of that asset. If the intangible asset is a marketed product, the amount capitalized is reviewed for impairment by comparing the net present value of future cash flows to the carrying value of the asset.

Under U.S GAAP long-lived assets chiefly relate to amounts capitalized in connection with acquired intangible assets. These assets are amortized over their estimated useful lives, which generally range from ten to fifteen years. Management periodically reviews the appropriateness of the remaining useful lives of its long-lived assets in the context of current and expected future market conditions. In the event that we are required to reduce our estimate of the useful lives of any of our long-lived assets, it would shorten the period over which we amortize the affected asset and may result in a material increase of amortization expense prospectively from the date of the change in estimate.

#### Overview of UK and US GAAP difference

Under UK GAAP pharmaceutical products which are in the clinical trials phase of development can be capitalized and amortized where there is a sufficient likelihood of future economic benefit. Under US GAAP specific guidance relating to pharmaceutical products in the development phase requires such amounts to be expensed unless they have attained certain regulatory milestones.

#### Revenue Recognition

Prior to the sale of our US business in February 2004 we derived the majority of our revenues from the sale of pharmaceutical products. Under UK GAAP, we recognized revenue for the invoiced value of products delivered to the customer, less applicable discounts. Our normal sales terms allowed for product returns under certain conditions. We accrued for estimated sales returns and allowances and offset these amounts against revenue. We regularly reviewed our estimates against actual returns and also factored in other variables such as planned product discontinuances and market and regulatory considerations. Actual returns and deductions were processed against returns and deductions reserves and such reserves were updated to reflect differences between estimates and actual experience.

Under UK GAAP income under license agreements is recognized when amounts have been earned through the achievement of specific milestones set forth in those agreements and/or the costs to attain those milestones have been incurred by us. A minority of the license agreements provide that if we materially breach the agreement or fail to achieve required milestones, we would be required to refund all or a specified portion of the income received under the agreement. No provision is included for repayments of such income if the directors consider that this eventuality is remote.

Under US GAAP and in accordance with Staff Accounting Bulletin 101 Revenue Recognition in Financial Statements , as updated by Staff Accounting Bulletin 104 Revenue Recognition and Emerging Issues Task Force or EITF00-21 Revenue Arrangements with Multiple Deliverables , revenue from licensing agreements would be recognized based upon the performance requirements of the agreement. Non-refundable fees where the company has an ongoing involvement or performance obligation would be recorded as deferred revenue in the balance sheet and amortized into license fees in the profit and loss account over the estimated term of the performance obligation.

#### Overview of UK and US GAAP difference

Under UK GAAP milestone payments have been recognized when achieved. Under US GAAP, the Company's adoption of SAB 101 (which has now been updated by SAB 104) resulted in the deferral of revenue associated with certain up-front payments and refundable milestone payments. This deferred revenue is then released to the income statement systematically over time.

#### Revised Unaudited Proforma Financial Information contained in Form F-3s

Amarin has two registration statements on Form F-3 (registration numbers 333-121760 and 333-121431) (the "F-3s") on file with the SEC, into which this Form 20-F is incorporated by reference, that contain unaudited pro forma combined condensed consolidated financial information for the six months ended and at 30 June 2004 and for the year ended 31 December 2003 for Amarin Corporation plc and Laxdale. This unaudited pro forma financial information includes preliminary pro forma acquisition adjustments based on available information and certain assumptions made by Amarin management at the time.

In calculating equity shareholders' funds, under US GAAP, in the unaudited pro forma combined condensed consolidated balance sheet at 30 June 2004 included in the F-3s, the negative goodwill that arose on the acquisition of Laxdale was applied on a pro-rata basis to certain non-current assets. Instead of applying negative goodwill to certain non-current assets, under U.S. GAAP such negative goodwill should have been recorded as a deferred credit - see Note 41 to the financial statements beginning on page F-1 of this annual report. Had this deferred credit been included as a pro forma acquisition adjustment in the unaudited pro forma combined condensed consolidated balance sheet at 30 June 2004, the impact would have been to reduce equity shareholders' funds, under US GAAP, by approximately \$41,000,000. Further, if such negative goodwill had been recorded as a deferred credit the write-off of the intangible asset acquired would have been approximately \$48,000,000 instead of approximately \$7,000,000, as previously disclosed in the notes to the pro forma financial information.

#### Impact of Inflation

Although our operations are influenced by general economic trends, we do not believe that inflation had a material impact on our operations for the periods presented.

#### Governmental Policies

We are not aware of any governmental, economic, fiscal, monetary or political policies that have materially affected or could materially affect, directly or indirectly, our operations or investments by US shareholders.

## B. Liquidity and Capital Resources

Historically, we have financed our operations through cash generated from operations as well as the issuance of debt and equity securities. However, in the near term future we will likely be compelled to meet all of our liquidity needs through license fees from partnering our drug development pipeline and/or completing further equity based financings, until we are successful in commercializing our development products. Over the three years ended December 31, 2004, we have received \$31 million in cash from the issuance of shares (net of expenses) and \$11.9 million in loans, the loans having been provided by Elan, a related party until October 2004. We have made loan repayments of \$38.3 million during this three-year period. These repayments related to loans received during the three years ended December 31, 2004 and in earlier periods. During 2004, we settled and re-financed the Company's remaining debt. At December 31, 2004 we had approximately \$11.0 million in cash and \$2.0 million in debt with a cash maturity in 2009, if not previously converted to equity. For further information on liquidity and capital resources please see Note 1 to the consolidated financial statements beginning on page F-1 of this annual report

### Cash

As of December 31, 2004, we had approximately \$11.0 million in cash compared with \$2.1 million as of December 31, 2003. This cash has been invested primarily in US dollar and sterling pound denominated money market and checking accounts with financial institutions in the UK having a high credit standing.

Cash flows expended on continuing operations were \$11.1 million for the year ended December 31, 2004 as compared with \$5.0 million for the year ended December 31, 2003 and \$4.3 million for the year ended December 31, 2002. Cash flows generated on discontinued operations were \$1.0 million for the year ended December 31, 2004 as compared with cash flows expended on these discontinued activities of \$10.1 million and \$10.5 million inflow for the years ended December 31, 2003 and 2002 respectively.

The operating cash flows expended on continuing and discontinued operations reflect funding of the operating loss of \$11.1 million adjusted for non-cash depreciation and amortization (\$0.8 million), and a net inflow on working capital of \$0.2 million. In 2003, the operating cash flows expended on continuing and discontinued operations reflect funding of the operating loss of \$38.9 million adjusted for non-cash depreciation, amortization and impairment charges (\$16.1 million), and a net inflow on working capital of \$ 7.6 million.

Cash flows generated from investing activities were \$28.5 million in 2004 as compared to \$16.8 million expended in 2003. Our principal investing activities related to the acquisition of Zelapar \$7.9 million outflow and subsequent disposal to Valeant as part of API, as described above. The intangible assets included within the API disposal generated cashflows of \$36.4 million. Our principal investing activities in 2003 related to the purchase of the remaining US rights to Permax from Elan for which \$16.1 million was paid in 2003 and \$10.9 million in 2002.

In 2004, cash of \$0.8 million was expended on the professional fees and other costs associated with the acquisition of Amarin Neuroscience Limited, together with the assumption of \$2.7 million in overdrafts and loans. \$1.8 million of cash was also eliminated from the Company upon the disposal of API. In 2004, cash of \$1.6 million was received for the disposal of shares in API offset by cash outflows of \$11.8 million associated with the API disposal. Such outflows included \$9.3 million in inventory management fees, legal and transaction fees of \$2.3 million and \$0.2 million in rental payments in respect of the now vacant premises formerly occupied by API in Mill Valley, California. In 2004, cash of \$0.8 million was received relating to the remaining escrow proceeds of the 2003 disposal of ADAB.

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In 2003 \$13.4 million (net of expenses) was received from the sale of Amarin Development AB and the purchaser additionally assumed a \$0.3 million overdraft. There were no significant acquisitions or disposals of assets in 2002 or 2001.

Cash inflows from financing activity in 2004 were \$5.5 million compared to cash inflows from financing activities in 2003 of \$1.4 million and cash outflows of \$3.0 million in 2002. Net cash provided by financing activities in 2004 comprised a private placement of ordinary shares (\$12.775 million) offset by issuance costs of \$953,000. Net cash outflows on financing activities in 2002 primarily related to repayment of Elan loans.

The 2002 purchase of the remaining US rights to Permax consisted of a non-cash movement due to the negotiation of a series of deferred payments, which were in the amount of \$27.5 million. In January 2003, Elan agreed to waive \$7.5 million of the deferred payments and during 2003 \$16.1 million was paid, \$5 million in two quarterly installments and \$11.1 million from the proceeds received on the sale of ADAB (see commentary above). As of December 31, 2003, \$3.9 million in deferred payments was outstanding.

As described in Item 4 Information on the Company History and Development of the Company, we completed a private placement of 13,474,945 Ordinary Shares, raising gross proceeds of approximately \$12.775 million in October 2004. The net proceeds of our October 2004 private placement (taking into account professional advisors fees associated with filing the related registration agreement with the SEC, cash fees of our placement agent and government stamp duty but not our travel, printing or other expenses) were approximately \$11.8 million.

As described in Item 4 Information on the Company History and Development of the Company, we completed a private placement of 6,093,728 Ordinary Shares, raising gross proceeds of approximately \$21.2 million in January 2003. As part of the private placement, we issued warrants to acquire 313,234 Ordinary Shares at an exercise price of \$3.4785 per share, which warrants are exercisable between January 27, 2004 and January 26, 2008. The net proceeds of our January 2003 private placement (taking into account the cash fees of our placement agent but not our legal, travel, printing or other expenses) were approximately \$19.1 million. We applied a portion of these net proceeds, together with available cash reserves, to satisfy certain payment obligations to Elan. See Contractual Obligations, Item 7 Major Shareholders and Related Party Transactions Related Party Transactions and our financial statements beginning at page F-1 of this annual report

At December 31, 2004, Amarin had total debt of \$2.0 million with a cash maturity in 2009. This is reduced from debt of \$35.4 million due on demand at December 31, 2003. The \$35.4 million of debt was settled in the first quarter as referred to above, following the sale of Amarin's U.S. operations in the first quarter of 2004. On September 29, 2004, Amarin's non-executive chairman, Mr. Thomas Lynch, signed an agreement with Elan to acquire its remaining debt and equity interests in Amarin, including the remaining \$5 million of loan notes owed by Amarin to Elan. On October 7, Mr. Lynch agreed to convert \$3 million of the \$5 million of loan notes into 2,717,391 ordinary shares with an option to convert the remaining \$2 million at the offering price of any future equity financing. Amarin's debt was thus reduced to \$2 million with a maturity in 2009, if not previously converted.

All treasury activity is managed in the corporate head office. Cash balances are invested in short-term money market deposits, either dollar or sterling. No formal hedging activities are undertaken although cash balances are maintained in currencies that match our financial obligations and forecast cashflows.

As of March 31, 2005 and on the basis of forecast cash flows, we have sufficient cash to fund our operating activities, including the commencement of planned phase III trials for Miraxion in Huntington's disease, through the end of the summer of 2005. We intend to obtain additional funding through earning license fees, from partnering our drug development pipeline and/or completing further equity-based financings in the forthcoming year. There is no assurance however that our efforts to obtain additional funding will be successful. If efforts are unsuccessful, there is uncertainty as to whether we will be able to fund our operations on an ongoing basis. We will also require further capital investment 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. Depending on market conditions and our ability to maintain financial stability, we may not have access to additional capital on reasonable terms or at all. Any inability to obtain additional financing when needed would adversely affect our ability to sustain and to grow our business.

### **C. Research and Development**

Following the acquisition of Laxdale Limited on October 8, 2004, Amarin has an in-house research and development capability and expertise, supplemented by retained external consultants. Prior to their disposals, as discussed above, Amarin undertook research and development activities through ADAB and API. Costs classified as research and development are written off as incurred, as are patent costs. Such costs include staff costs, professional and contractor fees, materials and external services. Details of amounts charged in the three years ended December 31, 2004, are disclosed above. Specifically, we incurred \$3.5 million in 2004, of which \$2.5 million was in respect of obligations to fund Zelapar safety studies, which we undertook in connection with the sale to Valeant, and \$1.0 million was in respect of costs attributable to research and development activities as incurred by Laxdale, our newly acquired subsidiary. In 2003, we incurred costs of \$5.4 million (2002: \$6.2 million) relating such expenses incurred by API and ADAB. To date Amarin had managed development risk by structuring agreements such that our development partners incur the cost of the research and development activities for products we license from them. Following the acquisition of Laxdale our expenditure will be increasingly focused on proprietary research and development, as we pursue our goal of becoming a leader in the research, development and commercialization of novel drugs for CNS

disorders. In addition, we plan to commence two phase III trials with Miraxion in Huntington's disease by mid 2005 and have engaged external clinical research organizations and consultants to assist us, as detailed below in part F. This will result in our research and development expenditure increasing significantly in 2005 when compared to the levels incurred in prior years.

Under US GAAP, in 2004, Amarin incurred an in process research and development charge of \$48,235,000 representing the write off of the Miraxion intangible asset that arises on the acquisition of Laxdale (See our financial pages beginning on page F-1, Note 41, 2J).

The acquisition of Laxdale provides Amarin with three significant in-process R&D projects:

The full rights to Miraxion for Huntington's Disease ( HD ) in the United States over and above the rights as licensee in the United States already possessed by Amarin prior to the acquisition. As noted above in Item 4A History and Development of the Company Laxdale Acquisition , prior to the acquisition, Amarin had an exclusive licence from Laxdale for the US rights to Miraxion for HD, subject to a 40-45% royalty payable by Amarin to Laxdale (*i.e.*, the acquisition eliminated a 40-45% royalty on US sales of Miraxion for HD previously payable by Amarin to Laxdale).

The rights to Miraxion for HD in the European Union.

The rights to Miraxion for depression in the European Union and the United States.

Miraxion, at the time of the acquisition, had completed a Phase II trial and an initial Phase III trial for HD. The post hoc data analysis from the initial Phase III trial had illustrated a statistically significant benefit in a significant subset of HD patients. This subset of HD patients represents 65-70% of all HD sufferers. No product has ever been approved for HD in the United States. Final, large Phase III trials need to be designed and completed prior to submitting a New Drug Application (an NDA ) to the FDA for review. There is no certainty that final Phase III trials will be successful in showing a statistically significant benefit in treating HD. Without successful trials, Miraxion will not be approved in the United States or the European Union.

Miraxion had also completed several Phase IIa trials in treatment-unresponsive depression. Approximately one-third of patients treated with standard depression therapy see no benefit and a further one-third see an initial benefit that wears off. In a number of Phase IIa trials, Miraxion provided benefit to these treatment-unresponsive patients. Before Miraxion can be approved for treating depression, further phase II studies and final Phase III studies must be completed. There is no certainty that such studies will be successfully completed.

Most current drugs for treating neurological and psychiatric disorders have mechanisms of action targeting receptors (surface proteins embedded in the phospholipid membranes) or neurotransmitters in the brain. Amarin's product, Miraxion, targets the bio-chemical imbalances in the phospholipids themselves and also influences other fatty acid



and eicosanoid pathways.

The following table presents each significant in-process R&D project acquired as part of the Laxdale acquisition:

Program	Indication	Strategy	Discount rate	Development risk adjustment	Expected completion (Regulatory filing)	Expected cash inflows (product launch)	Status	Fair value on acquisition \$ '000
Miraxion	Huntington's disease US (see below)	Directly market	16%	50%	H2 2006	H2 2007	Phase III	23,193
Miraxion	Huntington's disease EU (see below)	Partner/out-license	16%	50%	H2 2006	H2 2007	Phase III	15,250
Miraxion	Treatment-unresponsive depression	Partner/out-license	20%	5%	H1 2007	H1 2009	Phase II	9,792
Total								48,235

The above table also indicates Amarin's strategy with regard to Miraxion for HD and treatment-unresponsive depression. Amarin intends to directly commercialize Miraxion in the United States and out-license or partner Miraxion in the European Union. Amarin also intends to out-license or partner Miraxion for treatment-unresponsive depression.

The fair value calculations are based on the assumption that Amarin files for HD regulatory approval with the FDA and EMEA in the second half of 2006, and obtains approval by mid 2007, with product launch in the second half of 2007. It is assumed that product sales revenues in the United States commence in the second half of 2007. Miraxion has been granted Fast Track designation by the FDA. Whilst Miraxion is assumed to be directly commercialized by Amarin in the United States, in the European Union it is assumed to be partnered or out-licensed. For the European Union, it is assumed that Amarin earns milestone revenue from its existing European partners before and upon approval for HD in the first half of 2007, followed by royalty revenue once the product is launched in the European Union (assumed to be in the second half of 2007).

With respect to treatment-unresponsive depression, it is assumed that Phase III trials are completed and regulatory filing submitted by mid-2007. Approval by the FDA and EMEA is assumed to be obtained by the end of 2008, with product launch in the first half of 2009. It is assumed that Amarin earns milestones at each of these points, with royalties flowing from launch in 2009. There is, however, no certainty that such studies will be successfully completed.

As Miraxion is still in development, there is no historic pricing or margins though, as indicated above, development costs will arise to take the compound through clinical trials. Such costs include additional or incremental infrastructure and other indirect costs as well as direct costs associated with development. The forecast cashflows have been developed using assumed sales prices based upon the price levels of other therapies for similar diseases in the

neurology field. Amarin has assumed an inflationary increase in drug prices over the course of marketing exclusivity. Margins have been forecast using current estimates of the cost of

manufacture and supply of product based upon experience to date with the product and its supply chain. It is assumed that significant R&D expenditure will be incurred in the future to complete the Phase III studies and obtain regulatory approval for HD in the United States and the European Union amounting to \$32 million. This cost has been fully allocated to the US Miraxion program for HD in calculating its present value because all of this development work will need to be completed to obtain US approval. The development work and costs for US approval have been planned in a manner that will also support a filing and approval in the European Union. As the work and costs of obtaining approval in the European Union are essentially indistinguishable from the work and costs to be incurred for US approval, no arbitrary cost allocation is made to the EU program and, instead, the costs are fully allocated to the US program.

For depression, it is assumed that the vast majority of the cost of completing the clinical trials and obtaining approval is incurred and funded by a development partner. We have assumed that Amarin incurs \$1 million of additional costs on the depression program. Expenditure levels on commercialization are forecast based on management's knowledge and experience with establishing the infrastructure required to commercialize the product, such as a US sales and marketing operation for the direct marketing of Miraxion for HD in the United States.

The forecast cashflows are discounted using risk-adjusted discount rates reflecting Amarin's weighted average cost of capital and cash-flow related risks. For HD, these risks include those associated with the assumed level of the market penetration rates in the patient population, product pricing and the need to develop a sales and marketing infrastructure in the United States. All risks considered are reflected in the risk-adjusted discount rate used of 16%. Similarly, with respect to depression, the risks considered include those associated with the assumed level of market penetration rates, product pricing, the new mode of action of the drug and the risk associated with finding a development and commercial partner for this indication. Again, the risk-adjusted discount rate used of 20% reflects all risks considered.

The result of applying these discount factors to the forecast cashflows for each project is its present value. This is further adjusted by a probability adjustment to reflect the development risk. Typically, a product starting Phase III development has an approximately 65-70% chance of making it through to NDA approval. Due to the difficulty in achieving success in clinical trials in CNS disorders, such as HD, Amarin has applied a probability adjustment of 50% to reflect the development and regulatory risk remaining. The probability adjustment to reflect the development risk associated with the depression program is estimated to be significantly lower (5%) due to its earlier stage of development, the difficulty in showing efficacy in this difficult-to-treat and unresponsive patient group and the requirement of identifying and executing a development and commercial partnership with a global pharmaceutical company with the requisite skills to take the product through development and eventual marketing.

Prior to its acquisition, Laxdale had been developing the HD and depression projects and maintaining an infrastructure at its site in Stirling, Scotland. Prior to



the acquisition, costs were not recorded on a project-by-project basis and, therefore, a specific analysis of historic costs by project is not presented here. However, a broad indication of the costs of running the site and associated activities, including taking Miraxion through its initial Phase III trial for HD and Phase IIa trials for depression is the accumulated expenditure from 1997 (the year in which Laxdale was established to develop this intellectual property) to December 31, 2004 which amounted to approximately £17,772,000 (\$30,392,000). For Laxdale's fiscal years ended March 31, 2002, 2003 and 2004 the total expenditure of Laxdale was £4,476,000 (\$6,416,000), £5,635,000 (\$8,719,000) and £3,612,000 (\$6,159,000) respectively. For the period ended April 1, 2004 to the acquisition date of October 8, 2004, the total expenditure was £1,316,000 (\$2,377,000). For the post acquisition period to December 31, 2004 total expenditure was £1,428,000 (\$2,943,000).

The key risks and uncertainties associated with completing development on schedule include:

Obtaining FDA clearance to commence the remaining clinical trials for each program (both HD and depression);

Recruiting patients that meet the entry criteria to the trials in a timely fashion;

Ensuring patients remain in the trials to completion and adhere to the trial protocol;

Ensuring Amarin maintains adequate cash levels to commence, conduct and complete the remaining R&D work on each of the programs;

Compiling the NDAs, including clinical, preclinical and toxicology data; and

Obtaining a timely review by the FDA of the NDA.

The consequences if the development program is not timely completed are as follows (these should be read in conjunction with Item 3D Risk Factors):

Competition in the pharmaceutical industry is intense and is expected to increase. Therefore, any delay or lack of success with any clinical trials or regulatory approval for Miraxion will increase the possibility that another

competitor's drug may get to market first.

We are dependent upon the success of a limited range of programs and, in particular, on Miraxion for HD. If regulatory approval is not forthcoming or is significantly delayed for Miraxion for HD, our business will be materially and adversely affected.

**D. Trend Information**

Following the sale of our US assets to Valeant we do not have significant short-term revenue generating assets. In 2005, it is likely that our only revenues, if any, will be from earning up front license fees from partnering our development pipeline, such as entering into a license of Miraxion for depression. We will not earn product sales until a product from our development pipeline is approved by a regulatory body or we acquire a revenue generating product. Future results for the Company in its current form will primarily reflect expenditure on our research and development pipeline and corporate activities. Following the acquisition of Laxdale Limited in October 2004, our expenditure will be increasingly focused on research and development, as we pursue our goal of becoming a leader in the research, development and commercialization of novel drugs for CNS disorders. We plan to commence two phase III trials with Miraxion in Huntington's disease by mid 2005. This will result in our research and development expenditure increasing significantly in 2005 when compared to the levels incurred in prior years.

The success of our development efforts is dependent in part upon the ability of the 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 U.S., the European Union, Japan and elsewhere. In the U.S., 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.

## E. Off Balance Sheet Transactions

Although there are no disclosable off balance sheet transactions, there have been transactions involving contingent milestones see Note 40 Related Party Transactions in the financial statements.

## F. Contractual Obligations.

The following table summarizes our payment obligations as of December 31, 2004. The operating lease obligations primarily represent rent payable on properties leased by the Company. Some of the properties leased by the Company have been sub-let and generate rental income.

	Payments due by period in \$000 s						
	Total	Less than 1 year	1-2 years	2-3 years	3-4 years	4-5 years	Thereafter
Long term debt	2,000					2,000	
Capital / finance lease							
Operating lease	6,584	1,432	1,432	1,070	622	622	1,406
Purchase obligations							
Other long term creditors							
<b>Total</b>	<b>8,584</b>	1,432	1,432	1,070	622	2,622	1,406

During 2005, Amarin Corporation plc has opened an office in Dublin; the amount payable for the one year lease is \$32,000.

There are no capital commitments relating to the Miraxion development project. However, under the purchase agreement for Laxdale, upon the attainment of specified development milestones we will be required to issue additional Ordinary Shares to the selling shareholders or make cash payments (at the sole option of each of the selling shareholders) and we will be required to make royalty payments of 6% on future sales of Miraxion (consisting of 5% payable to Scarista Limited and 0.5% payable to each of Dr. Malcolm Peet and Dr. Krishna Vaddadi). The final purchase price will be a function of the number of Ordinary Shares of Amarin issued at closing and actual direct acquisition costs, together with contingent consideration which may become payable, in the future, on the achievement of certain approval milestones. Such contingent consideration may become payable upon marketing approval being obtained for approval of products (covered by Laxdale's intellectual property) by the FDA and EMEA. The first approval obtained in the US and Europe would result in additional consideration of £7,500,000 payable, for each approval, to the selling shareholders of Laxdale Limited in either cash or stock (at the sole option of each of the selling shareholders). The second approval obtained in the US and Europe would result in additional consideration of £5,000,000 payable, for each approval, to the vendors



of Laxdale Limited. (See note 33 to our financial statements beginning on page F-1 of this annual report).

Subsequent to the year end, Amarin has engaged various clinical research organizations and consultants to assist in the design, project management and roll-out of the planned two phase III trials with Miraxion in Huntington's disease by mid 2005. We entered into a clinical trial agreement with the University of Rochester on March 18, 2005. Pursuant to this agreement the University is obliged to carry out or to facilitate the carrying out of a clinical trial research study set forth in a research protocol on Miraxion in patients with Huntington's Disease in the U.S. Additionally, we intend to appoint a clinical research organization to carry out a similar study in the European Union and expect to make such appointment in the second quarter of 2005. The cost associated with the clinical trial agreement with the University of Rochester is estimated as follows:

	Estimated Payments due by period in \$000 s from 1 January 2005						
	Total	Less than 1 year	1-2 years	2-3 years	3-4 years	4-5 years	Thereafter
Clinical research	5,857	2,691	1,883	1,283			

**Item 19 Exhibits**

Exhibits filed as part of this annual report:

- 12.1 Certification of Richard A. B. Stewart required by Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 12.2 Certification of Alan Cooke required by Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 13.1 Certification of Richard A. B. Stewart required by Section 1350 of Chapter 63 of Title 18 of the United States Code, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- 13.2 Certification of Alan Cooke required by Section 1350 of Chapter 63 of Title 18 of the United States Code, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

**SIGNATURES**

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

**AMARIN CORPORATION PLC**

By: /s/ RICHARD A. B. STEWART  
Richard A. B. Stewart  
Chief Executive Officer

Date: October 17, 2005

**Amarin Corporation plc**

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description</b>
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